Novartis AG

Novartis AG - Q3 2023 Earnings Call

Tuesday, October 24, 2023 8:00 AM

Event Participants

Executives 3
Samir Shah, Vasant Narasimhan, Harry Kirsch

Analysts 11
Andrew Baum, Kerry Holford, Emmanuel Papadakis, Florent Cespedes, Seamus Fernandez, Simon Baker, Richard Vosser, Graham Parry, Mark Purcell, Steve Scala, Peter Welford

Operator Operator

Good morning, and good afternoon, and welcome to the Novartis Q3 2023 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 Mr. Samir Shah, Global Head of Investor Relations. Please go ahead, sir.

Samir Shah Executive

Thank you very much, everybody, for joining once again. Just before we start, I'll just read you the safe harbor statement. The information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These may cause the 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, its most recent quarterly results on Form 6-K that respectively were filed with and furnished to the U.S.

Securities and Exchange Commission.

With that, I'll hand the call to Vas.

Vasant Narasimhan Executive

Thank you, Samir, and thanks, everyone, for joining today's conference call. As you saw, we had some really strong results. But I wanted to also take a step back and note that this is an important moment for the company after many years of focusing the organization to become a pure-play medicines company. With the spin of Sandoz, we've completed that multiyear

journey.

Along the way, we've been able to create multiple important companies for the world in consumer health and eye care devices and now Sandoz in generics, alongside exiting our Roche stake and taking a number of shareholder-friendly actions, which we'll talk more about on the call. But I think this quarter demonstrates that Novartis is well positioned as a pure-play innovative medicines company to consistently drive top and bottom line growth for the years to come.

So coming to the first slide. As you saw earlier this morning, we delivered strong sales growth, margin expansion, and we were able to raise our guidance for the third time this year, along with the successful spin of Sandoz. Sales grew 12% and core operating income grows up 21% on the quarter. On the 9 months, sales were up 10%, core operating income grow 19%, all in constant currencies. And this allowed us to raise our guidance, which Harry will go through in more detail.

We also had a number of important innovation milestones, and I know many of you were on the call earlier with respect to Pluvicto's data presentation at ESMO as well as other results and milestones over the course of the quarter, which I'll go through the presentation.

Now moving to Slide 5. That growth that you saw was driven by our key growth drivers and really a broad-based performance across the company, which I think is reflecting the focus that we have in the organization now on 4 key TAs, 9 key brands, a simplified organization and really a focus on execution. This portfolio grew 41% in constant currencies, and we expect that growth to continue. We also saw the normalization of health care systems in many of our key markets, which also buoyed many of our established brands and older patented brands.

Now moving to Slide 6. In going through each brand in turn, starting with Entresto. Entresto delivered 31% growth on the quarter, reaching $1.5 billion. That growth was driven by performance both in the U.S. and in the ex-U.S.

market. You can see in the center panel, our weekly TRx in the U.S. continues to reach new highs every week.

With respect to some more of the details, the U.S. growth was driven by 28% -- U.S. at 28% constant currency growth, 1.4 million TRxs in the quarter. Ex-U.S. sales were up 34%, and I think importantly, we're seeing strong performance in China and Japan from the hypertension indications that we've been able to achieve in these 2 markets.

Importantly, in Japan, we have protection for Entresto out into the early 2030s. So we're confident in the continued growth of this medicine. We have a strong guidelines position in the U.S. and the EU. We expect further penetration in heart failure and hypertension.

As a reminder, our pediatric approval in EU confirms our RDP to November 2026. And we continue to prosecute our appeal in the U.S. to the recent patent rulings as well as filed to uphold our existing patents, and we continue to guide to a mid-2025 loss of exclusivity in the U.S. as we continue to prosecute that patent portfolio.

We have no generics approved to date by the FDA.

Moving to the next slide, Slide 7. Cosentyx returned to growth, and we expect a stronger quarter 4 as we start to lap some of the revenue adjustments that we had in the prior year. You can see this growth was driven both by a stabilization in the U.S. as well as strong performance outside the U.S. U.S.

sales were down 3%. But when you adjust for the revenue adjustment items, they were broadly flat, supported by volume growth. And then ex-U.S. sales were up 15% as we were able to grow in each of our core indications. We expect stronger growth in quarter 4, continued volume growth, lower prior year base effects from the RD true-ups.

In addition, in Europe, our hidradenitis suppurativa indication has been approved, and the launch is on track, and we're beginning to already see early signs of uptake from this new indication.

From a life cycle management standpoint, we've received approval in the U.S. for our IV formulation, which allows us now to bring this medicine to patients and providers who prefer to take advanced medicines for rheumatological indications in an IV setting. We're the first non-TNF so novel agent that's now approved with an IV formulation, and we look forward now to bring that medicine to those health care practitioners.

In addition, we're on track for the hidradenitis approval in the U.S. in quarter 4. Three Phase III studies ongoing, giant cell arteritis, PMR and rotator cuff tendinopathies that also remain on track. So overall, solid performance for Cosentyx setting us up well for the coming years.

Moving to Slide 8. Kesimpta continued its strong launch trajectory across regions. We did have a onetime revenue adjustment in the EU, which accounted for some of this growth, but it's important to note that our underlying sales growth was still 86% for this brand. In the U.S., we're growing faster than the market. TRxs were up 75%, NBRxs were up 30%.

And I would note that the B-cell NBRx share is still only 56% of the MS market, TRx is much lower, showing that the whole B-cell class has a long room to grow to get as many patients as possible with the most effective therapy.

In Europe, we're seeing a solid launch momentum, 29,000 patients now treated. Most of those patients are naive or first switch. Our Q3 sales included that revenue deduction adjustment. And importantly, we're also seeing solid performance in Asia as well with this brand. So we're confident in the continued future growth of Kesimpta.

Only about 1/3 of MS patients are on B cell therapies and will continue to drive that growth of the B-cell class as well as Cosentyx share within the B-cell class. We have NBRx leadership in multiple key markets such as Germany, and we have a compelling product profile that I think you know well, 1-minute-a-month dosing from home or anywhere, 5-year efficacy, strong safety and tolerability and a very attractive profile from a local adverse event profile when the medicine is given unlike the recently approved subcu IV formulation of a competitor product.

Now moving to Slide 9. Kisqali sales grew 76% to $562 million in the quarter. And I think this is really a reflection of the increasing recognition of the differentiated benefit risk profile we have with this medicine. You can see the growth is broad-based across geographies on the left-hand panel. In the middle, our NBRx share has now reached 46%.

Clear leadership from a metastatic breast cancer setting as we continue to gain in this setting based on the strong data that we show here on the right-hand panel data, you all know well. Three OS wins in MONALEESA-2, 7 and 3, NCCN guidelines supporting the use of the medicine. The Right Choice data, which recently showed a benefit versus doublet chemo in aggressive metastatic breast cancer. And of course, an adverse event profile that is increasingly understood and well managed by practitioners around the globe. So in the metastatic setting, we continue to believe Kisqali has a multibillion-dollar potential and is now demonstrating that with its strong growth.

Now moving to the next slide. In the quarter, we also completed the Phase III NATALEE iDFS analysis with 500 events now complete and are on track for a submission in quarter 4. In addition, in quarter 3, we did submit in the EU. As a reminder, on the left-hand side of the panel, you see the data that we showed at ASCO, which demonstrated a consistent profile for Kisqali across all of the various subgroups that you see here listed as well as RFS and DDFS.

At ESMO 2023, early this week, actually yesterday, we also put forward data that showed the consistent iDFS benefit across subgroups regardless of stage, menopausal status, age or nodal status, as well as a good tolerability profile for the medicine. So as mentioned, we filed in Europe, 500 iDFS event milestone reached. The data was consistent with what we've already seen at the ASCO data set and we will be presenting that data at an upcoming medical congress in quarter 4, and our U.S. submission is planned for quarter 4 as well.

Now moving to the next slide. Now Pluvicto grew to $256 million. And it's important to note that our supply now is fully unconstrained as our Millburn facility is fully up and running with multiple lines approved. Our Indianapolis facility is now filed, and we're focused on initiating new patients.

Now I wanted to say a word on the quarter-on-quarter growth that we saw with Pluvicto. It's important to note that for this medicine, it is provided in 6 doses, 6 weeks apart. So this is a 36-week medicine, so over 9 months. Earlier this year, when we experienced our supply disruption, we had 2 factors that impacted our sales in quarter 3 of this year. One, we had sicker patients being put on the therapy given that practitioners wanted to provide the therapy to the patients most in need.

Many of these patients only completed 2 to 4 cycles of Pluvicto.

Then separate from that, we also had much fewer patient starts through quarter 2, which limited the base of patients receiving Pluvicto for their third, fourth, fifth, sixth doses through quarter 3. Now what I would want to highlight is we're seeing 50% -- already 50% patient growth in quarter 3 over quarter 2, and we expect that growth to continue. We're seeing solid bookings into next year. So as we rebuild the base of patients that are ongoing on Pluvicto and adding new patients above, we would expect then growth to get back to where we expect it to be.

We continue to be on track for around $1 billion of sales for this year for Pluvicto as we previously guided. And you can see here some of the other elements of the story, 200 active centers ordering in the U.S. and onboarding another 130 centers. Ex-U.S. reimbursement is continuing to progress well.

And as I mentioned, our capacity is now unconstrained and we look forward to bringing online the Indianapolis site to really provide us enough capacity to fully meet the U.S. market. We're also in the process now of adding additional facilities in Asia as we prepare to launch the medicine across multiple geographies in the Asian landscape as well.

Now moving to the next slide, Slide 12. Now as you saw already with the presentation earlier today as well as at ESMO yesterday, the PSMA study -- PSMAfore study showed robust efficacy and favorable safety, and I won't go through all of the data again, so I believe many of you were on the call. But I think the data set is compelling. We believe that it had clearly demonstrated the benefit of this medicine. We presented it at ESMO, and there was, I think, a strong positive vibe.

I was at the Congress myself and really felt like practitioners really excited about bringing this medicine to more patients. Our submission for FDA is now planned. Our current plan is to submit the medicine to FDA when we reach a 75% information fraction at OS because we believe that will provide us an adequate data set, both for crossover adjusted, unadjusted OS as well as all of the excellent data that you see on the slide.

Now moving to Slide 13. Scemblix sales grew across all regions, and I think that demonstrated the high unmet need for CML. Now a few things to note when you look at the Scemblix sales. While the sales reflected continued demand from patients for Philadelphia positive CML, CP-resistant or patients who are intolerant to 2 or more TKIs, really later-line therapy, and we continue to have a strong third line market share. We did also see a slowing of some of the patients with specific mutations that are indicated for Scemblix, which did lead to some of the slowdown as well as some revenue and inventory adjustments in the quarter.

I think really now the key for Scemblix is to continue to drive strong growth in the third-line setting. But for the medicine to become a very significant part of our portfolio, what will be critical is moving into earlier line. We are on track for the readout of the preferred first-line registrational study in the first part of next year with a filing, if positive, expected in 2024, as well as Phase IV studies in the second-line setting as well. If those studies are positive, we do believe this medicine has the potential to be a multibillion-dollar medicine to continue to support Novartis growth and importantly, provides CML patients with an improved next-generation therapy following our legacy of Gleevec and Tasigna.

Now moving to Slide 14. Leqvio continued to expand steadily in the quarter as we've guided. This will be a long build as we continue to build out the buy-and-bill pathway and educate physicians. We think this performance benchmarks well versus other PCSK9 launches. And interestingly, also benchmarks well against other asymptomatic Part B therapies that have been launched over the last 2 decades.

So I think we're on a solid trajectory, but this will be the long haul to get to the full potential multibillion-dollar potential for this medicine.

Our adoption was now at 3,100 facilities, which is about 16% up from quarter 2, 55% of the business is now from buy and bill, and we continue to expand that. And our enablers for future growth really haven't changed. It's to drive depth in our key accounts. We know that once key accounts get up to 8 to 10 patients on Leqvio that really drives higher -- even higher

utilization in those accounts. We need to continue to educate and expand buy and bill across the entire landscape of cardiology offices, and we're looking now to hyper target physician groups that we think are most likely to have urgency to treat patients with elevated risk following a cardiovascular event.

Importantly as well, we have a rollout now with the medicine approved in China and Japan. And thus far, we are seeing strong early uptake in China and hopeful that we can expand that utilization with NRDL listing in the coming years in China as well.

Now moving to Slide 15. Now turning to the pipeline readouts in 2023. We've covered most of the Kisqali and Pluvicto milestones already. I would note as well that iptacopan, we'll cover the PNH as well as -- PNH, I should say that we're on track for the FDA and EMA, and those problems are continuing to be reviewed, and we're on track with those. The APPLAUSE-IgAN study, I'll go through in a few slides, and the APPEAR-rC3G Phase III readout remains on track as well for quarter 4.

As well after our recent acquisition that we've closed for Chinook, our atrasentan readout for IgAN is also -- continues to be expected in quarter 4 of this year.

Now moving to Slide 16 and turning to our '24 to '25 time frame. I'll cover remibrutinib in a few slides. I've already mentioned that Scemblix remains on track. Our Pluvicto hormone-sensitive prostate cancer readout is also on track for 2024, and we continue to pursue Pluvicto in full range of earlier lines of prostate cancer therapy. I would note as well our OAV-101 SMA intrathecal study is now with a readout expected in '24, with the submission planned in 2025.

Pelacarsen and ianalumab, all the studies also remain on track. And we have a number of additional indications for iptacopan, which you'll see in a few slides.

Now moving to Slide 17. Now turning to remibrutinib, where we read out 2 studies in the quarter, both demonstrated consistent, clinically meaningful and statistically significant benefit in CSU. As a reminder, the REMIX 1 and 2 studies randomized 450 patients to remibrutinib or placebo with a primary endpoint at week 12. At week 24, patients on the placebo group rolled over on to remibrutinib for an additional follow-up out to 52 weeks, which then enabled for the final submission in that -- with the safety data collected during that open-label treatment period.

Of note, all participants were on a stable and locally-label approved dose of a second-generation H1 antihistamine throughout the entire study. Remibrutinib met all primary and secondary endpoints at 12 weeks. There was a clinically meaningful and statistically significant reduction in urticaria activity. We saw a very fast symptom improvement as early as 2 weeks. The medicine was well tolerated, good safety profile, balanced liver function test, which I think is really critical for this class, and an oral medicine.

And this allows us to bring remibrutinib forward. We hope, with a filing in 2024, the data will be fully presented at ACAAI in 2023. And all of us to bring this medicine for a well ahead of our multiple sclerosis readout. And we continue to also explore it now in other indications given the strength of the readout that we saw here, other autoimmune indications that could also be addressed by remibrutinib.

Now moving to Slide 18. When you think about how we're going to position remibrutinib, it's an opportunity for an efficacious oral therapy with a fast onset of action in between the use of antihistamines and biologics. There is a CSU treatment gap. There's about 400,000 patients that are not controlled with standard of care. They have a high unmet need after antihistamines, and that's where we'd like to position this medicine.

And given the data that we've seen with efficacy that is in the range of biologics, that gives us the opportunity, we believe, to position this medicine successfully in the future.

Now moving to Slide 19. Iptacopan or oral selective factor B inhibitor, we read out the APPLAUD study. I think you all well know, we had positive data both in APPLY and APPOINT in PNH. That data is now filed. C3G is on track.

We also have a who is have IC-MPGN as well as other Phase IIb and Phase III readouts that are ongoing, including lupus nephritis.

And so if you go to the next slide, I wanted to just say a word about the APPLAUSE study. Iptacopan the study demonstrated clinically meaningful, highly statistically significant proteinuria reduction in the study. For -- as a reminder, this is the study of biopsy confirmed patients with IgA nephropathy, who are at risk of progression. They had an elevated proteinuria of over 1 gram per gram despite stable background therapy. They were randomized 1:1 placebo to iptacopan.

This is the data from the interim analysis at 9 months, looking only at proteinuria. The end of study resolved once all patients are enrolled and are fallout fully would occur in 2025, and that would look at eGFR. The positive top line results at this interim analysis showed superiority versus placebo and proteinuria reduction, and this is on top of optimized supportive care. This result is clinically meaningful, highly statistically significant. I think very, very pleased with the results that we saw.

Safety profile was consistent with what we've previously shown, and again, as you know, in oral medicine. So we're in discussions with FDA now to submit the medicine for accelerated approval. The study continues to a blind ed to assess superiority in eGFR slope.

Next slide, please. Now turning to Lutathera. This was a positive surprise that we had in the quarter, which is the Phase III NETTER-2 results, which highlighted the potential for radioligand therapy in earlier disease settings. And this is consistent with what we've reviewed earlier with Pluvicto. It does appear as we move these radioligand therapies into earlier lines, we're seeing stronger results than we saw even in the later lines.

We also saw strong results.

In this study, we demonstrated a clinically meaningful significant benefit. We met the primary endpoint for PFS, the secondary endpoints for overall response rate. The safety was consistent. This study randomized 2:1 Lutathera over octreotide LAR versus high-dose octreotide LAR. And we followed up every 6 months for 3 years.

So what this allows us to do, and important to note that Lutathera technically already has this indication within its U.S. label, but without data to support its widespread use.

This data would allow us to move Lutathera from the second, third line, which covers about 30% to 45% of patients into the frontline setting where over 50% of patients with GEP-NET are treated currently with various SSAs. This would allow us then to add Lutathera on top and really, I think, benefit these patients in a really meaningful way. So we plan to present this data in the first part of next year. And in the case of the U.S., we wouldn't need further label expansion and we plan to really move forward and educating the community on the importance of this data to move Lutathera into the frontline setting and in other jurisdictions around the world will now evaluate how to further expand the label from a regulatory standpoint.

So moving to the next slide. With that, I'll hand it over to Harry.

Harry Kirsch Executive

Yes. Thank you very much, Vas. Good morning, good afternoon, everybody. I'm now going to walk you through some of the financials for the third quarter and the first 9 months. As always, my comments refer to growth rates in constant currencies, unless otherwise noted.

Also, throughout the presentation, I'm only going to talk about continuing operations. Just as a reminder, that continuing operations include the retained business activities of Novartis comprising of the Innovative Medicines Division and the continuing corporate activities, which is, of course, the majority of them.

Discontinued operations include Sandoz and selected smaller parts of corporate activities attributable to the Sandoz business, as well as certain expenses related to the spin-off.

Let's go to the next slide, please. Before I go into the details of our robust performance in quarter 3 and year-to-date, I wanted to show you this slide with restated numbers post the Sandoz spin so that you can have a like-for-like comparison. We published these restated numbers also a couple of weeks ago on our website in order to help you with your modeling. In due course, we will also provide continued operations numbers for years before '22.

On this slide, we want to illustrate a strong continuing operations performance throughout 2023. And for the net sales and core operating income, as you can see, we had strong consistent growth, we have also tried of course, our margin improvement. And in addition to the sales growth, the cost savings related to our ongoing productivity programs that we started last year also contributed to our significant core margin expansion.

Next slide, please. So Slide 24 details the robust double-digit top and bottom line performance during quarter 3 and for the first 9 months. The top line grew 12% in the quarter and 10% year-to-date, with broad-based performance across our core therapeutic areas and key geographies. Core operating income was up 21% in quarter 3 and 19% in the first 9 months, again, mainly driven by higher sales and savings from the ongoing productivity despite a bit of inflation, which is very much in line with what we outlooked earlier this year.

Core EPS grew 29% to $1.74 in the quarter and 28% to $4.95 in the first 9 months. Core EPS grew, as you can see, a bit faster than core operating income, helped by our ongoing share buyback program.

We also delivered very healthy free cash flow with $5 billion in the quarter, which, as we look back, is the highest quarter in over 5 years for us, and $11 billion in the first 9 months. To note, quarter 3 net sales growth of 12% benefited from about 2 points from one-off items that are unlikely to recur in the future, including Kesimpta revenue reduction adjustment in Europe, which Vas mentioned when he reviewed the Kesimpta slide. As well as in there, we have in our net sales now that Sandoz is a third-party, separate company. We have also our contract manufacturing to Sandoz in our contract manufacturing sales line, you see that actually also in our interim financial report as a separate line.

And in the quarter, we had around $100 million, $150 million higher sales to Sandoz as some inventory buildup as part of the spinoff happened, right? Sure, we can talk about it later. But operationally, the underlying growth was more in line with 10% in the quarter versus the reported of 12%.

But still, in summary, a very strong first 9 months of the year as our efforts to focus and streamline the business continue to pay off.

On the next slide, Page 25. Yes, this chart becomes -- gets less and less rows. Those of you who are with us a long time, right, we started with 6 or 7 rows now we basically have 1 left. And of course, we do show the first 9 months of discontinued operation. But the full focus is on our new shape as a focused innovative medicines company, sort of continuing operations.

So again, you see the net sales growth and all of that, which I explained beforehand, and Vas, but certainly, Kesimpta, Entresto, Kisqali and Pluvicto once again stood out as growth contributed in the quarter.

And with that, of course, our increase in core operating income and margin to 37.4% in the quarter, which is quite similar to our year-to-date 36.9% core margin. And more importantly, even as we are tracking very well to reach our 40% target for margins in the midterm. And to note, our margin is now calculated on net sales, which includes sales to discontinued operations and future Sandoz contract manufacturing.

Slide 26, please. Yes. Guidance also becomes a bit simpler, right? So here is our guidance. We continue to expect sales to grow high single digit.

However, we raised the guidance for core operating income by 2 notches to grow mid- to high teens, up from the low double digit to mid-teens. We do expect to see continuing strong sales growth in quarter 4 and likely expect to be at the high end of the sales range guidance. It's even possible we might just hit the 10% growth on revenue for the full year given we have delivered 10% in the first 9 months.

Our key assumption continues to be that there are no Entresto generics, nor Sandostatin LAR generics entering in the U.S. in 2023.

Next slide, please. So we are committed, of course, to create value for our shareholders. I've tried to summarize this here on 1 page, some of the corporate actions we have taken over the years, if you will. And that, of course, is there to bolster our future growth as well in our replacement power. And we have, as you know, a substantial cash generation from our operations, which allows us to do both, invest optimally in our organic business and bolt-on

M&A and BD&L deals, as well as returning capital back to our shareholders.

The majority of the reinvested capital funds R&D, and we have spent over $45 billion in the past 5 years in R&D. Of course, we supplement this with business development in the form of bolt-on acquisitions in our core therapeutic areas. The other side of the equation is what we return to our shareholders with a strong and growing dividend in Swiss franc over many years since the company creation and that will be continuing so in the future, including through the spin-offs of Alcon and Sandoz, for which we never have and will rebase.

In addition, we have also completed over $30 billion of share buybacks during the past 5 years, and we just initiated, as you know, a new share buyback of up to $15 billion in July this year. Not to be forgotten is that we have also created value via major strategic actions, which you see here at the bottom. As Vas mentioned, we have created new businesses, in a tax-efficient way with Alcon and most recent Sandoz spin-offs to become the global leader in eye care and generic sector. Alongside this, we have exited the Roche stake at an attractive valuation. And of course, we divested the Consumer joint venture stake in 2018.

With that, I'll hand it back to Vas.

Vasant Narasimhan Executive

Great. Thanks, Harry. Thanks, Harry. In summary, if we go over to Slide 29, we had a very strong quarter 3 as you saw a 12% growth, 21% core operating income growth, which really demonstrates that the transformed Novartis with our focused strategy is delivering growth drivers are continuing to perform well, and we'll continue to work hard to accelerate them further. A lot of pipeline milestones, and we look forward to additional data that will be generated over the coming quarters and years.

As Harry highlighted, the completion -- completed the spin of Sandoz, and now we've raised our 2023 guidance. And with that, I want to hand it to Samir to highlight our Capital Markets day...

Samir Shah Executive

Yes. Just a quick plug for our Capital Markets Day, which will be in person as well as webcast at the end of November from London. Obviously, we're going to focus on our key R&D assets, which would include Kisqali, Pluvicto, Scemblix, iptacopan and remibrutinib. In addition, there will be a short update on strategy from Vas.

And with that, we'll hand the course for the Q&A.

Vasant Narasimhan Executive

Yes. [Operator Instructions] Operator?

Operator Operator

[Operator Instructions] And the first question comes from the line of Andrew Baum from Citi.

Andrew Baum Analyst

Has the probability that you unblind ORION-4, your cardiovascular outcome trial at an interim next year materially increased. The reason for the question is the IRA has obviously increased the urgency to accelerate Leqvio in the U.S. ORION-4 is a very well-powered trial. If you unblind next year, you know you're going to get significance with the magnitude of MACE way higher than the 15% of the monoclonals, though perhaps less than 30% if you waited until 2026.

You've got your Victorian-2P second outcome trial to show a significant reduction in MACE and likely CV death in '27. So it would seem to me that this is a very viable opportunity. Alternatively, do you think you need to have a 30% MACE reduction because of the competition from -- in the near term Amsterdam and then Merck with their [role] at the end of the decade?

Vasant Narasimhan Executive

Thanks, Andrew. Great question. So first on ORION-4, the study is fully enrolled. And I think we've been able to manage the study well with the NHS and the U.K. teams that we're working with.

And so the study is very much on track.

We currently continue to plan to follow these patients out for the -- this was -- rather than doing an event-based study, we're doing a time-based study because of the data sets that you obviously know well that indicated that with further follow-up in these studies, you can get on the order of 30% CVRR. And that continues to be our strategy, of course, with Victorian-2 Prevent and in Victoria-1 Prevent also now running as well. Of course, we'll continue to assess as we move forward. We don't have any plants on unblind.

Now with -- and the reason for that is we believe that having a very compelling data set on the order of significant -- with that sort of significant CVRR will set us up well, not only for Leqvio, but our subsequent portfolio of SiRNAs, which we continue to advance, including, of course, longer-acting SiRNAs that hopefully can be administered once a year, combination SiRNAs, that are all currently being worked on within our research labs.

I would also say we're very focused and determined on trying to address the IRA in total to get to 9 to 13 for the all small molecule and NDA drugs, but also specifically to address the issue of genetically targeted drugs, siRNAs and ASOs, where there has been bipartisan legislation tables and we're hoping [Audio Gap].

Operator Operator

And your next question comes from the line of Kerry Holford from Berenberg.

Kerry Holford Analyst

A question on Pluvicto, please. So from the slides that we see, your peak sales target remains unchanged over USD 2 billion. And I recall previously, you noted success in the first-line setting to significantly expand the target patient population. So I wonder if you could just walk us through your -- what your peak sales guidance assumes with regard to indications approved? And whether there's a specific reason why you've not raised that target post

PSMAfore readout?

Vasant Narasimhan Executive

Yes. Thanks, Kerry. So we continue to believe Pluvicto is going to be a multibillion-dollar medicine. We're guiding to the rounded $1 billion on VISION in its first full year of launch, and we continue to see runway in the VISION population on its own to continue to grow at a healthy clip into next year. PSMAfore will obviously significantly expand depending on the final population 2 to 3x from where we are today with VISION.

And it's important to know, we still haven't really launched Pluvicto outside of the United States in a really meaningful way. So there's opportunity for global expansion as well.

Then stepwise from there, the PSMA EDITION study, which moves us into the hormone-sensitive setting with a readout in 2024, also has the potential of a further expansion on the level of what we would get from PSMAfore, so a similar expansion in patient population that's addressable. We've also launched additional studies in biochemical recurrence in oligometastatic prostate cancer moving into even earlier lines. Certainly, the potential is here for the medicine to be a very significant medicine. And so that will, of course, depend on the data sets and the timings of approval.

We don't plan to provide any sort of peak sales guidance at the moment beyond what we've already provided on Cosentyx and Entresto. We will do that as the product gets more mature, additional data sets come out, and we'll be in a better position to guide you as to how large the medicine could be.

Operator Operator

Your next question comes from the line of Emmanuel Papadakis from DB.

Emmanuel Papadakis Analyst

Perhaps I can start with Pluvicto and 'try and squeeze in a question I didn't get the chance to ask on the call beforehand. The question is really just relating to the trial design. In your estimation, what percent of patients are typically eligible for a switch of ARPI rather than being moved to chemotherapy?

And do you think adoption will be restricted to that switch subgroup based on the data? I'm asking because you've emphasized it will triple the eligible patient population with PSMAfore result. But obviously, you do not have any head-to-head chemotherapy data. So do you think physicians are going to extrapolate this beyond just confidence in use in that ARPI switch up group? Or is it really going to be restricted to that subgroup in its own or anyway...

Vasant Narasimhan Executive

Yes. Thanks, Emmanuel. So I think one of the things to note is it's much more -- we like to think of these things as linear, but it's much more fluid and very dependent on how you assess patients. I think there's going to be a few dynamics that will determine when Pluvicto is approved in the PSMAfore population, how it will be utilized. One, we know there's a large number of patients who, in the end -- a large proportion of patients who are chemo ineligible

for a variety of reasons.

And those patients, of course, would be patients you would want to use an alternative therapy like Pluvicto in.

We also know that there is a rapid expansion of F-18 PET scans that are being used in the metastatic population. And if you have an F-18 PET that's positive for PSMA, you might opt to use Pluvicto because obviously, you can treat to the scan, and you might use that ahead or after ARPI depending on the clinician's decision.

So I think there's going to be a very fluid nature in this pre-chemo setting where there's going to be ARPIs, there's going to be Pluvicto, maybe some physicians want to cycle ARPIs. But I think what we can say is that versus what we currently address in the VISION population, and we still have a significant opportunity just to expand within the VISION population. We would expect a significant increase with the move into that pre-taxane setting.

As Jeff also highlighted, we do have Phase II data that was generated as well in a head-to-head versus chemos, of course, not fully powered, but I think it did also indicate that Pluvicto compares favorably to so-called therapy study favorably versus chemo as well.

So I think a lot of data there that physicians can utilize. And speaking to at least my own conversations, I'm sure all of you will have your own interviews with them at ESMO, I think there's a lot of excitement. And I think the excitement is driven both by the efficacy of Pluvicto, but as important is the safety. And I think one of the things that's a shift in cancer care right now is that patients are demanding therapies that maintain or at least enable them to have a reasonable quality of life.

And one of the reasons we see -- we believe we see some strong uptake of Pluvicto in the VISION population is Pluvicto is very well tolerated. We certainly have some issues with the xerostomia and some mild issues as well with bone marrow, but overall, well managed and much better tolerated than some of the alternative therapies.

If you looked at the data that Jeff presented, even versus a switch ARPI, you saw lower rates of severe adverse events as well as Grade 3/4 adverse events, which again indicates that this is end of quality of life indicators. This is a well-tolerated therapy for patients. And I think there will be patient demand to avoid having to be on heavier loads of either ARPI or chemo if they can have a safe, highly-effective therapy. So I think all of those are favorable. But of course, there will be patients who physicians choose to cycle through ARPI as well.

So not a direct answer, but I hope that gives you some of the dynamics that we'll certainly be working on over the coming years.

Operator Operator

Your next question comes from the line of Florent Cespedes from Societe Generale.

Florent Cespedes Analyst

On emerging markets, you delivered pretty consistent growth quarter-over-quarter. I was just wondering how confident are you to continue to deliver such growth? Or is there any loss of

exclusivity to come in certain countries, notably in China that could impact this trajectory?

Vasant Narasimhan Executive

Yes. Thanks, Florent. I mean so we have, I think, very good growth in our international markets. In Europe, of course, we're currently working on overcoming a number of expiries that we have. You have -- certainly Lucentis has recently gone off.

You have other medicines that have recently gone off as well. And so the European growth has moderated and then we expect Europe to come back now over the coming years as new medicines launch to replace those expiring therapies.

China is seeing very robust growth, double-digit growth, which we continue to see in that market. We will, of course, come up against Entresto inclusion in the BBP framework, but we expect we'll be able to manage that. And then with the launches of other medicines, including Cosentyx, Leqvio, to continue the strong growth in China. Japan is growing double-digit at the moment on the back of the Entresto launch, and we'll soon be launching Leqvio as well in Japan. So very dynamic performance in the Japanese market.

So with all of those dynamics, we expect the international markets to continue to have very solid growth over the coming years. And that's driven primarily by the new launches.

Operator Operator

We will now take the next question and the question comes from the line of Seamus Fernandez from Guggenheim Securities.

Seamus Fernandez Analyst

So just to -- can you quantify the magnitude of contribution from Kesimpta in the quarter? And also just give us a sense of the directional trajectory? And then just a second question we've been getting from investors repeatedly on PSMAfore relative to the FDA, just wondering, relative to the Lumakras questions that were raised around that study and trial design, how confident are you that PSMAfore is on track for approval? And can you just update us on the timing of the filing?

Vasant Narasimhan Executive

Yes. Thanks, Seamus. So on Kesimpta, Harry?

Harry Kirsch Executive

As I assume the onetime contribution from the revenue deduction, right? So as you have seen, Kesimpta overall contributed $368 million as growth to the quarter, right, being now close to $660 million total sales. And of that, roughly $110 million is from this revenue deduction true-up. So if you take that out, still significant contribution of roughly $250 million, $260 million and also still a growth of 86%. Is that answering your question?

Seamus Fernandez Analyst

Yes.

Vasant Narasimhan Executive

Yes. On -- I will allow the second question this time, Seamus. So on PSMAfore, so as I stated, our plan is to file with -- when we get to a 75% information fraction. And we do feel confident that given the overall data set that we have generated with respect to all of the data, you hopefully saw at ESMO and in the earlier presentation that we have a very compelling benefit/risk profile, and we'll have to then navigate that with the agency with respect to the adjusted OS and the unadjusted OS as well.

We're a little bit in new territory. And so far as the FDA, I think, has made a significant shift affecting all cancer drugs with respect to the expectations of OS at the filing with PFS. But I think this is a really unique situation from the other situations that you mentioned. One, this study was extremely well designed and well conducted.

And you look at the dropout rates, which were very low because we allow crossover. You look at the time frame with which we're collecting the data. If you look at the rigor with which we collected the data, and you look at the size of the PFS benefit, where you have a doubling of the PFS benefit, significant gains in ORR, significant gains in patient-reported outcomes, a very clear safe, clean safety profile. I think taken together, that is a very different profile than maybe what you were referring to.

In addition, we have demonstrated OS in another study as well, which I think is an important factor as well when you think about this. Our belief is that with a 75% information fraction, we'll have collected adequate data to demonstrate the overall profile of the medicine. We'll, of course, file it. We'll deal with the review questions and then manage it from there. But I think based on all of the feedback we've heard from physicians and experts very clear that this is an important medicine that needs to eventually get approved and get out to patients.

Operator Operator

[Operator Instructions] The next question comes from the line of Simon Baker from Redburn.

Simon Baker Analyst

A slightly bigger picture question. Back in early September, you announced that NIBR was changing its name. I wonder if you could update us on what else is changing beyond the name at NIBR?

Vasant Narasimhan Executive

Yes. Thanks, Simon. We're excited about the outlook now for what we call now biomedical research within the company. We've made a number of changes in our overall R&D strategy. One, we're focusing very clearly now on 4 TAs, cardiorenal, neuroscience, oncology and immunology.

And you've seen also, I hope, in our filings that we've had a significant pruning of the portfolio down to what we believe is now approaching peer median in terms of the size of the portfolio, but that allows us to increase the number of scientists that we have on each one of our projects, which we hope will accelerate the prosecution of those projects, get us to data and readouts quicker, and hopefully get us to more and higher-value medicines overall.

So we've focused the portfolio and focused our R&D operations. Second, we've really created a system now where there's early commercial input even into research, something that Novartis had not really had between 2002 and last year. So now we have an integrated approach. We call it the RDC continuum, research, development and commercialization.

When we enter -- when we have a new project that's going to enter into the portfolio of research, that is reviewed by our executive leadership team to make sure we're all aligned that this is a medicine we want to pursue, it has significant potential, we do allow, of course, the appropriate amount of experimentation within biomedical research, but we want that early commercial input to ensure we're developing medicines that will matter for the world and matter for Novartis.

So there is also improved integration between research, development and commercial. And then, in addition, we're trying to make research and development as seamless as possible. So now we are increasingly having integrated teams. So if you CART and immunology, if you look at radioligand therapies, and some of our key areas, we're having integrated research and development teams to ensure that projects move seamlessly Phase I, Phase II, no big handoffs, which I think will also enable us to move much faster.

And lastly, we're changing how we measure ourselves. We're measuring ourselves solely on do we generate medicines in research that advance into late-stage development. If we generate data that's interesting, but not advancing, if we generate data that's ultimately leading to out-licensed drugs, that's not the goal of our company. Our company has to be to use our research dollars to develop medicines and ultimately get to market, and that's what we're very much focused on as well.

So I'm very grateful for the NIBR team, or the research, I should say, biomedical research team doing a really good job with this new strategy and look forward to higher productivity from research in the years to come.

Operator Operator

Your next question comes from the line of Richard Vosser from JPMorgan.

Richard Vosser Analyst

One on Cosentyx, please. Could you talk about your submission on HS? There's some discussion around in the market around potential label changes with regard to suicidal ideation, and I think one of your competitors has had placed on their IL-17 AF label. So just your thoughts on the submission time line, how that's going for HS? And also your thoughts on the emerging competition given that differential or different label that they have in terms of the warning?

Vasant Narasimhan Executive

Yes. Thanks, Richard. So for the recent approval of Cosentyx and IV as well as our ongoing assessments of Cosentyx HS, we've had no indications of any changes to our safety labeling from what has already been established based on the 10 years of experience we have with Cosentyx in the market. Many hundreds of thousands of patients treated, many millions of

patients -- ultimate patient years that we have on the medicine. So we have no indication, and we're in advanced discussions as well on the HS label right now for any labeling shifts.

And that's based on the data that we've consistently generated with respect to all safety signals and the clean profile that I think Cosentyx has demonstrated consistently over time.

Now with respect to the competitiveness, given that Cosentyx does not have suicidal ideation, the need for liver enzyme monitoring and very low rates of candidiasis, we believe that Cosentyx is positively differentiated versus the competitor product. Our strong reimbursement positions in the U.S. as well as outside the U.S. markets puts us in a very strong footing against any entrant, especially an entrant that has to overcome some safety liabilities. So I think we're very well positioned in that regard.

I would close by saying it's important to note that IL-17A inhibitors are distinct from IL-17AF inhibitors. Previously, as you all well know, brodalumab in 20 -- I think it was 2016, already has demonstrated that with IL-17F inhibition, you can have some of these adverse consequences for that medicine.

So I think mechanistically, it's also important to treat these medicines fundamentally different, and that's certainly what our position is as well. So looking forward for Cosentyx. The focus is continuing to drive and get back to growth in the U.S. behind the IV launch, as well as the upcoming HS approval in Europe, maintained a strong position in PSA, AS and psoriasis, but then also now drive the HS approval and then continue to complete the additional indications that we have ongoing to eventually reach the $7 billion peak sales that we've guided to.

Operator Operator

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

Graham Parry Analyst

This one for Harry. So 3 this year. You've had positive NATALEE data, PSMAfore, iptacopan for C3, IgAN I should say, since your last midterm guidance. So just wondering when is the right time to update that midterm guidance and how conservative that's looking now? And does the PSMAfore OS data still pending actually push out when you might provide the market with an update on midterm?

And then actually, I'll just [indiscernible] follow up on about the market comparison as well. I think one of the issues that's being raised in the market valves is the fact that there were some issues around the conduct of VISION and the early dropout that we saw in that study around the PFS analysis. So then you actually have that data on label. So if perhaps you can just compare and contrast the conduct of PSMAfore with VISION on the PFS endpoint? And any concerns the FDA might have there would be useful.

Vasant Narasimhan Executive

Thanks, Harry, on the guidance.

Harry Kirsch Executive

I think those were 4 questions.

Vasant Narasimhan Executive

Graham has about the same...

Harry Kirsch Executive

Graham, thank you. So I think overall, you nicely mentioned that we have taken up 3x the guidance this year, absolutely on top line 2x, now bottom line twice. I think in the end, of course, I don't think I've done it in my 10 years before, and it's not on purpose ever, right? Each moment of time, of course, we try to give you a very balanced picture.

You would say it's, of course, a little bit prudent, yes, but not to this extent. And I think we have seen, I think Vas mentioned from the beginning, we have been positively surprised how well the whole -- entire Novartis team, we are now 76,000 colleagues, right, after the Sandoz's spin, have responded to our transformation for growth program and the focus as a single innovative medicines company.

Of course, including some harder action, which in some countries depending on unit work, and so that took a bit longer of uncertainty, unfortunately. But now that we are through that, the majority is still here or there, some things to implement, we have seen that this gives us more agility, faster decision-making and better impact in the market. That's one thing.

And on the bottom line, we do execute slightly ahead of plan that helps, right? But of course, the most important in any pharma company is, the top line growth that has been done so well. There's a little bit of market expansion by probably 1 or 2 points. IQVIA global market has grown faster in the end versus initial estimates beginning of the year, but it doesn't explain 2x top line upgrade.

So it's really the vast majority of that I contribute to our new leaner way of operating in the company. So from that standpoint, very confident that we continue to drive good growth. There's, of course, we have the LOEs, smaller points, but attractive growth. And then Vas will give an outlook on the midterm growth potential of the company at the R&D Day.

Vasant Narasimhan Executive

Absolutely. So we continue to hold to the 4% and 40% margin, '22 to '27, and then we'll update further in the R&D day, Graham. Now with respect to the VISION versus PSMAfore, it's very different situations. The VISION study was partially inherited. There was no crossover allowed in the VISION study, so you had a high dropout rate, which was one of the things that we had to navigate with the FDA.

But ultimately, the compelling data set, both for rPFS, which then was not included in the label because of the dropout issue, but OS, which was in the outstanding safety profile, we were able to bring the medicine to patients without going to an advisory committee.

Contrast that to PSMAfore, where it was a very patient-friendly study, highly -- well-conducted, low dropout rate. I think when you look at the conduct of the study, very highly -- high integrity study that was conducted. And so really a very different situation and one where we really followed the guidance that FDA has given, which they encourage crossover for cancer studies because they want patients -- patient-friendly studies supported by the

patient community so when a patient progresses, they should be able to cross over onto the experimental therapy to achieve the full benefit.

Now what we have to navigate is, on the one hand, FDA encouraging us to do crossover, but then on the other hand, not letting us adjust for the crossover when we do the OS analysis. So now we're in -- I think companies across the industry are in a little bit of a conundrum as to how to manage that, and we're certainly planning on navigating that. So VISION is fully in the label. PSMAfore, a really well-conducted study that we're going to now take forward at the 75% information fraction.

Operator Operator

Your next question comes from the line of Mark Purcell from Morgan Stanley.

Mark Purcell Analyst

It's a question on Kisqali and the outlook. My understanding is that from early next year, there's going to have to be prioritizations behind Ibrance and Kisqali is in the pole position to take hold of that business with the NCCN 1 guideline recommendation.

So your NBRx share on a 3-month rolling basis was 46% in the presentation. How high do you believe that could go given that my understanding is about 1/3 of physicians are still only prescribing Ibrance.

And then just a housekeeping question, sticking on Kisqali. You've now hit 500 iDFS events. I was just wondering whether you could communicate if the upper confidence in for an overall survival is fallen below 1.0, it was 1.07 at the 46 iDFS events stage? And if not, your confidence in that reaching scale significance?

Vasant Narasimhan Executive

Yes. Thanks, Mark. So first, on Kisqali and [NBRx], obviously, it's hard to predict. And we certainly know that the MonarchE program will also read out in OS at some point in time. But nonetheless, we see very strong trends across the board on Kisqali.

We think the -- given our superiority the -- or I should say, given their strong OS data across 3 lines versus 1 competitor and the other competitors largely positioned as a second-line therapy after CDK4/6 failure, we're seeing very strong uptake. And we continue to believe we can become the leading -- consistently the leading NBRx player. And most importantly, that to start to translate consistently on TRx share which, of course, is the long term what was going to drive the sales potential.

So we don't see any signs at the moment of a slowdown on the trajectory that we -- you saw on that slide. And I would note that we see that trajectory not only in the U.S., but Kisqali now is achieving market leadership for NBRx in our key markets in Europe as well as elsewhere around the world, which I think really demonstrates that the -- in the metastatic setting, we're extremely well positioned for this medicine.

And as I noted, we believe in the metastatic setting alone you have a multibillion dollar potential. And then, of course, the adjuvant early breast cancer settings would come on top. I

can't comment on the details of the -- of course, on the data that will be presented later this year on the full 500 iDFS event. But we're really confident on the data set that we've seen. It's consistent, and I think only continues to support our case that this medicine should be approved in both the intermediate and high-risk settings, and that's what we tend to follow for.

Operator Operator

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

Steve Scala Analyst

There's a lot of momentum in the Novartis business as evidenced in the guidance raises. There's no reason why the momentum would suddenly stall as we begin 2024, yet consensus does show a bit of a slowdown. I assume you think consensus is underestimating the outlook in 2024. So where do you think consensus is misunderstanding the outlook for next year?

Vasant Narasimhan Executive

Yes. Thanks, Steve. So we won't provide, of course, any guidance at the moment on 2024. I mean if you just go through some of our key brands, and I actually am not up to speed on the precise numbers for 2024 consensus. As I've learned, it's better to focus on driving the medicines and not to pay too much attention to where consensus is.

But you look -- look, Entresto has continued momentum. We expect it to continue to grow across our key markets as we outlined. We think Cosentyx being back to growth on the back globally on the back of the HS -- a stronger growth than the back of the HS in IV indications. Kisqali is really on a strong growth trajectory, and we see no indications of that slowing down in the metastatic setting. And it is our intention to use a priority review voucher, assuming that the FDA agrees to accept it and get the early breast cancer indication moving with respect to Kisqali as soon as possible.

You've seen Kesimpta with really strong growth. And Kesimpta independent of the revenue adjustment item, very dynamic, 86% growth. And we see, again, no reason for that not to continue as the B-cell class share growth in Kesimpta's share of the B-cell class also grows over time.

Pluvicto, given the patient growth numbers that we see and getting the supply now fully unconstrained and getting the centers back up and running, adding more centers, focusing on demand generation, I think that's an exciting opportunity. And then we'll see, I think Lutathera in the frontline setting. This all just builds our radioligand therapy portfolio for the longer term to drive growth also in next year.

And then, of course, Leqvio, Scemblix, iptacopan all have the potential to make meaningful contributions as well. Scemblix, I think it's going to moderate the growth given that the third line setting is starting to get tapped out, but we eventually hope to be able to move it into earlier lines.

Leqvio will be slow and steady, but climbing that cardiovascular curve, which we've proven we know how to do over the years with Diovan, Entresto, Exforge, Lotrel. So we'll keep climbing

that curve. And then the opportunity to launch iptacopan in PNH. I would say that launch will be a tougher launch initially, but we believe over time, we can drive iptacopan to be the standard of care in PNH. And then hopefully get the approvals in C3G and IgAN in the later part of the year.

So I think that's the profile on those 9 key brands. Harry, anything you wanted to add?

Harry Kirsch Executive

Yes. Just one comment, of course. One thing we have to watch here together for is, of course, how the currencies are moving. I have mentioned this in my prepared remarks. But as we have outlined on Page 40 of the IR deck, and as you know, we update this every month on our website.

In '24, when you look at consensus at the moment, what we see on the in-house, right, is 3% on the top line roughly and then 7% on the bottom line. The FX is at the moment seen as a minus 1% to minus 2% on the top line impact if the currency stay where they are, and minus 3% on the bottom line, given that in the recent weeks and months, the dollar has strengthened.

So just 1 element as you model, right, and watch this. And of course, on top of that, we see a little increasing generic and LOE impacts and [excite our] divestment. Again, I don't want to talk down 2024, but we have to carefully model these things. I do expect that we have a continued excellent momentum on our growth drivers, of course.

Vasant Narasimhan Executive

Go ahead. I think it's one more question.

Operator Operator

We will now take our last question for today. And the question comes from Peter Welford from Jefferies.

Peter Welford Analyst

A quick, more broader one on radioligand therapies, given we've seen some big competitors potentially trying to get into this area. I'm curious if you can remind us of the barriers to entry that you see you build in this space? And also what your thoughts are in terms of presenting data internally from both the actinium and also potentially using antibodies together with your radioligand rather than just some of the peptides that are currently used in the portfolio.

Vasant Narasimhan Executive

Yes. Thanks, Peter. The first thing, of course, is building up the supply chain. And here, you've got to be able to source the upstream source materials, be able to produce the lutetium and then have the ability to do the manufacturing of a radioligand in a sterile environment. And then have the ability to run that supply chain with 5 days to get it -- or less, actually, it's really 3 days, you have to get it to the physician in their office to be able to administer -- or in their centers to be able to administer.

This is a major logistical challenge. We've worked on it now for many, many years. We've built up the global supply chain to have really unconstrained supply between our sites in Europe and our 2 sites in the U.S. with plans to add additional sites in Asia and potentially add additional capacity in Europe and the U.S.

I would also say on the supply side of things, we've invested heavily in semi-automated and automated lines, which puts us at the forefront, we believe, technologically in the industry to produce high volumes of radioligand therapy. So I think that's one piece of the puzzle is really solving that supply chain topic. We've had our bumps along the way. But I think it's not straightforward for a biotech or pharma company that lives in the world of inventories and not -- and having the luxury of having 6 months of inventory on hand to having a medicine that has 0 inventory in which patients and physicians expect the medicine to be delivered on time every time.

So really just-in-time delivery. Second is to build up the expertise to have a broad RLT pipeline. Right now, we have a broad number of agents. We'll be covering that in the upcoming R&D day. We've really built up the clinical trial network and the internal research and technical development expertise to have a portfolio of radioligand therapies.

Of course, we life cycle managed Pluvicto, we've life cycle managed Lutathera. We have our FAPi currently in Phase II studies. We have our [indiscernible] in Phase II studies. We have an Integrin. We're moving forward to folate as well as, as you mentioned, working on peptide -- other peptide fab fragment and antibody-based technologies that would allow us to use radioligand with these antibodies, including, I would say, established ADC targets, where if we can get the biology right, there could be the opportunity that radioligand therapies have an improved therapeutic index given the safety profile that we've seen for RLTs versus ADCs.

That's to be proven, but certainly, you have that opportunity when you build out that development portfolio. And then I think third is having the commercial infrastructure to actually be able to deliver this, manage this. It takes IT systems, patient flows and expertise on the ground that we've really consistently now built up around the world. So I think together, these 3 things consistently built with years now of investment and effort give us a substantial lead versus any competitor. But that said, we take competition very seriously.

We agree that there are many people now looking at the space, and we have to continue to raise the bar on how we execute to ensure that we remain the leaders in radioligand therapy in the long run.

And I think that's the last question. So I appreciate everybody's time today, and we look forward to giving you an update again at the R&D Day. I hope everyone will be able to join and thank you again for your interest in the company. We'll continue to work hard every day to keep delivering value for all of you, our shareholders. All the best.

Operator Operator

Thank you. This concludes today's conference call. Thank you for participating. You may now disconnect.