2022 Q2 results presentation and transcript

2022 Q2 results presentation

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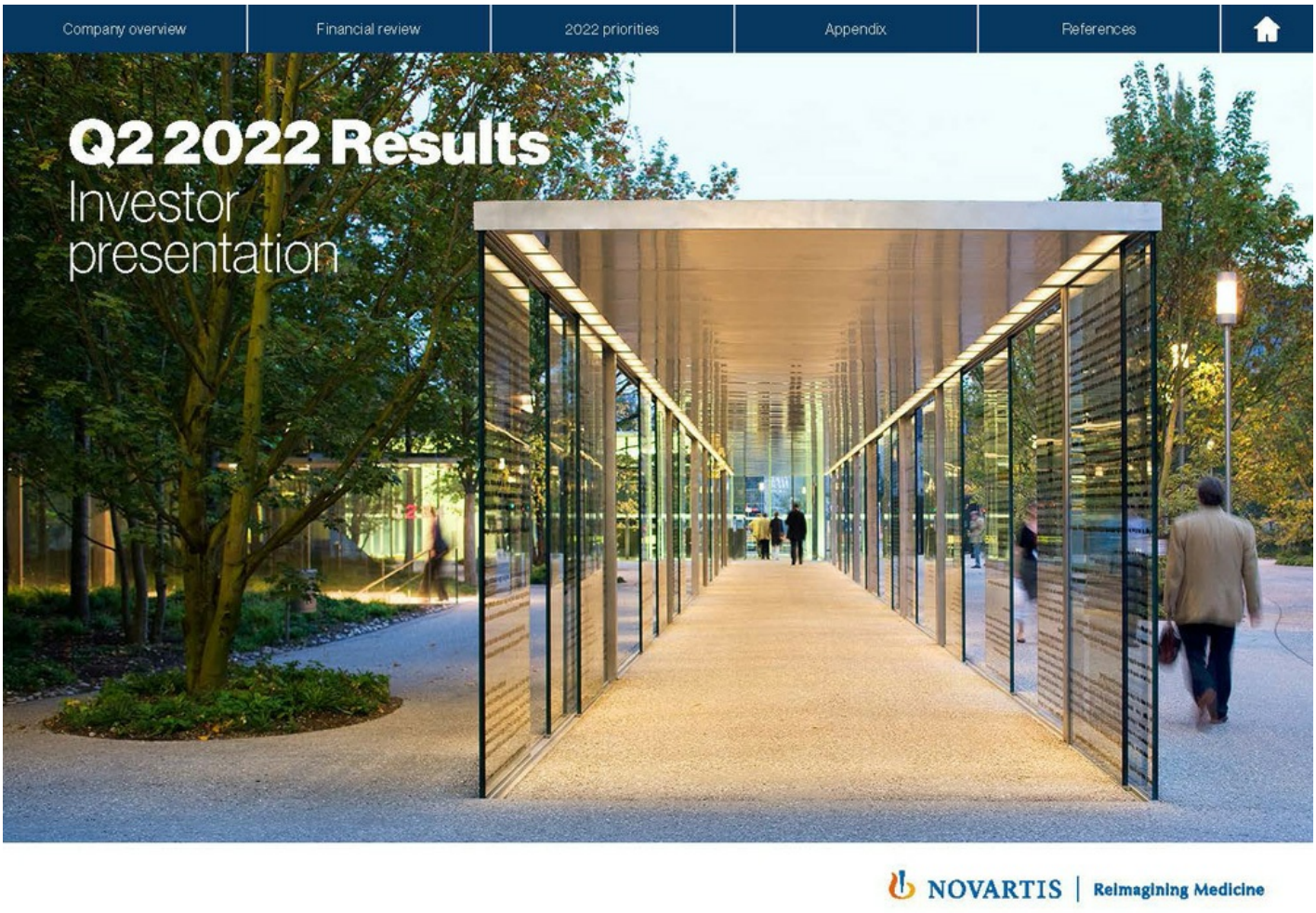
Transcript

View the 2022 Q2 results presentation and read the transcript slide by slide

Slide 1 - Samir Shah, Global Head Investor Relations



Thank you very much, and thank you to all of you who have joined us today on this beautiful summer's day for Novartis' quarter 2 results.

Slide 2

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 actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. For a description of some of these factors, please refer to the company's Form 20-F and its most recently quarterly results on Form 6-K that, respectively, were filed with and furnished to the US Securities and Exchange Commission. And with that, I'll hand across to Vas. Thank you.

Slide 3 - Vasant Narasimhan – CEO of Novartis

Vas Narasimhan
Chief Executive Officer

Company overview

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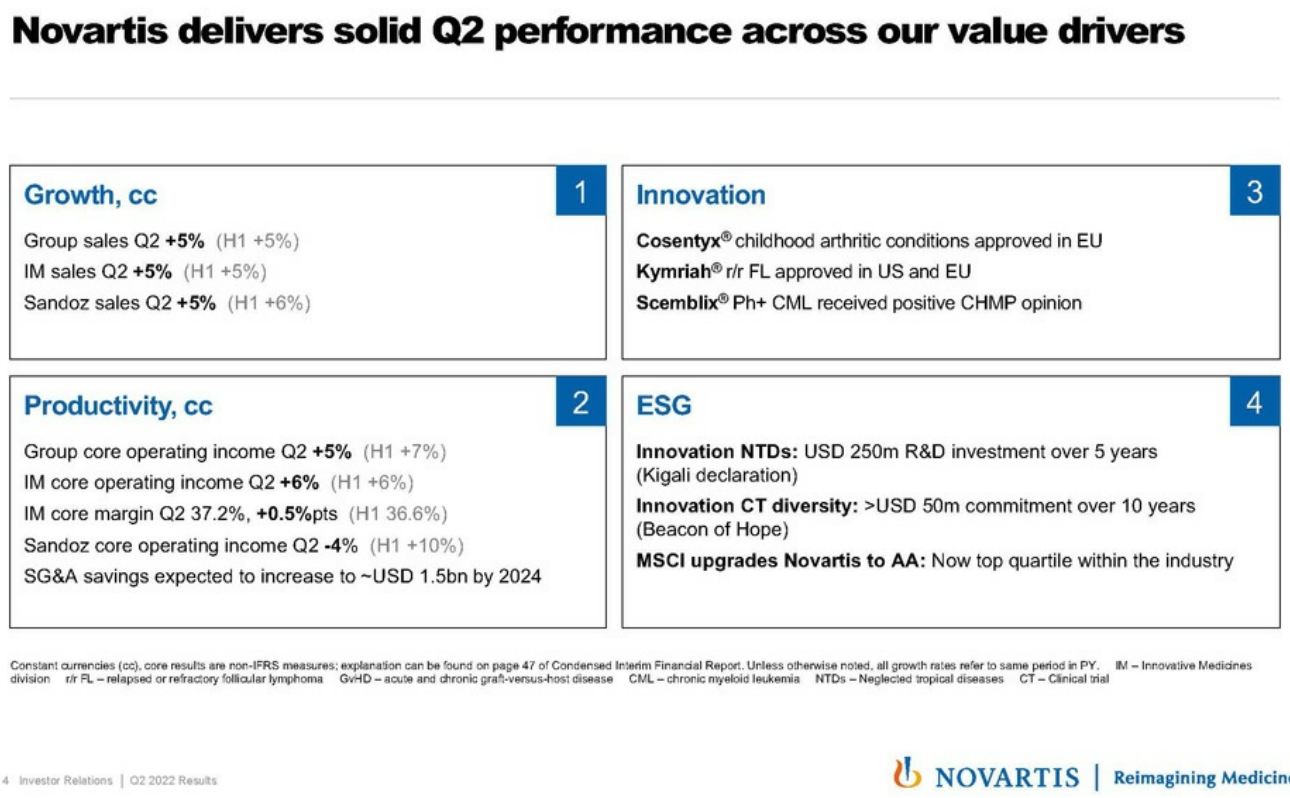
Thank you, Samir, and thanks, everyone, for joining today's conference call. We're pleased to go over the results. I have with me today, Harry Kirsch, our CFO; and Karen Hale, our Chief Legal Officer.

Slide 4

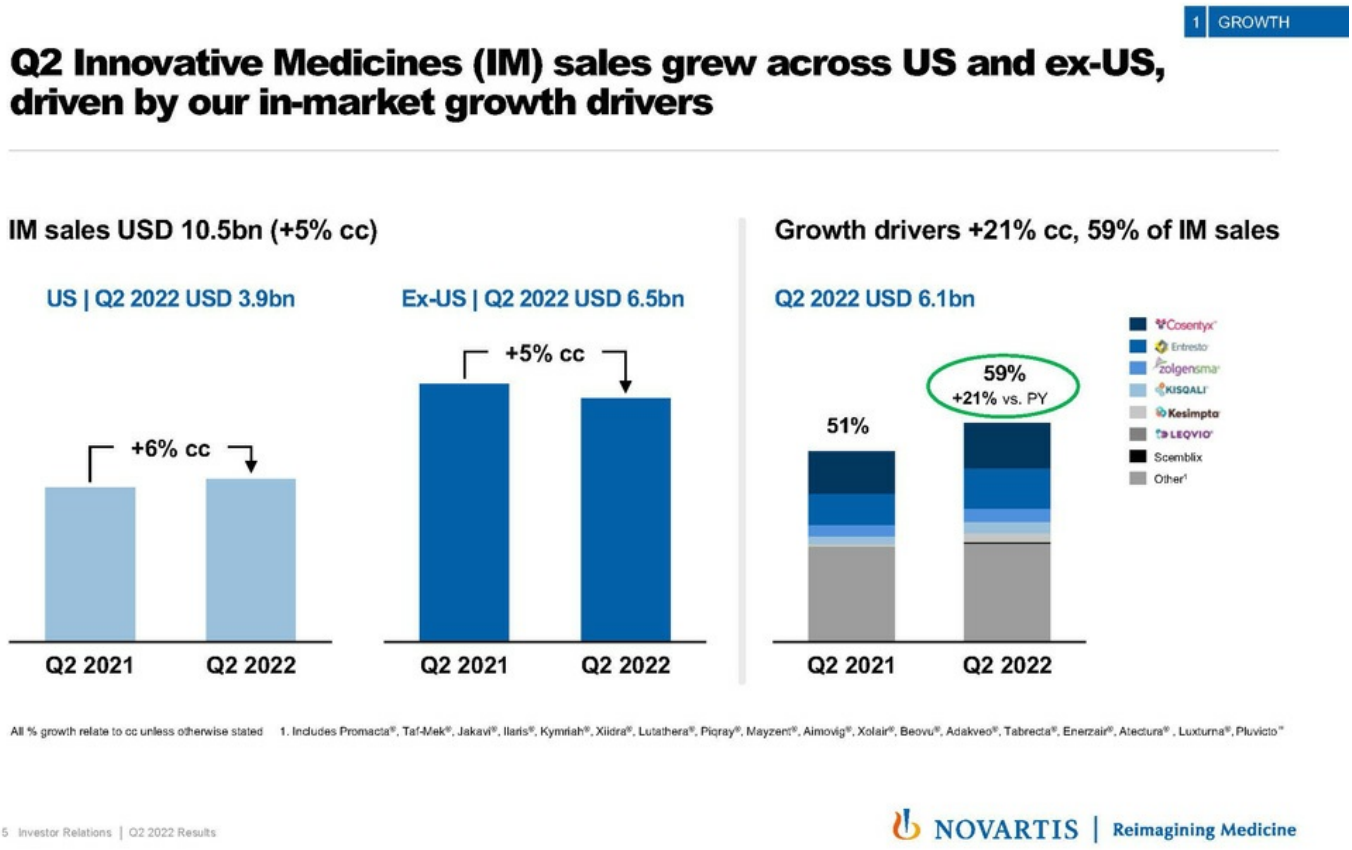


Moving to Slide 4. As you saw in the release earlier today, we delivered a solid quarter 2 across each of our key value drivers, 5% growth across the entire company as well as in Innovative Medicines and Sandoz, continuing our productivity agenda with solid core operating income growth across the business as well as continued margin expansion in constant currencies as well as an upgrade to our expected savings from our transformation program to now USD 1.5 billion.

Some innovation milestones. Notably, we continue to garner approval for Scemblix®, our new medicine for CML, including a positive CHMP opinion.

And then lastly, three milestones within our ESG efforts. First, the USD 250 million R&D commitment as part of the Kigali Declaration for neglected tropical diseases. We've increased our commitment to clinical trial diversity over the next 10 years through our Beacon of Hope project. And we also had an upgrade from MSCI to now a AA rating, top quartile within the industry. And we continue to work to further improve our overall ESG profile.

Slide 5



Moving to the next slide. When you look at Innovative Medicines sales, we grew consistently across the US and in our ex US markets, primarily driven by our key growth drivers. We had 6% sales in the US, 5% sales ex US. And you now see on the right-hand side of the chart, 59% of our sales come from our key growth drivers, and those key growth drivers are now growing at 21%.

Slide 6

1 GROWTH

Strong performance of Entresto®, Kesimpta®, Cosentyx®, Kisqali®, Zolgensma® and launching Leqvio®...

Q2 sales[1]

	Sales USD million	Growth vs. PY USD million	Growth vs. PY cc
Entresto	1,125	239	33%
Kesimpta	239	173	270%
Cosentyx	1,275	100	12%
KISQALI	308	83	43%
zolgensma	379	64	26%
SCEMBLIX	31	31	nm
ILARIS	275	28	20%
Tafinlar + Mekinist	452	27	13%
PROMACTA	534	21	10%
LEQVIO	22	20	nm
MAYZENT	85	16	29%
PLUVICTO	10	10	nm

Constant currencies (cc) is a non-IFRS measure; explanation of non-IFRS measures can be found on page 47 of Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY
nm – not meaningful 1. Innovative Medicines division

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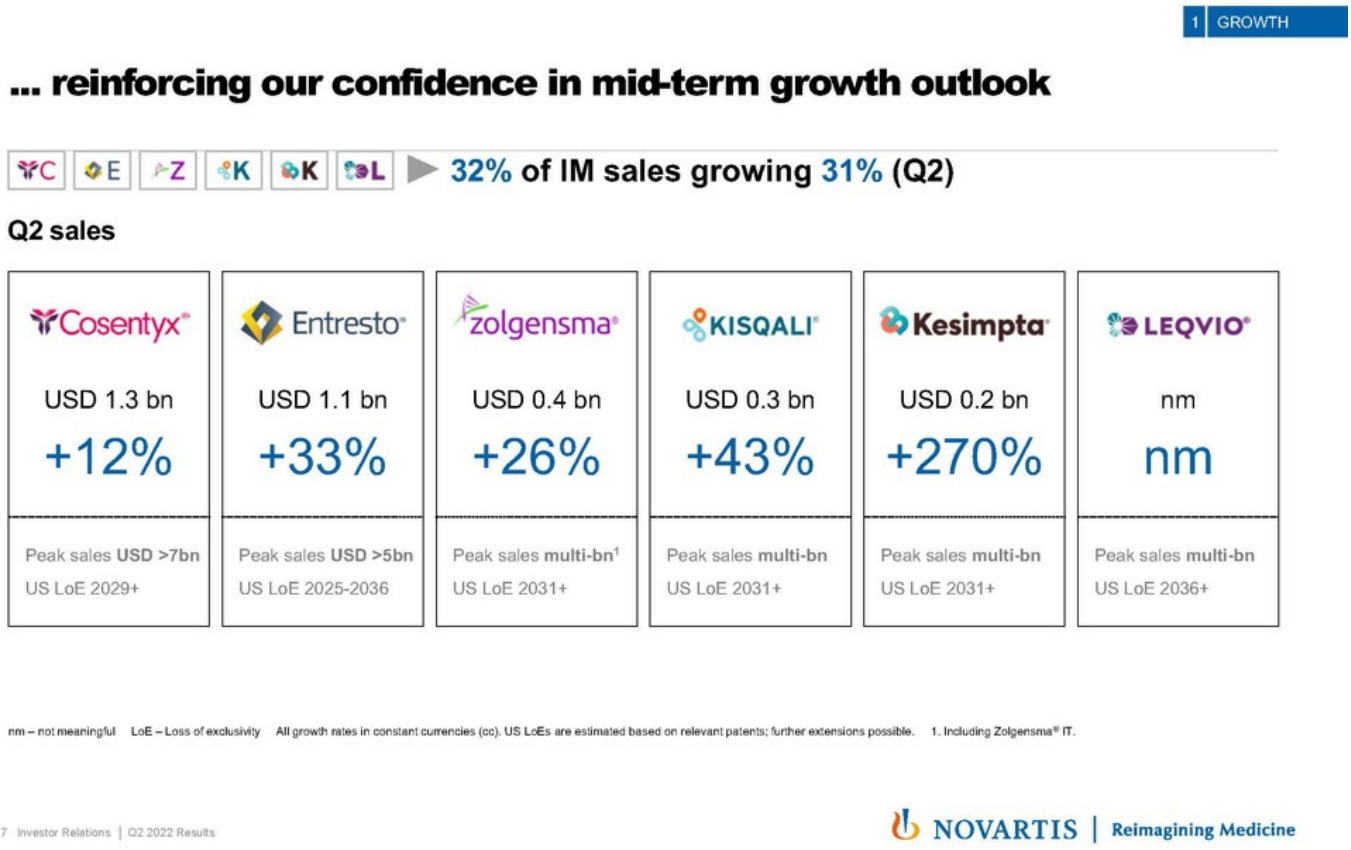
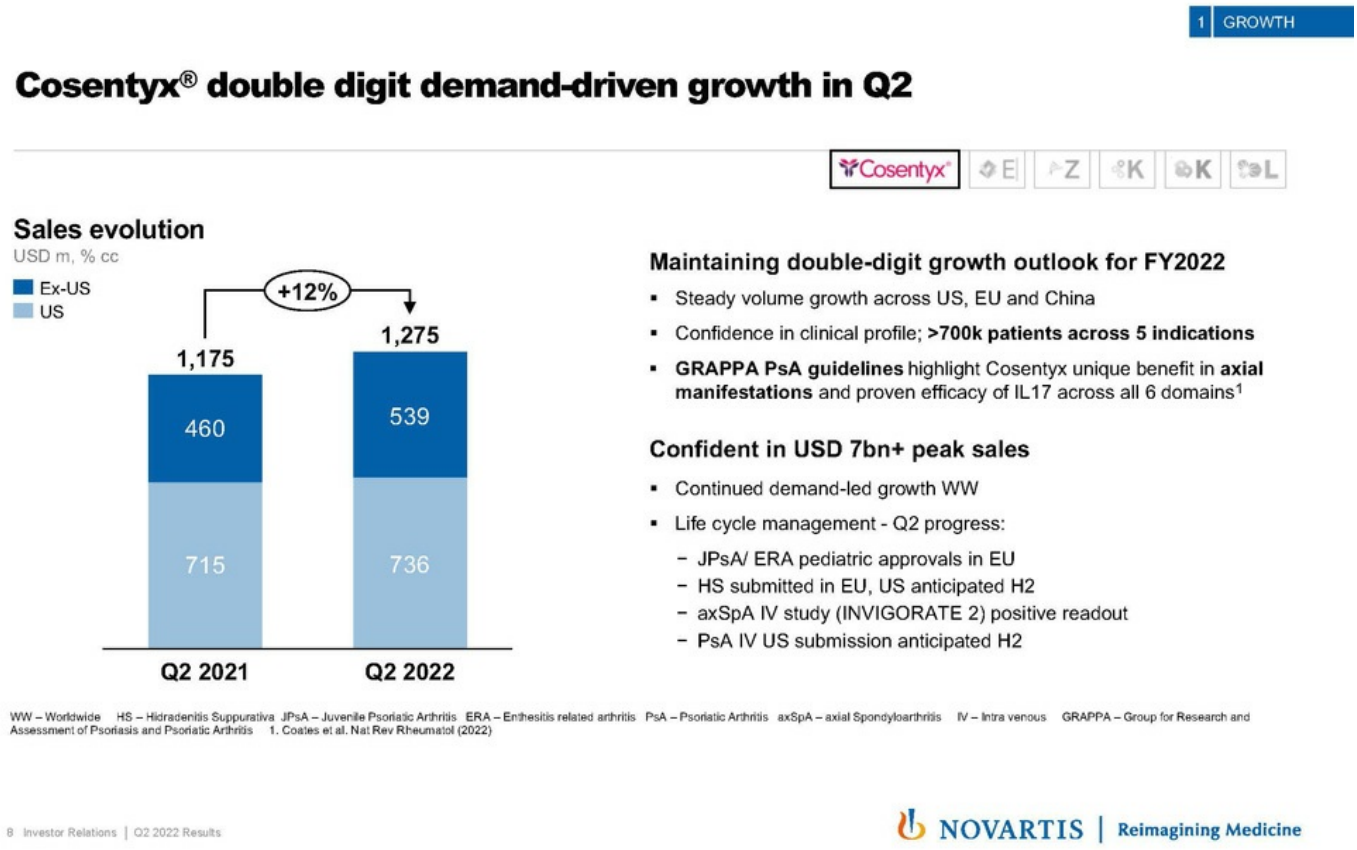
And moving to the next slide and zooming in a little closer on the quarter. You saw pretty consistent performance across our key medicines, and we'll go through this in a bit more detail. Two things – two products I wanted to particularly call out. Kesimpta® had a very strong quarter, I think, demonstrating its overall profile as a multiple sclerosis therapy of choice. And Kisqali® as well is now gaining momentum in breast cancer – in metastatic breast cancer patients, and we'll talk a little bit more about that throughout the call.

Slide 7



Now moving to the next slide. We've really focused attention as a company on six key growth drivers, we believe, which will enable us to deliver the growth profile we've outlined both in the next 5 years and also beyond. Notably, Cosentyx® and Entresto® continued their outstanding performance towards their respective peak sales goal. We'll talk more about Zolgensma®, which continues its global expansion. Kisqali® and Kesimpta®, I've already mentioned. And Leqvio®, we are building a strong base with which we believe will enable this medicine to reach a significant sales potential over time. Taken together, these six brands now constitute 32% of Innovative Medicine sales, and they're growing at 31%, I think giving confidence in the growth outlook that we've outlined.

Slide 8

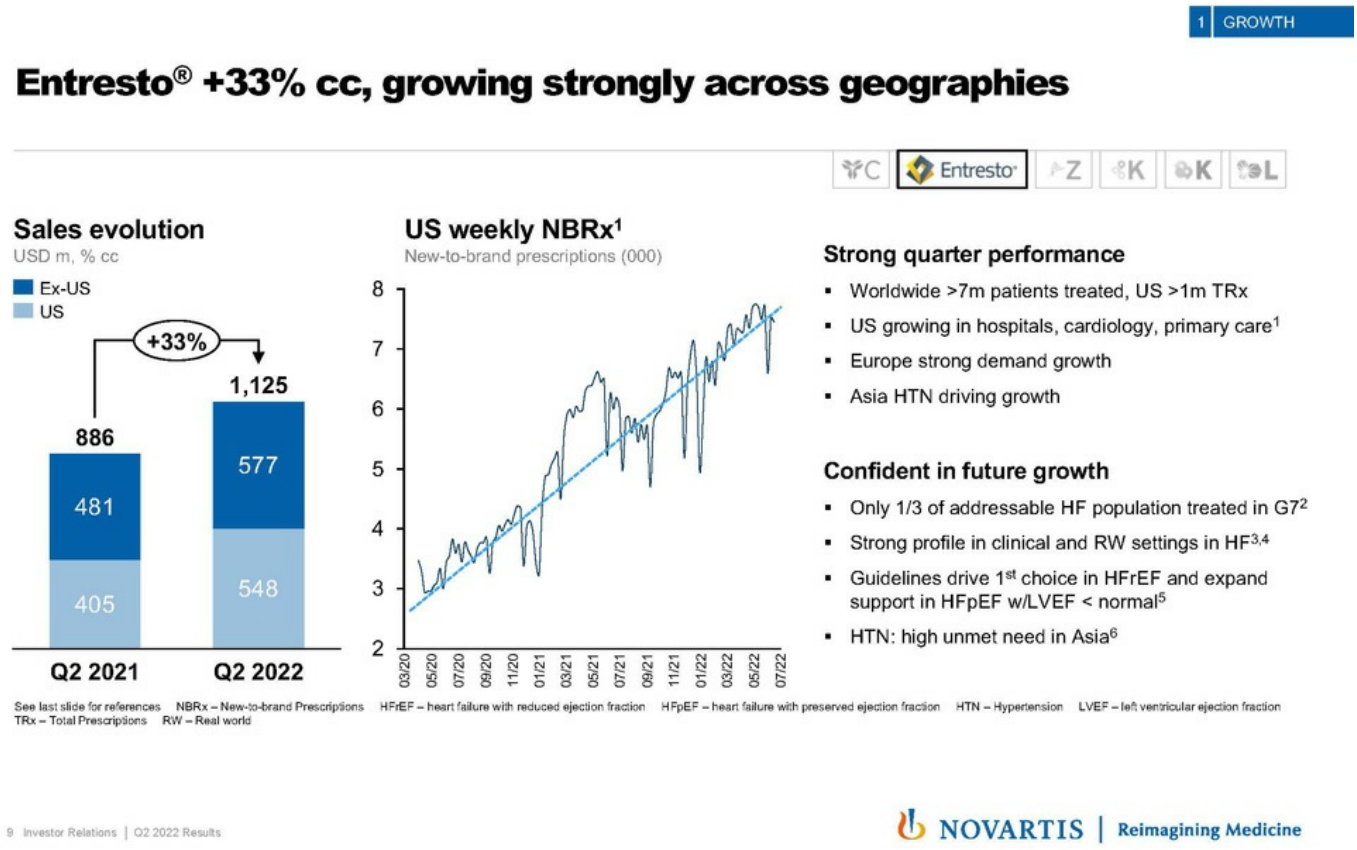


Now moving to Slide 8 and going through each of these key brands, starting with Cosentyx®. Cosentyx® delivered sales 12% sales growth on the quarter. When you look at the outlook for Cosentyx®, we continue to guide to a double-digit growth, driven by steady volume growth in the key geographies, US, Europe and China.

We're very confident in the overall clinical profile now that we've treated over 700,000 patients across five of the indications indicated for Cosentyx®. And we continue to get important guideline recommendations, including the GRAPPA psoriatic arthritis guidelines, which highlight Cosentyx®' unique benefit versus alternative therapies, including the IL-12/23s; and its ability to tackle axial manifestations of this disease.

Overall, we're confident in the USD 7 billion-plus peak sales potential. This will be driven by global expansion of the product as well as life-cycle management, where we had some good progress in the quarter, including approvals in pediatrics in Europe. We've submitted hidradenitis suppurativa in the EU, and we expect to submit in the US in the second half. We have positive data on an IV study looking at Cosentyx® use in axial spondyloarthritis. And lastly, we do anticipate an IV submission in the US as well in psoriatic arthritis. Four proof points of our ongoing efforts on life-cycle management for Cosentyx®.

Slide 9



Then moving to the next slide, Slide 9. When you look at Entresto®, Entresto® is continuing its really dynamic growth globally. And in the US, you can see we delivered 33% growth with Entresto®. Our weekly NBRx continues its strong progression with continued strong growth. We've now treated over 7 million patients globally and over 1 million patients in the US, growing in hospitals, cardiology and primary care. So really strong growth across geographies.

And we're confident in the future growth and delivering the USD 5 billion-plus peak sales potential for this brand. There's only 1/3 of the addressable population that's been treated. And we see a strong profile consistently regardless of the setting the medicine is used in. And lastly, with the approval of Entresto® in hypertension in Japan and China, where there's a high unmet need, it gives another opportunity for future growth.

Slide 10

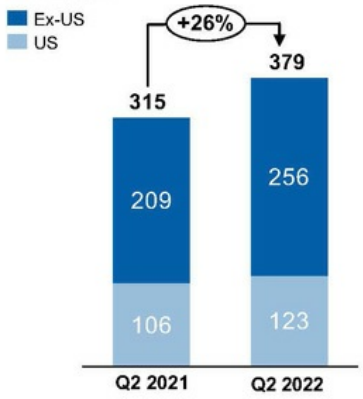
1 GROWTH

Zolgensma® grows +26% in Q2 driven by strong ex-US growth

Continued geographic expansion as the foundational therapy for SMA

Sales evolution

USD m, % cc



Q2 highlights

- 2300+ patients now treated worldwide; treatment of choice for SMA type 1 newborns[1]
- Recent reimbursement decisions in Australia, Switzerland and Greece
- NC multi-product manufacturing facility achieved FDA & EMA commercial licensure approval

Future growth drivers

- Increase uptake worldwide, now approved in 43 countries to-date
- Newborn screening: 97% in US and 30% in EU
- OAV101 IT data[1]: STEER currently enrolling; STRENGTH to start in 2H22

Nature Medicine publication: transformational benefit in pre-symptomatic SMA

- Age-appropriate development for most patients when used pre-symptomatically in 3-copy SMA; 14/15 patients walking alone, 11 of them within normal developmental window

NC – North Carolina SMA – Spinal muscular atrophy 1. Source: Symphony Anonymous Patient Level Data

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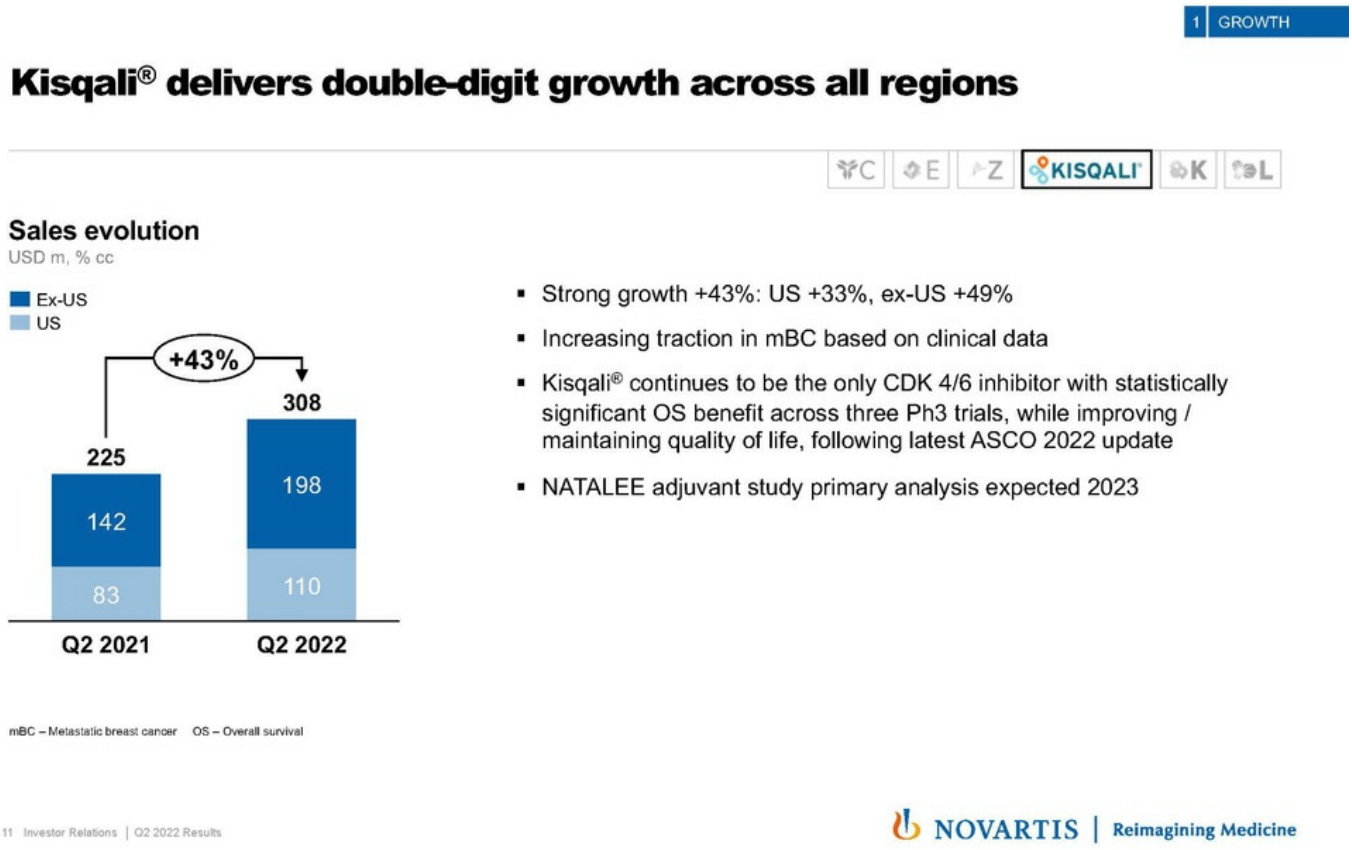
Now moving to Slide 10 with Zolgensma®. Zolgensma® is continuing to demonstrate the power of a onetime gene therapy to treat really – in a dramatic way, treat a terrible disease like SMA. 26% growth driven by global expansion, 2,300 patients now treated. We had recent reimbursement decisions, positive reimbursement decisions in Australia, Switzerland and Greece. And we recently received approval for our North Carolina new manufacturing facility, which further expands the capacity of our gene therapy network and really brings online the state of the art facility, continuing our leadership in the gene – AAV gene therapy space.

Now future growth drivers for Zolgensma® are going to be that continued global expansion, 43 countries to date and growing. We also want to enable stronger newborn screening programs outside of the United States. 97% of newborns are screened in the US, but only 30% in Europe and those numbers are similar or lower in many other geographies. As we can get more newborns screened, then we believe Zolgensma® is the treatment of choice for these babies, allows for normalization of their overall development.

And we saw that in a Nature publication that recently summarized the data from one of our earlier studies, with 14 out of 15 patients walking alone and 11 of them in the normal development window when treated early with Zolgensma®. I also want to note that both our STEER studies and STRENGTH studies are progressing well. And we continue to outlook a submission in intrathecal for Zolgensma® for 2- to 18-year olds in 2025.

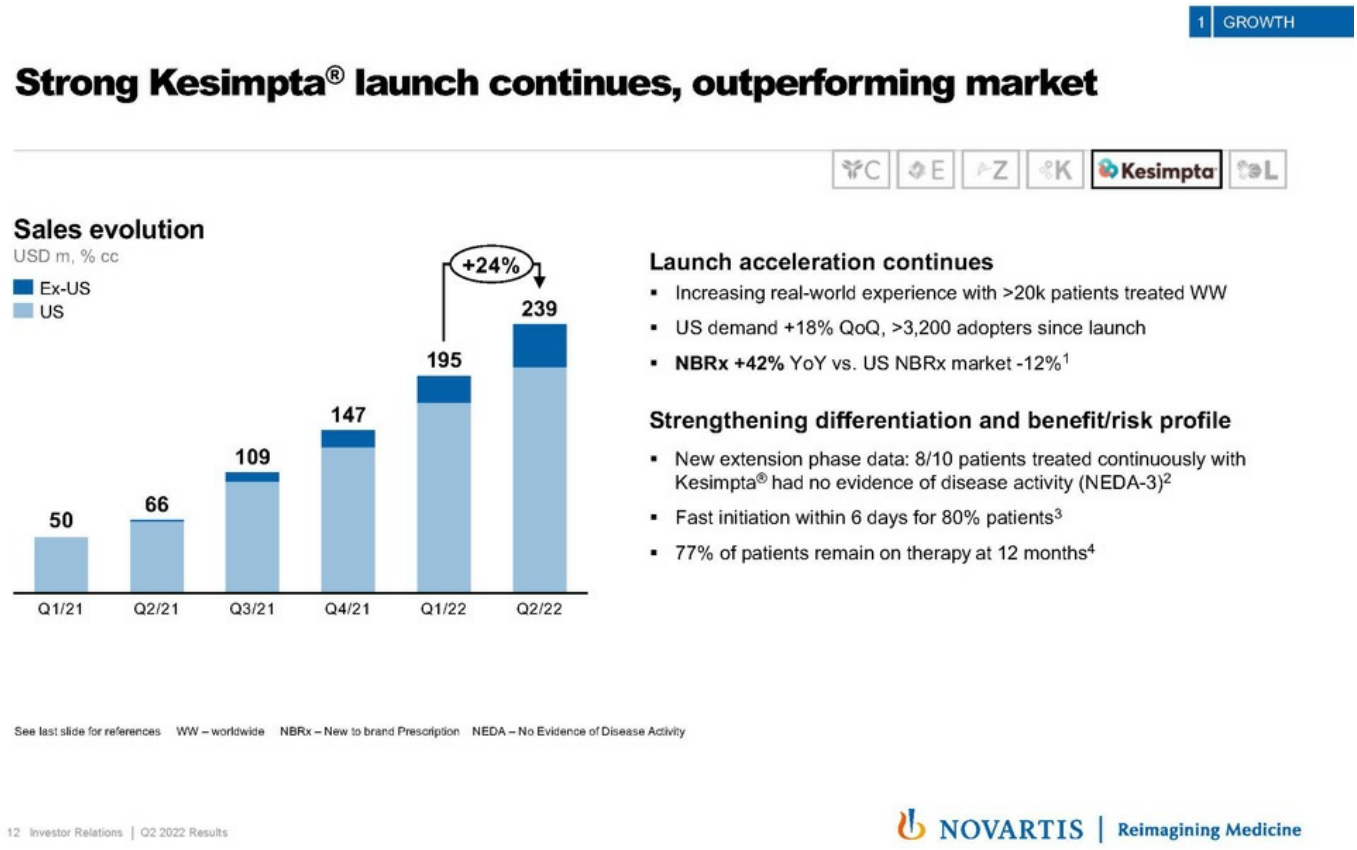
Slide 11



Then moving to the next slide with Kisqali®. We continue to deliver double-digit growth, you see 43% growth. And we see this as a brand that, given its recent data releases, is really coming into a strong profile and a strong growth profile. We're seeing increased traction based on the clinical data. I'll talk more about that a little bit later in the presentation.

And we saw that, at ASCO, once again, we were able to highlight some of the data sets, particularly around OS in the first-line setting, which demonstrates the strong profile of Kisqali®. The NATALEE adjuvant study, primary analysis is expected in 2023 and continues to progress on track. And I'll talk more about that in the pipeline section.

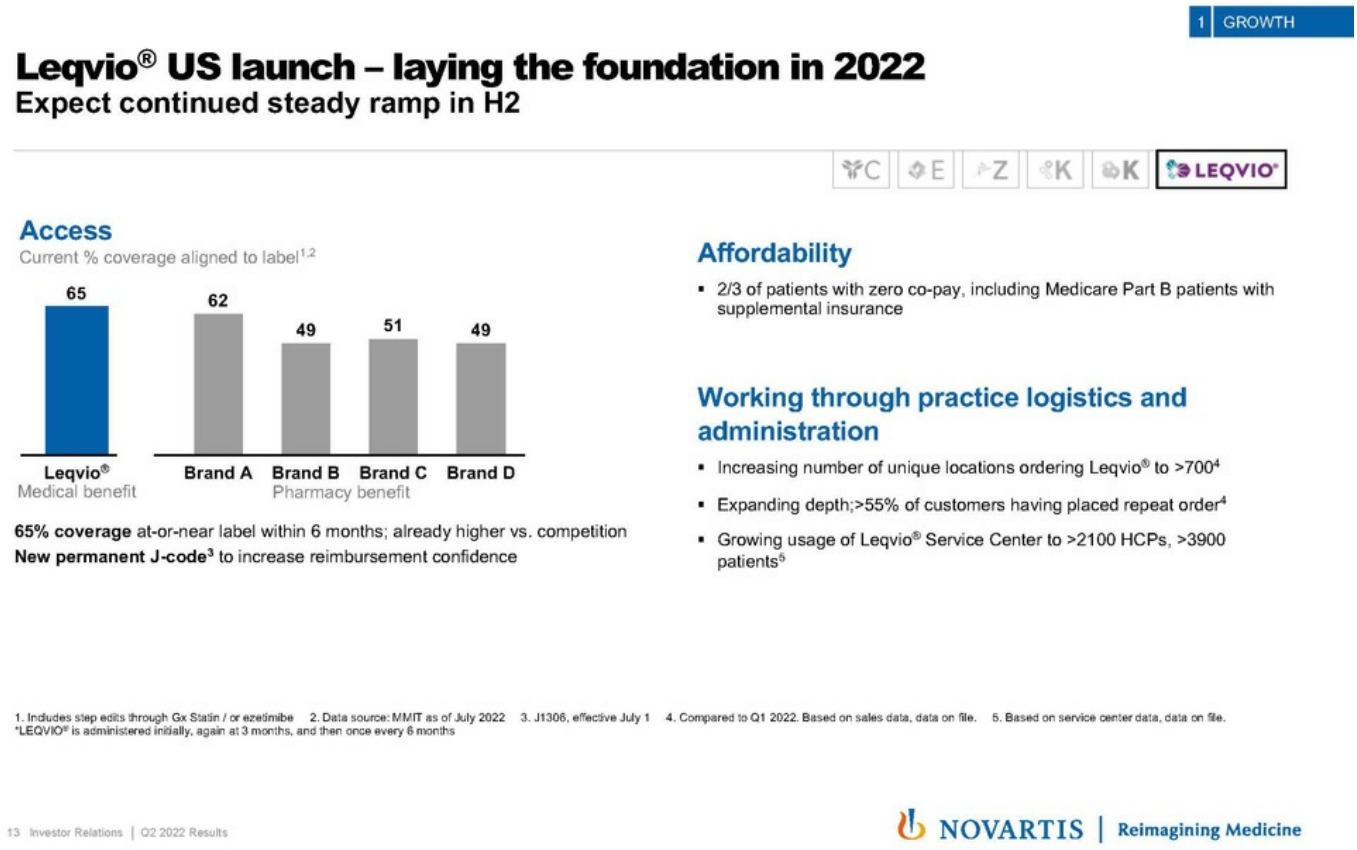
Slide 12



Now moving to Kesimpta® on the next slide, Slide 12. The launch is continuing to – and really continuing on a strong trajectory. We see an acceleration of the brand in the US, and we continue to work towards providing the medicine globally in our key markets. We have US demand of 18% growth quarter-over-quarter. We have 3,200 adopters, physician adopters, since launch. You can see the NBRx up now 42%. It's really dynamic growth for this medicine.

And we're working to continue to strengthen the profile and differentiation. We have new extension data which demonstrated 8 out of 10 patients treated continuously with Kesimpta® had no evidence of disease activity. From an operational standpoint, we continue to work to drive fast initiation. Patients are now getting on therapy within 6 days, 80% of patients are achieving that goal. And 77% of patients remain on therapy at 12 months, which I think, again, demonstrates the medicine's impact as well as its ease of use for patients. So very excited about the outlook for Kesimpta®.

Slide 13



Now moving to the next slide, on Slide 13. With Leqvio®, we're laying the foundation, as we've outlined, in 2022, for the ramp we expect over the coming years. And we continue to expect the remainder of 2022 for a steady ramp-up of Leqvio®. But I think there's important proof points that we're beginning to lay that groundwork successfully.

First, with respect to access. And as a reminder, Leqvio® is under the medical benefit. We have 65% of patients now covered with – aligned to our label or near our label, and that's within 6 months of launch. This is higher than relevant competitor brands, both from PCSK monoclonal antibodies and/or other recently launched anti-cholesterol therapeutics, and those brands have been in the market for many years. So I think that it demonstrates we've been able to drive fast access. And the J code now is in place as of July 1. So I think from an access perspective, we're progressing well, progressing on or ahead of our plan, and I think that sets us up well for the future.

Secondly on affordability, we can now confirm the 2/3 of the patients have 0 co-pay for Leqvio®, including Medicare Part D patients with supplemental insurance. This, again, we believe, will enable a strong uptake and strong adherence to this medicine so patients can get the benefit that they need from lower cholesterol.

And lastly, we're making progress working through logistics and administration for this medicine in cardiologist offices as well as in relevant hospitals and medical centers. We've increased the number of unique locations ordering Leqvio® to over 700. We're expanding the depth now with 55% of our customers already having placed repeat orders. And we're seeing growing usage now, with 2,100 HCPs and now 3,900 patients in the service center.

So all of this taken together, I think, points to a strong future for the brand. And we'll continue to work through the second half of this year to build out this base to enable long-term growth.

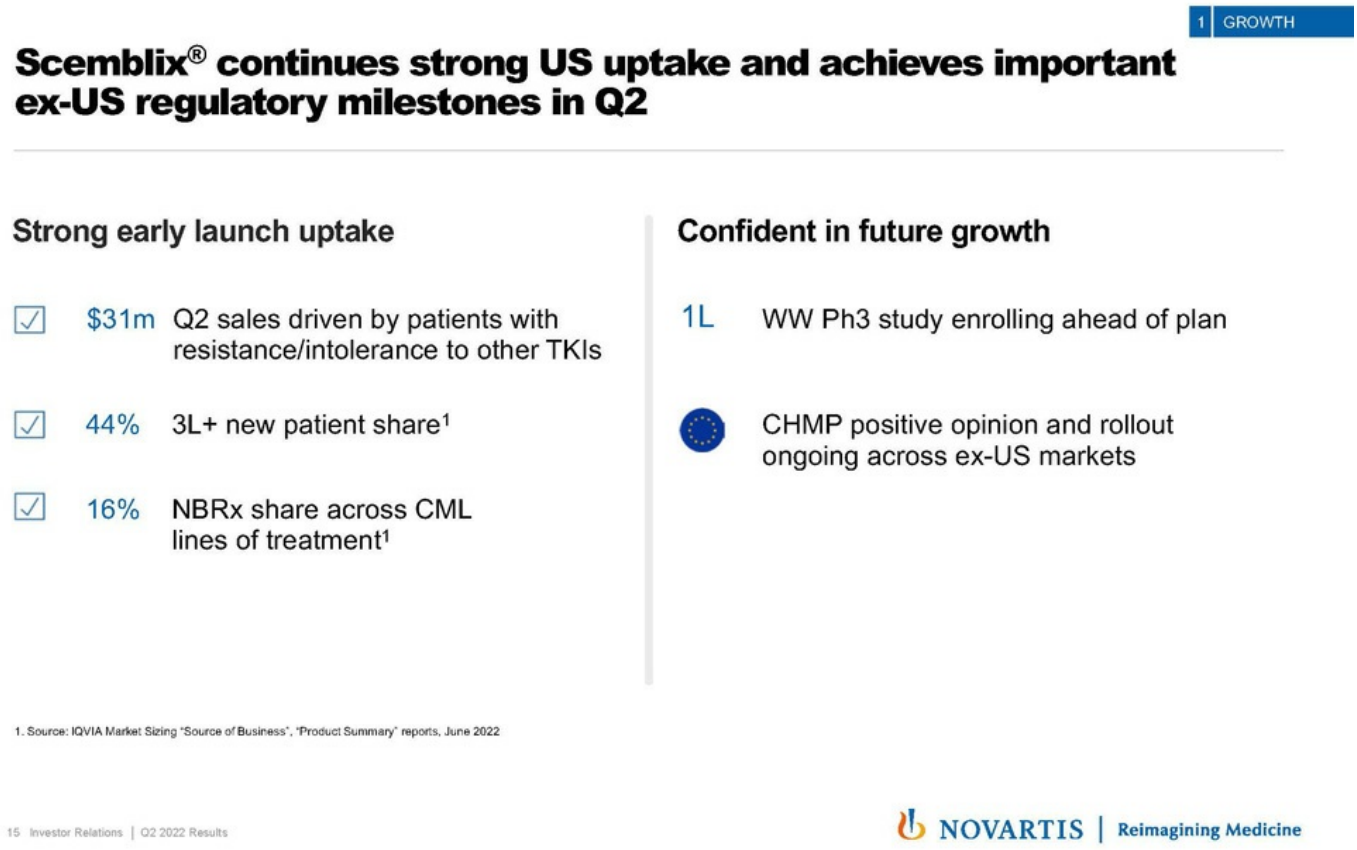
Slide 14

Then moving to the next slide, Slide 14, with Pluvicto®. And moving to our two recently launched medicines in oncology, Pluvicto® and Scemblix®. The Pluvicto® launch is really progressing in a strong manner, and it's either at or above our own expectations. We've seen our manufacturing issues remediated and we've cleared our backlog. Commercial and clinical supply resumed in June. We have a permanent A code that was granted in July and that will be effective in October. Over 50% of insured lives now are covered. We have over 100 RLT sites now operational, 40 sites have completed orders. So a strong trajectory from the start, and we're hoping to maintain that over the coming months.

We're preparing for further expansion with this medicine given the clinical profile we've seen to date. Both the Phase III studies are on track, both in the pre-taxane setting and the hormone-sensitive setting, with a readout for the pre-taxane study still slated for the – before the end of this year.

The manufacturing scale-up is ongoing. We have a new facility in Indianapolis that we plan to bring online in the second half of next year, and we have capacity and our expansions ongoing in our Italy and New Jersey sites. And we're making significant investments to ensure logistics can support access, as the patient population that can be reached by radioligand therapies continue to expand across Pluvicto®, Lutathera® and our pipeline.

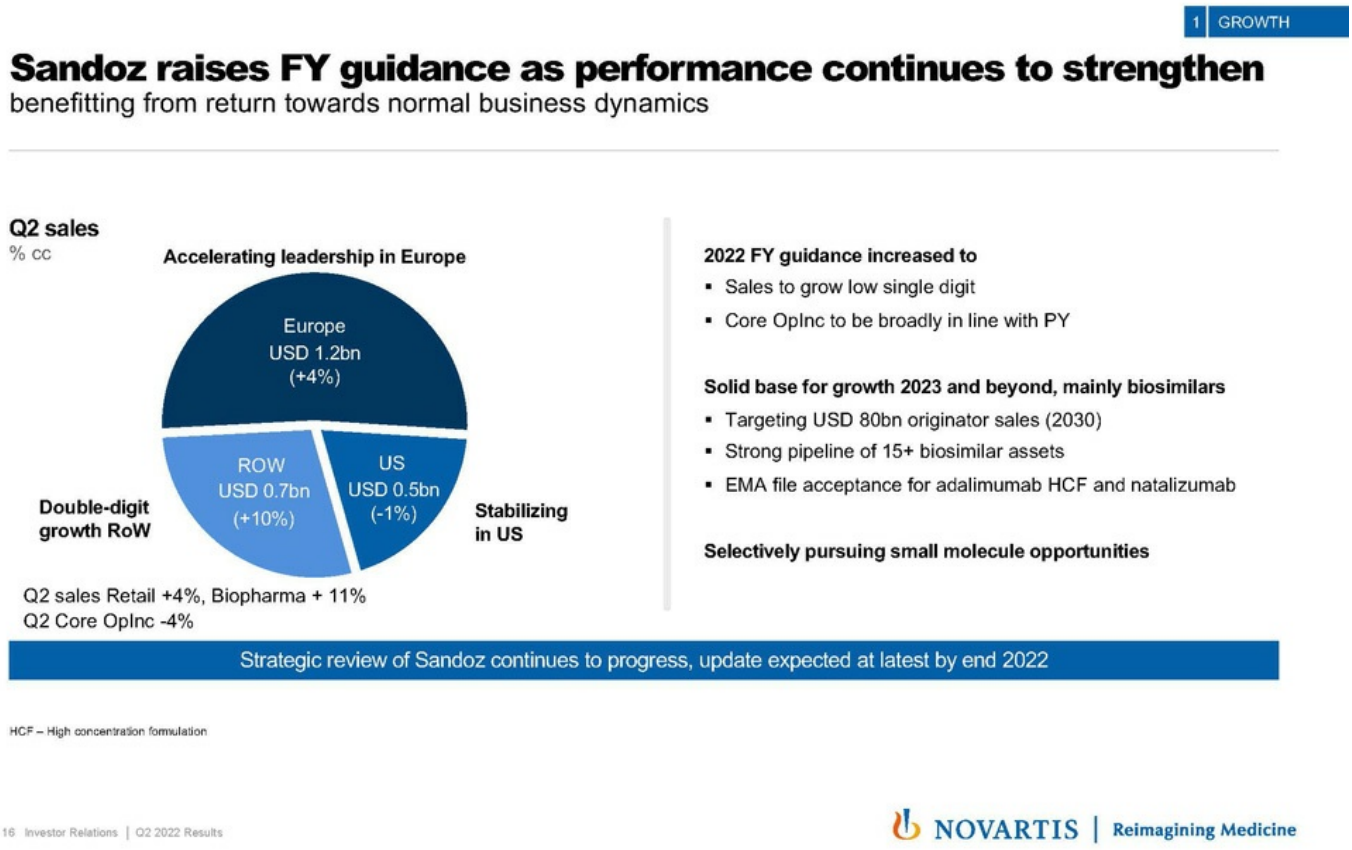
Slide 15



So moving to the next slide, Slide 15. Scemblix® as well is off to a very strong US launch. And then we achieved the, as I noted earlier, important regulatory milestones in the EU, USD 31 million of sales, primarily driven in that third-line setting. 44% share in the third line, which I think is a good marker given how recently we launched the medicine. And 16% NBRx share regardless of CML line of treatment.

In terms of future growth for Scemblix®, it's going to be driven by the first-line study which is enrolling ahead of plan. Just as a reminder, it's versus investigator choice of TKI. And the CHMP positive opinion in the ex US markets, where we continue to work to get a global rollout of the medicine.

Slide 16



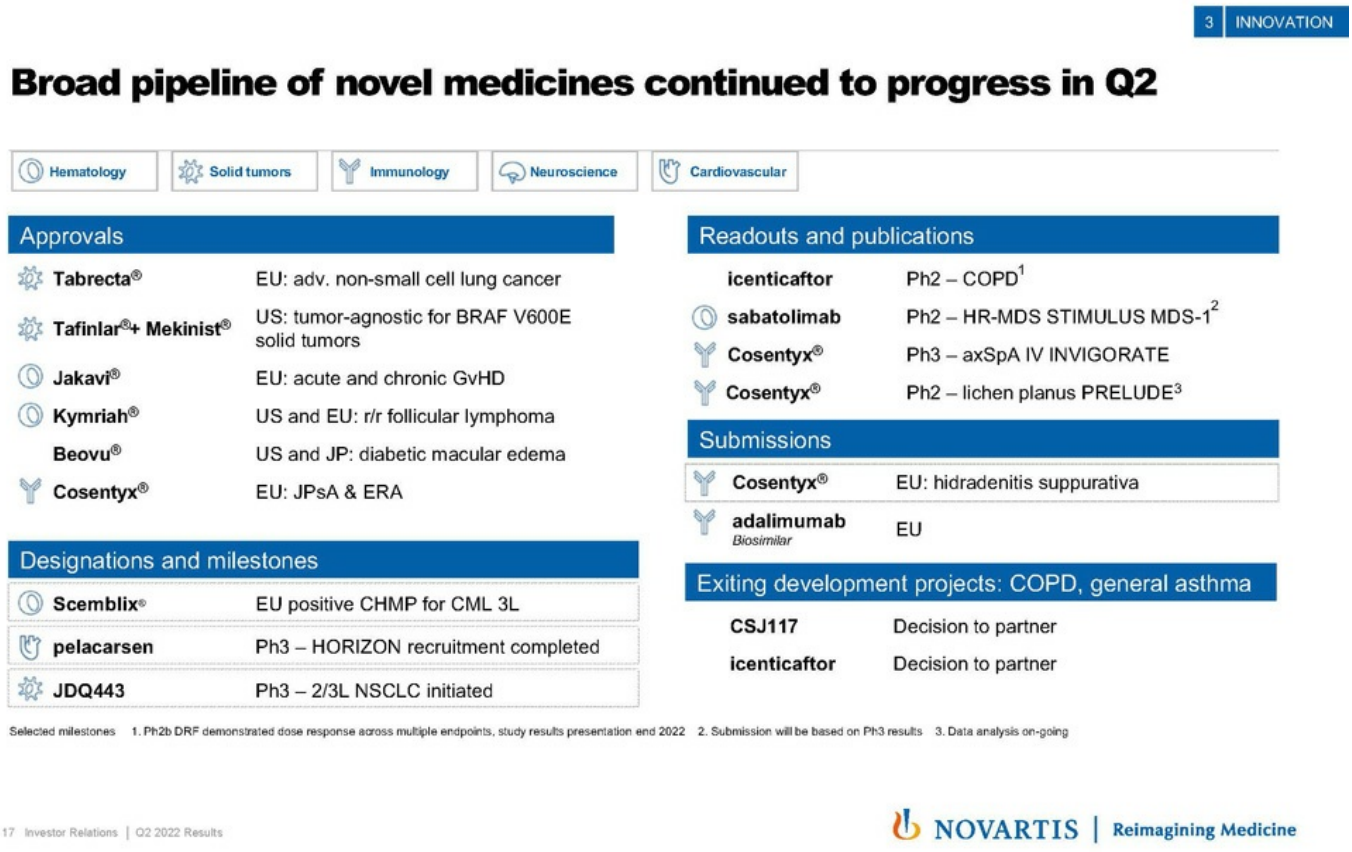
So moving to the next slide and turning to Sandoz. As you saw, Sandoz had a really solid quarter in quarter 2. And we raised the full year guidance for Sandoz, and Harry will talk a little bit more about that. When you look at the drivers for Sandoz's sales performance, it's primarily in Europe, where we are a leader, the leading generics company, with 4% growth driven by both launches as well as recovery of the health care systems.

We had double-digit growth in the rest of world markets, Japan and other emerging markets. And we've seen a stabilization in the US business, setting us up with future biosimilars launches and small molecules launches to drive growth in the US over the years to come. You can see our retail sales growth in the quarter was 4%, biopharma was up 11%, so we've raised the guidance as mentioned.

And when you look longer term, we believe this creates a solid base of growth – for growth 2023 and beyond. And a lot of that will be driven by the biosimilars portfolio. The portfolio of biosimilars and Sandoz targets USD 80 billion of originator sales. Over 15 assets in the portfolio. And some recent progress, including the acceptance of the adalimumab high-concentration formulation as well as natalizumab in the EU.

We're also continuing to pursue small molecule opportunities to bolster the small molecule portfolio. Overall, the strategic review for Sandoz is continuing to progress on track, and we expect an update at the latest by the end of this year.

Slide 17



So moving to the next slide on Slide 17. Our broad pipeline of novel medicines progressed in quarter 2, but we've also worked to focus our efforts, as you saw in both our earnings release as well as with some of our pipeline decisions, five core therapeutic areas while being opportunistic in other therapeutic areas. And we're trying to make consequential decisions to really ensure we're focused and getting scale in those five core therapeutic areas.

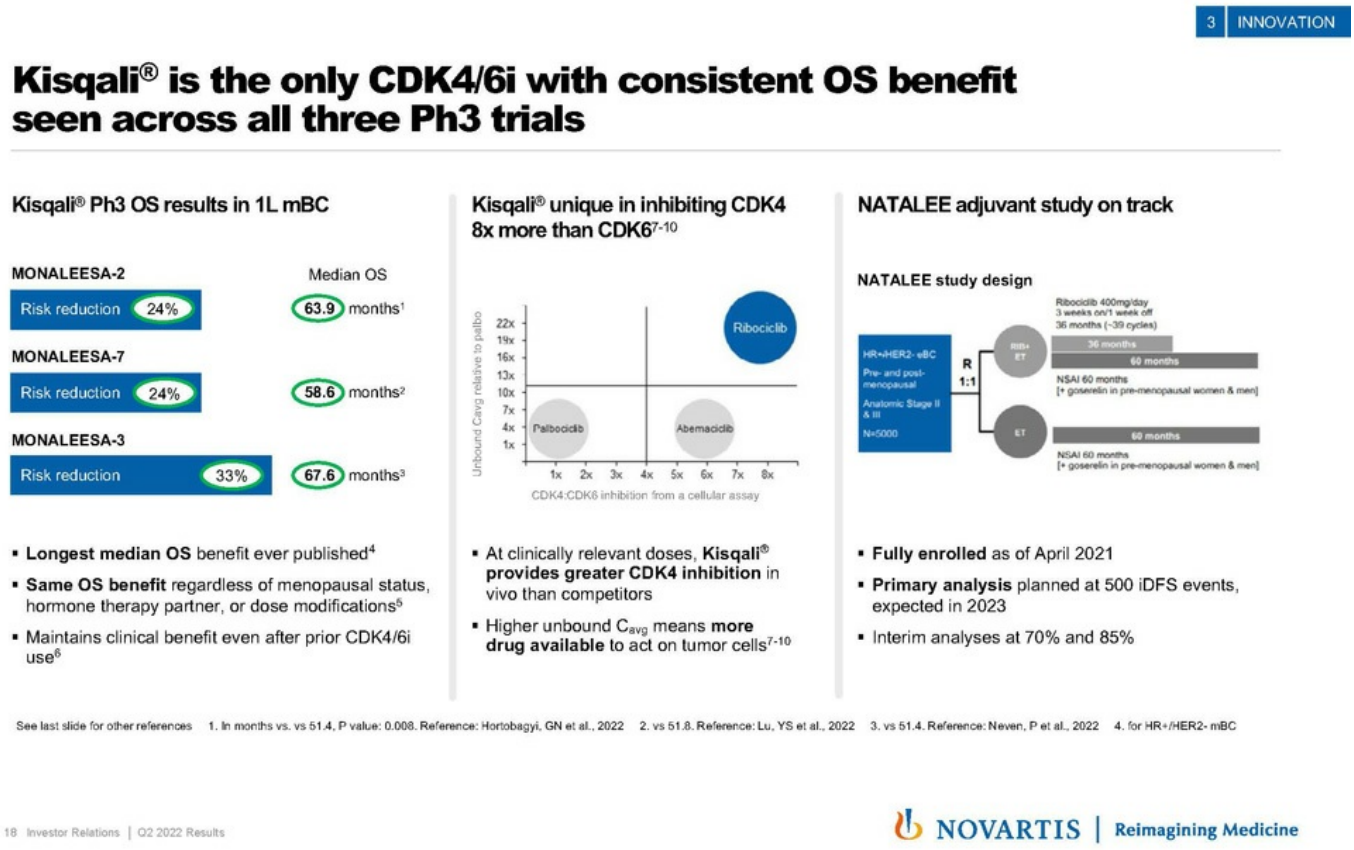
On this slide, a few things to highlight. We had important designations in milestones, Scemblix®, I've mentioned. Pelacarsen completed enrollment for the Phase III HORIZON study, so on track on its journey to become the first medicine to treat Lp(a)-driven cardiovascular outcomes.

JDQ443, our G12C inhibitor for solid tumors. The Phase III study in 2/3 line non-small cell lung cancer was initiated, and we continue to also progress combination studies for that medicine.

Cosentyx® was filed – had a filing for hidradenitis suppurativa in Europe, and we continue to work towards the US filing.

And then lastly, we continue to streamline the portfolio. We had a number of projects that we made the decision to either partner or stop. And notably, we're exiting our efforts – development efforts in COPD and general asthma with the decision to partner two assets in that portfolio. And we'll continue to look to streamline the medicine portfolio in our pipeline so that we can focus on the medicines that matter most in our core therapeutic areas.

Slide 18



So moving to Slide 18. I did want to say another word on Kisqali®. Given the OS benefit now we've seen across all three of the Phase III trials in the metastatic setting we've conducted to date, on the left-hand side, you can see the results that we've generated in the first-line metastatic setting. You can see impressive risk reduction, and importantly, median OS that's been achieved consistently across these three studies, the longest median OS ever published. And we've seen that same OS benefit regardless of situation. We also maintain that benefit even after prior CDK4/6 use. So we think this data set is part of the reason we're seeing the real growth acceleration behind Kisqali®.

Now in the middle frame, you see the reason for this clinically, we believe, is that Kisqali® is unique in its ability to hit the CDK4 target. And we hit it 8x harder than we hit CDK6. And that's relevant because we believe CDK4 is the key driver of the benefits you're seeing for this medicine. And you can see our relative performance versus – in preclinical studies versus our competition.

Now when you look at the adjuvant study, it's fully enrolled, as we've already noted. We've already cleared the first futility analysis. The primary analysis is planned at 500 IDFS events, and we expect that by the end of 2023. The two interim analyses are to be conducted at 350 and 425 events. We have not yet reached the first of those interim analyses. We expect that in the coming quarters. We do guide for the study to really complete at the end of next year when we reach a full number of events. But we'll of course keep the market updated as we progress through these interim analyses.

Slide 19

2022 events[1] (expected)

NME Lead

✓ Achieved ✕ Missed

Regulatory decisions	H1	Pluvicto™ mCRPC (US ✓ /EU)
	H1	Vijoice® PROS (US ✓)
	H2	Scemblix® 3L CML (JP ✓ /EU)
	H2	tislelizumab ESCC 2L (US)[10]
	H1/H2	Jakavi® acute & chronic GVHD (EU ✓ /JP)
	H1/H2	Kymriah® r/r follicular lymphoma (US ✓ /EU ✓ /JP)
	H1/H2	Beovu® DME (US ✓ /EU ✓ /JP ✓)
Submissions	H1	ensovibep COVID-19 (US ✓)
	H1/H2	Cosentyx® HS (EU ✓ /US)
	H1/H2	tislelizumab NSCLC (EU ✓ /US x[2])
	H2	tislelizumab 1L Nasopharyngeal cancer (US)
	H2	Cosentyx® Psoriatic Arthritis IV (US)
Submissions-enabling readouts	H2	canakinumab NSCLC Ph3 CANOPY A
	H2	iptacopan PNH Ph3 APPLY-PNH
	H2	Pluvicto™ pre-taxane mCRPC Ph3 PSMAfore[3]

Other readouts	H1	sabatolimab HR-MDS Ph2 ✓[4]
	H1	Cosentyx® Lichen planus Ph2 PRELUDE[5]
	H1	Cosentyx® axSpA IV Ph3 INVIGORATE-1 ✓
	H1	icenticaftor COPD Ph2b ✓[6]
	H2	UNR844 presbyopia Ph2 READER
Ph3/pivotal study starts	H1	Cosentyx® peripheral SpA x[7]
	H1	OAV101 SMA IT STEER ✓
	H1	ensovibep COVID-19 (EMPATHY Part B) x[8]
	H2	JDQ443 NSCLC mono ✓
	H2	ianalumab Sjögren's Syndrome
	H2	ianalumab Lupus Nephritis
	H2	ociperlimab solid tumors
	H2	Pluvicto™ nmCRPC
	H2	YTB323 2L DLBCL[9]
	H2	OAV101 SMA IT Ph3b STRENGTH

Note: Kisqali® NATALEE Ph3 readout removed (2023 event as shared at Q1 2023) 1. Selected. 2. No US submission planned at this time for monotherapy in NSCLC following FDA feedback. 3. Could move to early 2023. 4. Submission will be based on Ph3 results. 5. Ph2 data analysis ongoing. 6. Ph2b DRF demonstrated dose response across multiple endpoints, study results presentation end 2022. Out-licensing planned. 7. Strategy update. 8. No definite start date for the IV Phase 3 clinical trial can be provided at this time. 9. Development strategy being updated 10. FDA deferred action pending completion of required inspections

Then moving to the next slide on Slide 19. We're on track largely against our key 2022 events. Just three things to note. Three submission-enabling readouts coming up in the second half of this year: CANOPY-A; iptacopan in PNH; and as already mentioned, Pluvicto® in the pre-taxane setting. So we'll look forward to those study readouts and updating all of you as we get that data in-house. So with that, I will hand it over to Harry.

Slide 20 – Harry Kirsch – CFO of Novartis

Harry Kirsch
Chief Financial Officer

Financial review and 2022 guidance

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

Slide 21

Solid Q2 resulting in strong H1 performance

Group[1] USD million	Q2 2022	Change vs. PY % USD	Change vs. PY % cc	H1 2022	Change vs. PY % USD	Change vs. PY % cc
Net Sales	12,781	-1	5	25,312	0	5
Core Operating Income	4,270	-2	5	8,353	1	7
Operating Income	2,228	-36	-30	5,080	-14	-7
Net Income	1,695	-41	-34	3,914	-21	-14
Growth ex. prior year Roche income		*-36*	*-29*		*-12*	*-4*
Core EPS (USD)	1.56	-6	1	3.02	-5	2
Growth ex. prior year Roche income		*2*	*10*		*4*	*11*
EPS (USD)	0.77	-40	-33	1.77	-20	-12
Growth ex. prior year Roche income		*-35*	*-27*		*-11*	*-3*
Free Cash Flow	3,304	-22		4,224	-28	
Growth ex. prior year Roche dividend		*-22*			*-20*	

1. Core results, constant currencies and free cash flow are non-IFRS measures. Further details regarding non-IFRS measures can be found starting on page 47 of the Condensed Financial Report. A reconciliation of 2021 IFRS results and non-IFRS measures core results and free cash flow to exclude the impacts of the 2021 divestment of our Roche investment can be found on page 55 of the Condensed Interim Financial Report. The free cash flow impact represents the dividend received in Q1 2021 from Roche in relation to the distribution of its 2020 net income.

So on the next slide, yes, we show our quarter 2 and half 1 financial results summary. As you can see, quarter 2 sales and core operating income both grew 5% in constant currencies with sales benefiting from the continued strong performance of our key growth brands and core operating income growth driven mainly by the higher sales. However, operating income and net income declined significantly in the quarter. This was mainly due to prior year divestment gains from tail-end products and higher impairments and higher restructuring costs this quarter, mainly for the transformation for growth program.

Core EPS grew 1%. However, if you exclude the impact of the prior year Roche income, core EPS would have grown 10%. Overall, we delivered solid sales and core operating income growth for the quarter, resulting also in a strong operational half 1 performance, with sales growing 5% and core operating income 7%. Core EPS in half 1 grew 11%, excluding the Roche stake impact.

Slide 22

Continuing core margin improvements for Group, IM and Sandoz in H1

	Q2 2022				H1 2022			
	Net sales change vs. PY[1] (in % cc)	Core operating income change vs. PY[1] (in % cc)	Core margin[1] (%)	Core margin[1] change vs. PY (%pts cc)	Net sales [1] change vs. PY (in % cc)	Core operating[1] income change vs. PY (in % cc)	Core margin[1] (%)	Core margin[1] change vs. PY (%pts cc)
Innovative Medicines	5	6	37.2	0.5	5	6	36.6	0.3
Sandoz	5	-4	20.4	-1.9	6	10	21.6	0.7
Group	5	5	33.4	0.1	5	7	33.0	0.6

1. Constant currencies (cc), core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 47 of the Condensed Interim Financial Report .

22 Investor Relations | Q2 2022 Results

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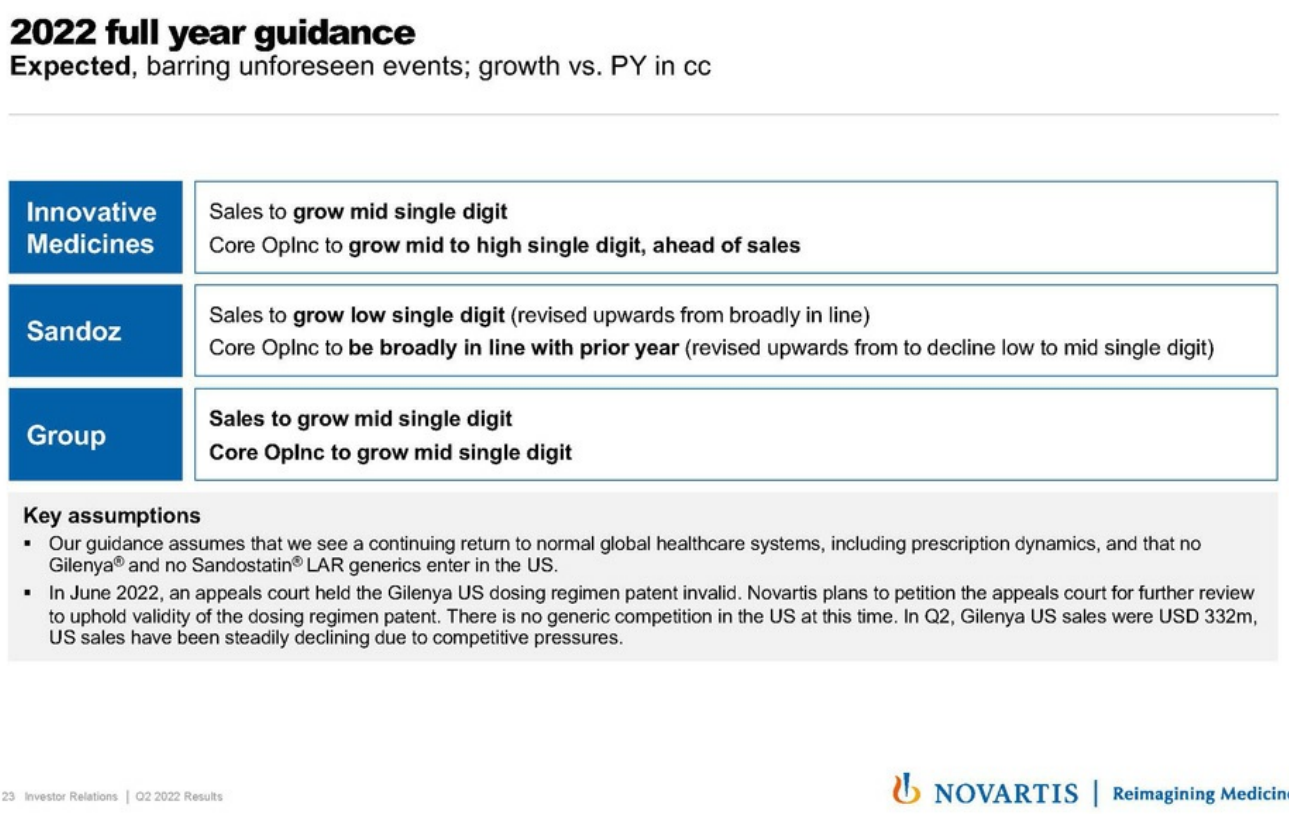
On the next slide, I would like to drill down a bit into the performance by division. So for quarter 2, you can see that Innovative Medicines top line grew 5% and the bottom line 6%, resulting an improvement in the core margin of 15 basis points to 37.2%. Sandoz net sales also grew 5%, although core operating income decreased 4%, mainly due to increased M&S investments and higher other expenses. This was reflected in the core margin, which decreased to 20.4%.

Overall for the first half, we saw a strong performance for Innovative Medicines and Sandoz, Innovative Medicines sales growing 5% and core operating income 6% in half 1. Sandoz grew 6% on the top line and 10% on the bottom line in half 1, driven by a very strong quarter 1. And as a reminder, as we discussed in April, Sandoz benefited from a return towards normal business dynamics compared to a lower prior year base. Our half 1 core margin improved by 30 basis points for Innovative Medicines, 70 basis points for Sandoz and 60 basis points for the total group.

Slide 23



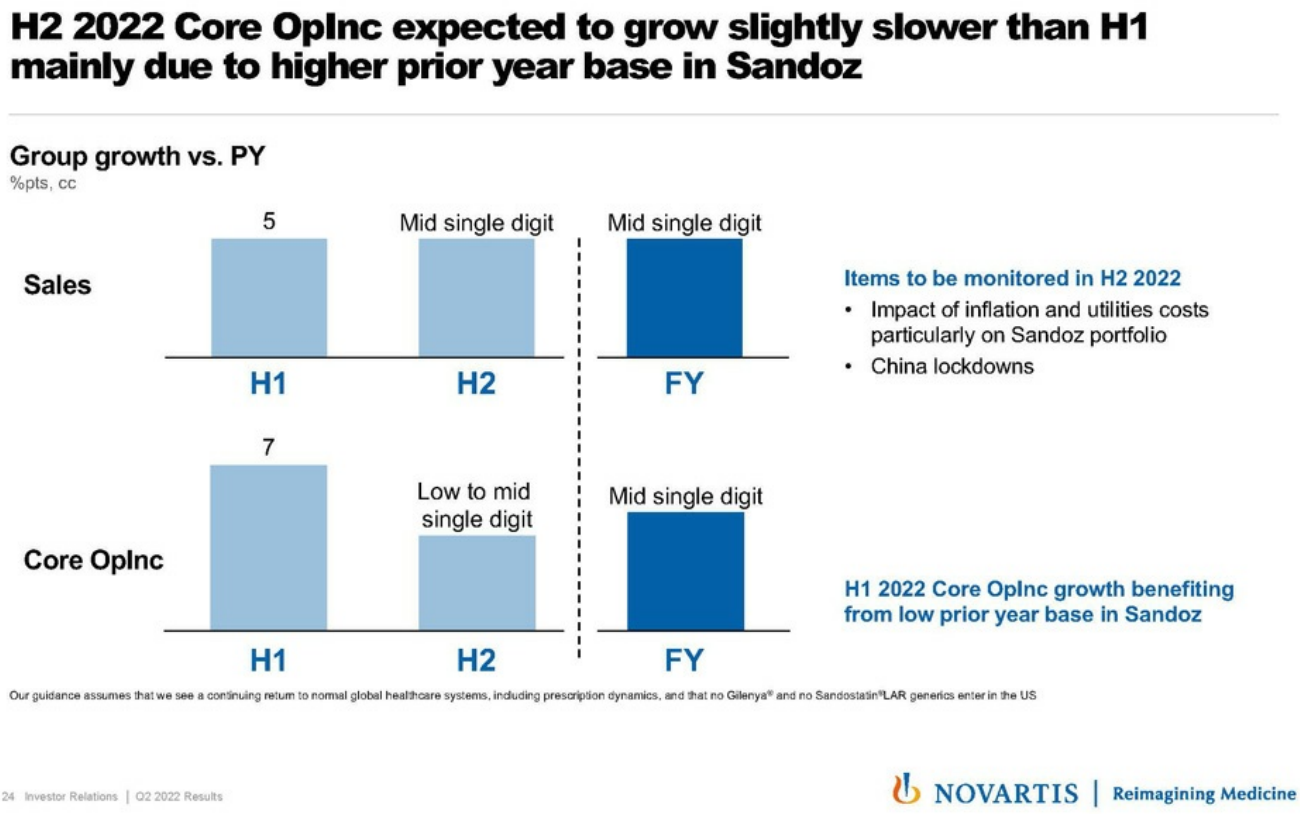
Turning now to our guidance on Slide 23. So within the divisions, we expect Innovative Medicines sales growing mid-single digit and core operating income growing mid- to high-single digit ahead of sales. The expected IM core margin increase will be driven by expected continued good top line momentum and continuation of our productivity programs, of course, including the new organizational structure giving us some benefits in the second half already.

For Sandoz, the performance year-to-date allows us to upgrade sales guidance to grow low single digit, which is a one-notch upgrade. And core operating income guidance is upgraded by two notches to now be broadly in line with the prior year.

For the group, we confirm our overall full year guidance. We continue to expect both top and bottom line to grow mid-single digit in 2022. The key assumption for this guidance is that we see a continuing return to normal global health care systems, including prescription dynamics, and that no Gilenya® and no Sandostatin® LAR generics would enter in the US in 2022.

As many of you know, in June of this year, the US Appeals Court held the Gilenya® US dosing regimen patent invalid. We plan to petition the Appeals Court for further review to uphold validity of this patent. And as a reminder, there's no generic competition in the US at this point in time. For Gilenya® and in quarter 2, US sales were USD 332 million for Gilenya®. It is worth noting that US Gilenya® sales have been steadily declining due to competitive pressures and of course our key focus in [multiple sclerosis] being on Kesimpta®.

Slide 24

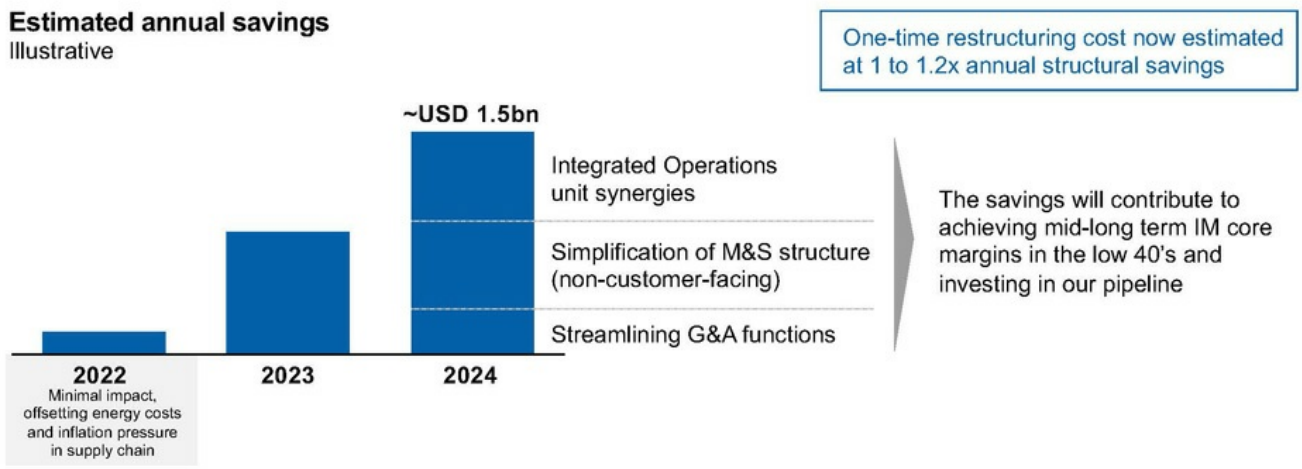


Next slide, please. I would like to provide some further details on the expectations for the second half dynamics on top and bottom line. We expect sales to continue to grow mid-single digits, bringing us to our guidance for the full year.

For half 2 core operating income, we expect to grow slightly slower compared to half 1 at low to mid-single digits. This is mainly due to the higher prior year base for Sandoz in half 2. And as you know, half 1 core operating income growth benefited partly from the very low prior year base at Sandoz. We will of course continue to monitor the impacts of inflation and utility costs, particularly on the Sandoz product portfolio as well as the situation around COVID-related lockdowns in China given that we are seeing improving signs as of June, which we will continue to monitor in half 2.

Slide 25

Simplified organizational model: SG&A savings estimate increased to ~USD 1.5bn fully embedded by 2024



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On the next slide, I would like to provide an update on our new simplified organization model and the financial impacts of the restructuring. As Vas discussed earlier, we have increased our estimates of SG&A savings to approximately USD 1.5 billion. We anticipate the savings to be fully embedded by 2024. This year, we also expect some savings, but the overall impact will be minimal as we will be offsetting higher energy cost and inflationary pressures.

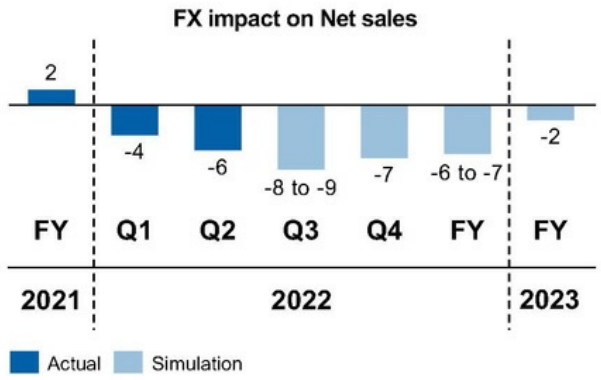
Part of the USD 1.5 billion savings, we expect to be reinvested into our pipeline, and a significant part will contribute to achieve our mid- to long-term low 40s Innovative Medicines' core margin guidance. With regards to the onetime restructuring costs, we could narrow this range a bit, and we estimate this now to be 1x to 1.2x of the annual structure savings of USD 1.5 billion.

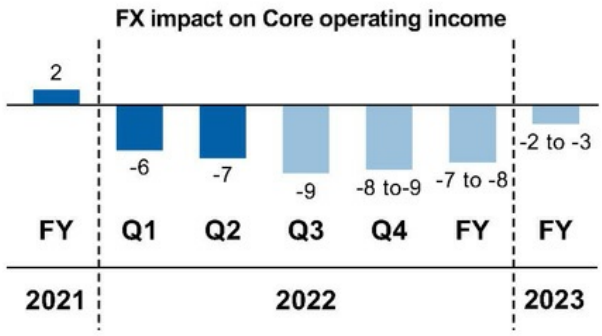
Slide 26

Expected currency impact for full year 2022 and 2023

Currency impact vs. PY

%pts, assuming mid-July exchange rates prevail in 2022 and 2023





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On Slide 26, I want to provide an update on expected currency impacts if currencies stay at the current levels. Obviously, currency impacts are significant this year given the strengthening US dollar against many currencies. So if currencies stay as they are now, for the full year, we estimate the impact on top line to be negative 6 to 7 percent points; and on the bottom line, negative 7 to 8 percent points.

And given it's volatile, we wanted to give you also a bit of an outlook for 2023. So for the full year in 2023, we would expect sales to be impacted by negative 2% and core operating income, negative 2% to 3% in 2023 versus 2022. As a reminder, we update these currency impacts on our website monthly. And I think, especially in these times, it's quite important to watch that.

Slide 27

Finally, on Page #27. Thank you. Finally, a reminder about our capital allocation priorities where we remain disciplined and shareholder-focused, of course. We aim to balance investing in the business with returning capital to shareholders via our dividend and share buybacks.

In the first half, our investment in the organic business was USD 4.5 billion in R&D and USD 0.5 billion in CapEx. We also had bolt-on M&A, which was around USD 0.9 billion, mainly for the Gyroscope acquisition.

Alongside this, as you can see, in terms of returning capital to shareholders, we paid our annual dividend of USD 7.5 billion earlier this year and have USD 9.4 billion still to be executed of our ongoing USD 15 billion share buyback program, of which, we have completed USD 5.6 billion by the end of June. And with that, I hand it back to Vas.

Slide 28 - Vasant Narasimhan – CEO of Novartis

Vas Narasimhan

Chief Executive Officer

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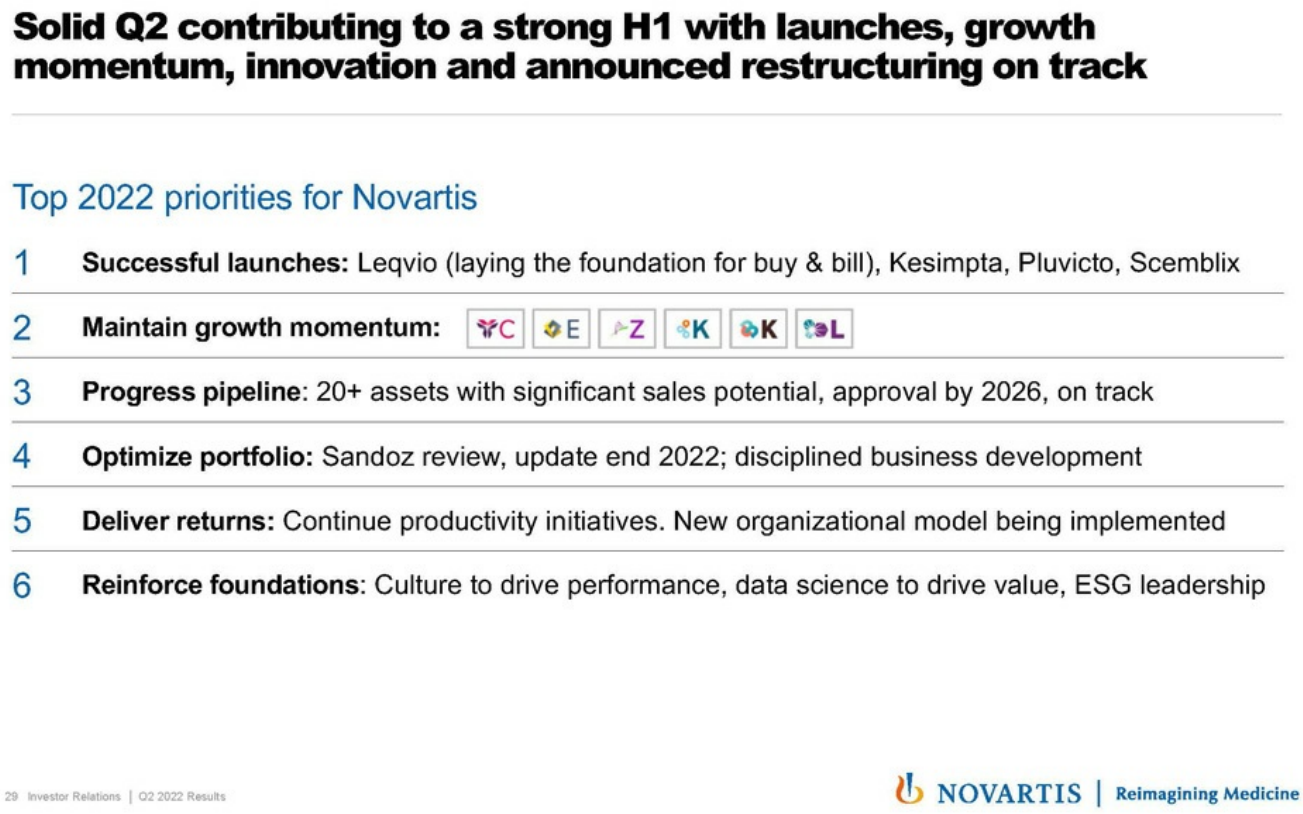
Thank you, Harry.

Slide 29



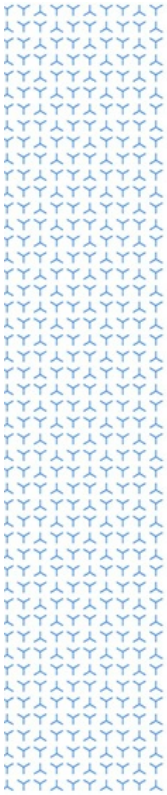
So if we move to the last slide, Slide 29. We continue to progress against our top 2022 priorities as we've outlined. Successful launches, particularly ensuring the foundation is laid for Leqvio®, but driving the dynamic performance of Kesimpta®, Pluvicto® and Scemblix®, which as you've seen, are continuing apace.

Maintaining the growth momentum across our six key in-line growth drivers. Progressing the pipeline, where we have 20-plus assets where we expect significant sales potential with approval potential by 2026 and the pipeline is on track. We're tracking well on our Sandoz review and with a solid quarter from Sandoz in quarter 2. We'll keep you updated as we move towards an update before the end of 2022 at the latest.

And we remain disciplined in our business development, looking for important opportunities to build out our pipeline, but remaining disciplined with how we allocate our capital, continuing to deliver our returns. And you've seen that with our productivity initiatives, our increase to USD 1.5 billion of SG&A savings with our new organizational model. And we continue to reinforce the foundations we believe that, in the long run, will drive Novartis' performance around culture; data science; and as I noted earlier, ESG.

So with that, we look forward to taking your questions. (Operator Instructions) So operator, we can open the line for questions.

Q&A



Q&A

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- Operator

(Operator Instructions) We will now take our first question from Matthew Weston from Crédit Suisse.

- Matthew Weston - Crédit Suisse AG, Research Division

Q. A question on Kisqali®, please, Vas. And you were – very clearly set out the interim analysis timelines and the final analysis time line. One question that we've received a lot in recent weeks is how you would communicate when you go past an interim. Would you consider that a material event, which you have to press release to the market? Obviously, if it's positive, it would be positive and we'd see a release. But if you simply pass an interim and move forward, would you see that as requiring a press release? Or would we simply learn that at the next quarter, where you would update the timelines?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Matthew. So I think as you outlined, clearly, if at any time in the study that we either get a definitive positive result as determined by the DSMB, or a negative result, we would update the market. Otherwise, our plan would be, at the quarterly call, to provide updates on where we stand on the study. We don't believe passing an interim analysis warrants any sort of further update.

- Operator

Your next question comes from the line of Tim Anderson from Wolfe Research.

- Timothy Minton Anderson - Wolfe Research, LLC

Q. Just a high-level question on health care reform. And just talk of reconciliation pushing ahead, it seems like it's finally going to happen, to us at least. Your thoughts on the likelihood of this happening and what it could mean to industry financials and to Novartis specifically over time. And if you have certain products that you think would be impacted the most.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Tim. I think as everyone is reading in the press, there is renewed momentum behind a reconciliation package, which would consist of a drug pricing reform and supporting ACA subsidies. Of course, our overall view remains that there are good and bad elements to the package.
Clearly, Part D reform is needed. The fact capping out of patient out-of-pockets will be, I think, a positive step, enable patients to refill their prescriptions and also enable, in our – from our sector, demand to be supported.

But of course, there are onerous elements as well which we think go too far and don't support long-term innovation, will have detrimental effects to the long-term outlook for the industry, particularly the negotiation elements.

Now from Novartis specifically, we view these as not significant impacts in the near to midterm. We've analyzed this quite in a detailed manner. I mean, I think as is well known, we're the #1 company, pharmaceutical company in Europe and a leader in many emerging markets. Our business in the US is one we plan to grow significantly over time. But our relative exposure to the peer set in terms of both government programs and over US – overall US sales is at the low end of the peer set. So we would expect to have a far lower effect than our – impact on us relative to our peers. And so I would say, in the near to midterm, not a significant impact overall, net of the positives we get from the Part D reform and of course the impact from inflation caps as well as negotiations. That's how we see it at the moment. But of course, we'll continue to analyze as the final bill text is available.

- Operator

Your next question comes from the line of Richard Vosser from JP Morgan.
Are you on mute? As there is no response from Richard, I will go to the next...

- Richard Vosser - JPMorgan Chase & Co, Research Division

Q. Sorry, apologies. Completely my fault. Just on Kisqali®, if you can hear me now. Just wanted to go back to the growth potential in the first-line opportunity. And how much of the Ibrance® market you think you can take with the OS benefit? Obviously, we can see Verzenio® benefiting as well, but just your thoughts there.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. With Kisqali®, we're starting to see a positive trend on NBRx in the first half of the year versus the competition in the metastatic setting. And that comes primarily from Ibrance®. And I think that's reflective of the data set that we have in OS, as I've outlined. It's important to note as well in many European and ex US markets, we are either #1 or close to #1, depending on the market. And we can, we believe, drive additional momentum in those ex US markets as well. So I think it's positive signs.

We want to see that trend continue for hopefully a couple more quarters, particularly given that now the dynamic market within breast cancer is starting to recover. I would note that it's just recently on our data coming back to where it was pre-COVID, which again is an opportunity for us to gain share as there's an opportunity to get either new patients or switching patients onto Kisqali®. So I think it's all positive directions, and we'll see how the trend goes in the coming months.

- Operator

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

- Emmanuel Douglas Papadakis - Deutsche Bank AG, Research Division

Q. Perhaps I'll take one on Sandoz, please. As you called out, biosimilars clearly the key to returning to reasonable levels of growth in the midterm. You recently filed the biosimilar Humira®, Hyrimoz® high-dose in Europe. Could you just give us an update on where you are with respect to the US for that opportunity, i.e., both as regard to high-dose filing and potential interchangeability? And how significant an opportunity you think that may be for business, and indeed, whether that would have any influence on your considerations on strategic options.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emmanuel. So we're on track overall to be launching Humira®, the adalimumab biosimilar at market formation in the US, and it's our intention to have the high-concentration formulation available. I think as soon as we have a file accepted by FDA, would of course put out a release and update the market. So I would say, overall, we're on track with respect to that.
I think clearly, the number of entrants when the adalimumab market formation happens will mean that it will be a highly competitive market set. But nonetheless, given the size of the opportunity, it will help meaningfully drive growth for the brand.

I would also note that natalizumab, where we are one of the early entrants, is a significant opportunity for Sandoz. And I think natalizumab both in the US and Europe is one we're excited about as an opportunity to drive growth within the next few years. And the other upcoming opportunity for us is denosumab, where again, I think we would be one of the earlier entrants amongst biosimilars players.
But those would be the three key upcoming biosimilar launches for Sandoz and particularly in the US.

- Operator

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

- Graham Glyn Charles Parry - BofA Securities, Research Division

Q. I'm just going a little on NATALEE, actually. So I think at the Q1 files, you said you were at 300 events. So I wonder if you could give us an update on how many events you're at in the trial.

And is that the sort of event rate, as it sits, that you still have a couple of months delay before the DMC reports to you what the outcome of those interims are?

And in the event you were to get positive data, to what extent can you put subgroup analysis, et cetera, in the press release? So whether you've hit across all subgroups, high-risk low risk, et cetera. Just what would be in the press release would just be quite interesting to know.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Graham. On Kisqali®, obviously don't want to get into what exactly the number of events are. I would say the event rate that we've seen – and as we noted previously, we had a slower event rate than we had originally projected and that event rate has continued. So there's no change in the overall event rate.

I would also note that you are correct that, from the point of a lock, it does take a few months to get the readout with the DMC. And particularly because we work with one of the large CROs in the US as part of the study. So that's, I think, important to note from a time line standpoint.

In terms of what's in the release. I mean, I think we typically would only comment on the primary endpoint. And in this case, that's the IDFS across both the medium- and high-risk patient populations. We wouldn't, of course, get into subgroups.

I would also note that the DMC's primary basis for stopping the study would be IDFS. We would hopefully see in the OS trend, but I think that's an important note as well. I would expect that – as would be the case normally in such an oncology study, OS takes more time to mature. And of course, we'll have to see how it all unfolds over the coming quarters.

- Operator

Your next question comes from the line of Yukie Aizawa from Cowen.

- Stephen Michael Scala - Cowen and Company, LLC, Research Division

Q. Can you hear me?

- Vasant Narasimhan – CEO of Novartis

A. Yes.

- Stephen Michael Scala - Cowen and Company, LLC, Research Division

Q. This is Steve Scala. On remibrutinib, is there any sign of liver tox similar to Sanofi's tolebrutinib? And is there any reason to believe that liver tox is a class effect?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Steve. We've been watching this space very closely. I mean, when you look overall at BTK inhibitors in cancer historically, liver has not been a signal, at least to our knowledge, that's been a significant concern. And also BTK is not differentially expressed within liver. So in our view, this is related to the drug itself, either metabolites or off-target toxicities in the liver.

To date with remibrutinib, we haven't seen any liver signals. We've taken it forward into chronic spontaneous urticaria as its first lead indication, where there are two pivotal Phase IIIs ongoing. And then similarly, now are progressing in our MS studies; and also evaluating taking the medicine into other areas of rheumatology, dermatology, et cetera.

Our hope and expectation is that the profile of remibrutinib continues to be clean relative to the peer set, particularly with respect to liver signals. We believe that, in the MS market, but also in the dermatology market, it's going to be critical to have a medicine that has a safe profile with – especially with respect to more complex side effects like liver.

So that's where we stand, and we remain optimistic on that unique profile of remibrutinib based on its chemical design and the lack of any off-target toxicities seen to date.

- Operator

Your next question comes from Florent Cespedes from Société Générale.

- Florent Cespedes - Société Générale Cross Asset Research

Q. A quick one on Kesimpta®. Could you elaborate a bit on how do you see the dynamic on the ex US sales? They are still quite small for the time being but are ramping up nicely. Could you give us what should boost the sales here?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thank you, Florent. With respect to Kesimpta®, already, we covered the US at length. I mean, we're starting to now move through, as you know, the longer reimbursement processes that were required in Europe, Canada and other global markets. So we would expect to see in the second half, and then moving into next year, more significant sales contributions from our ex US markets.
Of course, the big market's in Europe, but I was also recently in Canada, where there's a lot of excitement as well about the medicine. And then to a lesser extent, in Asia, Japan, et cetera, where MS rates are lower, but the market sizes are significant.

I mean, I think it's important to note in those markets, a monthly subcu patient-administered drug is very attractive because out of those markets, they're not the same incentive structures around infused medicines, as well as the ability to deload the hospital system by having at-home administration.

So we feel optimistic about the opportunity now for Kesimpta® as its next wave of growth to really be about a global expansion of the medicine.

- Operator

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

- Emily Field - Barclays Bank PLC, Research Division

Q. I just want to ask a question on the development plans for ligelizumab. I believe kind of the slides just mentioned food allergy. But on clinicaltrials.gov, the PEARL-PROVOKE study in CINDU still looks to be recruiting. So just any update on the other indications.

- Vasant Narasimhan – CEO of Novartis

A. Yes. With ligelizumab, as you know, we made the decision not to take it forward in CSU. But we continue the development program in seafood allergy and we'll complete the program as well in CINDU. And we continue to believe the medicine has potential in some of these indications where IgE inhibition has demonstrated the ability to impact asymptomatic disease as well as disease progression.

So we still think the medicine has potential, particularly in food allergy, where if we could find the right setting for its use and get a relatively broad label from the regulators, it would have a significant potential. So those development programs continue on track, and we would expect the readouts as we note in our documentation.

- Operator

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

- Simon P. Baker - Redburn (Europe) Limited, Research Division

Q. A quick 2-part product question, if I may, please. Firstly on Zolgensma®. Vas, you talked about the strong ex US growth, but actually, the growth in the US was pretty impressive this quarter. I just wondering if there's anything to add behind that.

And secondly on Leqvio®. I wonder if you could update us on the ex US performance, particularly the UK.

- Vasant Narasimhan – CEO of Novartis

A. Yes. With respect to Zolgensma®, we were pleased as well to see the performance in the US. That's primarily driven by expansion in newborn screening, where – you'll remember, when we launched the medicine, we were down to 60%, 70%, and now we're moving into the mid- to high 90s.

And as we get that newborn screening rate up, it tends to be the case that patients who are identified in newborn screening ultimately receive Zolgensma®. And so I think that will continue as we move up the newborn screening. But then of course we would expect that to be back to a steady state. As with all gene therapies, eventually, you get to the steady state of the ability to identify the diseases at birth in a so-called incident population.

When you look at the specifics on Leqvio® ex US, I'd say in the UK as well, we've been systematically building up towards what we hope will be a trend break. I think the UK NHS had to of course deal with COVID for much of the first part of this year.

In the last few months, we've now successfully upgraded and enabled NHS EHRs identify patients who would be able to use Leqvio®. We have now I think over 70% of primary health care units with Leqvio® available on their formularies. We've launched a large-scale education campaign in the UK. So I would expect to see as well, hopefully, a trend break in Leqvio® the UK and in the first part of next year as we continue to build that foundation in the second half, and as the NHS works through the backlog it has from other – from other diseases because of the COVID pandemic.

Beyond that, we see a very strong uptake in Germany with Leqvio®. On a per population basis, the uptake is very good. We've assigned successfully large-scale agreements with certain Middle East governments to roll out Leqvio® at scale in those markets. And then we also continue to work to bring Leqvio® forward in the large markets of Japan and also are finalizing the plan for filing in China as well.

But I'd say all of that is going – of course, again, as always, with cardiovascular launches, it takes time. But on this one, I mean, absolutely, our goal is to ramp this medicine faster than we were able to in Entresto®. And obviously, with a runway that goes to the late 2030s at the very least, the significant opportunity to make this a really, really significant medicine.

- Operator

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

- Kerry Ann Holford - Joh. Berenberg, Gossler & Co. KG, Research Division

Q. Focusing on radioligand therapies and the recent manufacturing delays. Can you now confirm that you – do you outsourced supply for running an inventory building for both Lutathera® and Pluvicto®?

I wonder if you can also elaborate on your plans for expansion of RLT manufacturing supply going forward and how you work around what you've learned through those recent delays.

And is there any risk with the recent manufacturing gap to result in a delay to the ongoing Phase III PSMAfore study? Which I think is due by year-end.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Kerry. So a couple of points on radioligand therapy manufacturing, which is a challenge, but also I think points to why, if we can get it right, creates a long-term competitive advantage.

This is a medicine where you cannot build inventory. We make the medicine, and depending on whether it's Lutathera® or Pluvicto®, we have between 3 and 5 days to get it to its relevant site. And so because of that, you have to be world-class with respect to the supply chain. And it's not something easy, I think, for anyone to build from scratch.

What we've learned is to increase capacity with redundant lines and different manufacturing sites to enable us

to ensure we have a steady supply if we were to have a disruption at any one of our sites. And within those sites, to segregate the lines, so that the one line having an issue doesn't affect any of the other lines. And we've been able to do that now at the relevant sites, particularly in our Italian site and in our US site.

So with all of that being said, we've cleared the backlog. We are now shipping to order successfully. We're also, with large centers, moving to a model where we provide Pluvicto® doses ahead, even if they don't have patients ready yet, so that the supply is there. And of course, that enables them to book additional patients with confidence.

And then to further expand the supply, we'll be bringing on a third large-scale manufacturing facility in Indianapolis. That will actually have automated lines, moving away from more manual lines, which just further increases capacity. So we would expect, by mid- to second half of next year, to have three separate US manufacturing facilities to support the US for both Lutathera® and Pluvicto®, giving us the redundancy, large-scale capacity and of course the ability then to fulfill what we hope, if the data supports it, a potential multibillion-dollar opportunity for Pluvicto® across lines of prostate cancer.

And I'd also take the opportunity to say that the feedback both from the nuclear radiology community as well as the urology community, which is an important customer base for this medicine, has been very positive to date.

With respect to the Phase III studies, we've been able to fully reopen enrollment. And we currently forecast is no change in time line, either for the pre-taxane study, which is slated to read out before the end of this year or the hormone-sensitive study, which is slated to read out in 2024. So both of those studies now are on track and, if anything, are enrolling slightly ahead of schedule.

- Operator

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

- Seamus Christopher Fernandez - Guggenheim Securities, LLC, Research Division

Q. Great. Just one quick question on iptacopan. Vas, just wanted to get your thoughts on relative positioning in PNH and aHUS versus the well-established C5 inhibitors. Just wanted to get your sense of the ability to compete in the treatment-naive setting as well as the sort of patients that are struggling as we look at this first data set, and then I think the treatment-naive data set will come in the first half of next year.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Seamus. We've done a lot of work with the US team here and really to understand the physician expectations and the dynamics. And overall, we believe that hematologists would be highly interested in iptacopan, both in the first-line setting and for patients who are not receiving – achieving an adequate response to the anti-C5 monoclonals.

I think unlike some of the other areas where a Part B infused medicine can create a barrier, this is a low-enough volume situation where we believe that patient ease of use to avoid having to come in and out of the hospital, also very safe drug that can be used across lines of therapy, would be highly attractive for physicians.

So you're correct. The first data set will be focused both on add-on therapy as well as switch. And then we'll have a second data set, the PNH APPLY study, which would then be in the frontline setting. And those two data sets together will support the overall filing. So we remain optimistic on that PNH. And that, of course, will translate as well into atypical hemolytic-uremic syndrome in that setting.

I'd also note that the opportunity for – hopefully, everyone on the call is aware for iptacopan is not only in that

hematology setting, but we also prepare in the renal setting, where this could be the first medicine approved for C3G, glomerulopathies, as well as an opportunity to treat patients on the severe end of the spectrum with IgA nephropathy. And then we continue to expand across a range of other Factor B-driven diseases. And the unique profile here is it's a twice-a-day oral with a very, very safe safety profile, which I think, for these rare diseases, will hopefully make a lot of sense.

- Operator

Your next question comes from the line of Andrew Baum from Citi.

- Andrew Simon Baum - Citigroup Inc., Research Division

Q. A question on your BeiGene collaboration, a couple of parts. So first, I'm curious whether you could provide some color on the FDA's guidance for you not to file in monotherapy. I assume that they have Western data, I think they do. So I'm just curious as to why. Is it because they feel the market's well served? Site inspections or some other?

And then second, you have an option on the BeiGene TIGIT. It sounds like Roche is now not going to be presenting the interim data at ESMO. When do you have to exercise that option? And can you give us any guidance on what you will do given the available data?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Andrew. On the first question on monotherapy, I think the FDA's assessment of our overall data set was that it didn't adequately reflect the US population in terms of the number of patients and the standard of care that was used in that BeiGene-driven first-line study.

So our focus right now is to finish the filing in the second-line small cell lung cancer – sorry, esophageal cancer. And then we had very good data in the first-line setting as well. As we announced, that's been pushed back as we await the ability for FDA to inspect the facilities in China. And then hopefully, we'd be able to have both first and second line in esophageal, we'd have then hopefully second line in non-small cell lung cancer, and we would expand from there.

I do think that the FDA is making it very clear now that they expect a – any studies to be filed, that they're global in nature, they have an appropriate amount of US patients, and that the standard of care used reflects standard of care in the US.

With respect to the anti-TIGIT, we haven't changed – no change from our option agreement. The option agreement is driven off of the data from ociperlimab, the BeiGene anti-TIGIT molecule. And so that option would be based on when their data set becomes available. And we'll continue to wait for that, their data to mature, which we would expect, I think, if I'm not mistaken, but we can verify in the second half of the – first or second half of next year.

Now in terms of the Roche data set, I mean, it doesn't change anything for us. We'll continue to wait and watch as the field evolves and then make an appropriate decision. I think it's important that we – everyone would like to understand where is the appropriate use of this medicine, and in which PD-1 subgroup? All comers? And if there is a place, which place would it actually be? But for us, there's no change to plan at this point in time.

- Operator

Your next question comes from the line of Laura Sutcliffe from UBS.

- Laura Sutcliffe - UBS Investment Bank, Research Division

Q. Could you help us understand who the typical US prescriber of Leqvio® is? Who's already prescribing to multiple patients? Or who is already a repeat prescriber?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Laura. I spent – it's a great question. I've spent three days now in the field here in the US meeting clinicians, visiting hospital centers, visiting larger cardiology centers. I'd say right now, where we see the strongest uptake are in group cardiology practices, where they already have the ability to run buy and bill, they make their own decisions on how they want to approach treating for cholesterol, and have, I think, the infrastructure largely set up and also the scale.

So I'd say group cardiology, mid- to large-sized group cardiology practices, have been really, I think, a key area so far for the medicine. Combined with, I would say, large-volume cardiologists and smaller practices who are leveraging alternative injection centers, where we continue to see solid uptake. And that's a solid base for us to grow from.

Now the goal is to move into larger centers where you of course have to work through the pharmacy and the various P&T committees to get everything set up. There now the J code being in place and the overall clinical experience increasing is helping. And then also moving towards smaller cardiology offices, where there is the need to set up buy-and-bill capabilities, which historically, have not been in place for those cardiology offices.

What I would say, though, is what I consistently hear regardless, and I think our teams here on the ground, is a lot of enthusiasm for a twice-a-year physician-administered medicine that can modify the single most important risk factor in cardiologists' mind for preventing repeat cardiology events, cardiovascular events.

And I think seeing that and hearing that again and again gives us confidence, gives me confidence, that we will work through the logistical hurdles, which seems to be the primary topic, and then get this medicine into wide-scale use.

I think we often hear back from practices, especially when they put the patient on the medicine, and then at the next visit, they see a significant drop in the LDL levels, that's a very winning proposition after a single dose. And then I think those practices get really excited about getting more patients on therapy.

So again, laying all the foundations, but I think all the right steps are being taken to get us to where we need to be.

- Operator

Your next question comes from the line of Keyur Parekh from GS.

- Keyur Parekh - Goldman Sachs Group, Inc., Research Division

Q. Vas, a big picture kind of capital allocation question for you. If we look at Slide 27, kind of first half, obviously, it's only first half, which shows that you kind of returned somewhere about USD 13 billion kind of to shareholders versus investing kind of about USD 6 billion in businesses and your kind of organic and bolt-on transactions.

As we look forward to the next kind of 12 to 18 months, do you expect that balance to be somewhat similar to what we have seen in the first half? Do you expect that to be more counterbalanced by greater investments, either from an R&D or an M&A perspective for Novartis?

And then just kind of more specifically, you were telling us that you'll provide us an update on Sandoz by the end of the year. What is that update expected to be? Are we going to get a decision on what you would do? Is

it going to be, if you plan to separate it, we will we get details on structuring of separation, et cetera? So just any color you might be able to provide on what that detail or what the update might involve.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Keyur. So I'll let Harry start and then I can add on. Harry?

- Harry Kirsch – CFO of Novartis

A. Yes. Thank you, Keyur. So on the capital allocation, of course, the whole thing is a bit skewed by our dividend being an annual dividend, right, at USD 7.5 billion. So if you want to do it mathematically, you almost have to half that and put it on two sides. But it's an annual dividend.

Overall, of course, all of these elements, R&D, we expect to continue to grow in line with sales at least. And so there will be continued growth on R&D investments. And we don't expect margin leverage from the R&D line as we go forward, more from the SG&A line where also our transformation for growth program is targeted at and where we have some gap to benchmarks and we can – we have found some structural opportunities, which is great.

And then in terms of how much it goes to bolt-on M&A, that obviously depends on the opportunities we find. And given our very attractive net debt position and strong cash flows and balance sheet, of course, we have quite significant bolt-on M&A firepower, if you will. And if we don't find the right opportunities, of course, share buybacks will always continue to be part of the mix.

In terms of Sandoz, I think you said it all. We make very good progress in line with our plans on the carve-out financials, on looking at all different options. So would be, of course, happy to give a preliminary decision by end of year. But this is, of course, subject to Board approval and from that – and the progress overall on our whole planning.

But end of year should be quite – giving you some good hints to what direction it goes, given that we take appropriate time for all the homework we are doing on the carve-out financial, separation cost, tax situations and all of that. So it would be – think end of year later, we should be in a good position to inform you about the next steps here. Vas?

- Vasant Narasimhan – CEO of Novartis

A. No, that's perfect. I think Harry said it all. Thanks, Harry.

- Operator

Your next question comes from the line of Naresh Chouhan from Intron Health.

- Naresh Chouhan - Intron Health

Q. Some of the work we've done suggests that people costs are around 40% to 50% of the total cost of the industry. And so my question is how we should think about the timing on the – of the inflationary impact on salaries? Is it fair to assume that on the whole 2022 salaries and, therefore your guidance, has factored in only last year's inflation? And that really, we have to wait until next year's salary rounds before we start to see this year's inflation baked into your cost base on the salary side?

- Vasant Narasimhan – CEO of Novartis

A. Thank you, Naresh. Harry, do you want to take that?

- Harry Kirsch – CFO of Novartis

A. Yes. You're absolutely right. I mean, the current inflationary effects, mainly on energy, utilities, freight costs and so on, those cost categories as we speak. On wages and salaries, not much yet, if anything. So that needs to be closely monitored. And I would expect this to come more in annual cycles.

If there is something short term, it's probably depending on certain countries. Of course, we always monitor the markets to be very competitive. And we have, of course, quite a big, if you will, workforce in Switzerland where inflation and wage increases are below, I would say, developed market average. So from that standpoint, our home base gives us also here a bit of a competitive advantage.

But we have to watch it, right? As you say, the wage and salaries are a large portion of the P&L of any pharma company, given its innovation-driven and people-intensive business. And we have to watch that and we'll monitor this, of course. I would say we believe it is manageable for us, but we have to monitor how the situation develops.

- Operator

Your next question comes from the line of Sarita Kapila from Morgan Stanley.

- Sarita Kapila - Morgan Stanley, Research Division

Q. Please, could you discuss where you stand on the development of the diabetes and obesity franchise? So you have the MBL949 in Phase II. I don't believe the mechanism has been disclosed, but it appears to be dosed every 2 weeks. And you also have an existing cardiovascular and metabolic commercial platform. And there are a number of assets focused on diabesity in Phase I/II, which remain unpartnered. So it looks like from today's update, respiratory is less of a focus. But it's not necessarily clear where you stand on diabesity and adding assets around Entresto®, Leqvio® and TQJ.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks for the question, and noted the Morgan Stanley report as well on obesity. Yes, I mean, I think we of course are observing the significant unmet need for better obesity medicines. And because we do have a dedicated cardiovascular research unit in-house led by Shaun Coughlin, really, I think a global leader in the thinking on developing world-class cardiometabolic drugs, we do have assets in our portfolio.
We have not disclosed MBL, but we are awaiting our Phase II data on weight loss with MBL. And if that's positive, that would be an exciting opportunity to hopefully address, with a unique mechanism of action, obesity on a large scale. And I think based on that readout, we would determine if we advance other earlier-stage opportunities and combination partners we would have for MBL as well as potential external opportunities.

So I think more to come. Certainly observing the need for better obesity drugs and hopefully alternative mechanisms to those already out there. It's something we're looking at, and we'll keep the market up to date as we learn more.

- Operator

Your next question comes from Peter Welford from Jefferies.

- Peter James Welford - Jefferies LLC, Research Division

Q. A question on Cosentyx®, please. You've talked a little bit about the aims for this year. Wondering if you could just talk a little bit about next year.

And in particular, you've also talked a lot about Humira® biosimilars in your plan there in the US. Can you just talk a little bit about how you see coverage negotiations for Cosentyx® next year?
And perhaps you could just talk about the impact of HS, which I guess is unlikely to be approved for the negotiating cycle this time around. But IV, on the other hand, also available, and how you think that fits into the potential patient access dynamics for Cosentyx® going into next year.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Peter. I mean, I think right now, our assessment is that with the introduction of adalimumab biosimilars, that it's a manageable situation. I mean, we already have significant gross to nets on Cosentyx® in some accounts. In other accounts, we have very strong overall positioning and as a first-line therapy.

And of course, we'll have to see as the upcoming year unfolds and also how some of the upcoming legislation that potentially might be passed by Congress will impact the gross to net environment, given that there would be, if the law passed as currently designed, less ability to offset increased rebates with price increases, I think there is a possibility we see a rethink on rebating at least on the industry side on how the whole structure of the market works. It's all to be determined and to be seen.

I mean, I think for us strategically on Cosentyx® in the US, the goal is, within rheumatology and dermatology to grow with the market and you see healthy market growth in both of those categories. And as you point out, expand both in terms of indications. We would hope to get hidradenitis approved over the course of next year, which then means, in 2024, it would be an additional labeled indication for us and a unique labeled indication for Cosentyx®.

But also to expand into – with IV into other payment settings and to have IV approved, hopefully, across both axial SpA as well as psoriatic arthritis would enable providers to also provide Cosentyx® in those reimbursement settings. And hopefully, that also helps us manage the overall payer environment.
It's probably the best answer I can give at this point in time. But I think as we learn more in the second half of the year, as we enter towards the January negotiations in Q4, we'll keep you posted.

- Operator

Your next question is from the line of Matthew Weston from Credit Suisse.

- Matthew Weston - Crédit Suisse AG, Research Division

Q. Just a couple of follow-on housekeeping items, please. Harry, the quarter, we saw a significantly lower finance charges and also significantly lower corporate costs than consensus was anticipating. I note there was a hyperinflationary write-back in the finance charge. Can you give us any help with what we should anticipate for both those lines for the full year?

And then if I can cheat and ask another question. Vas, you obviously deemphasized COPD within development. Does that mean that we can anticipate that you may consider divesting your legacy respiratory assets? Or that's something where you're going to maintain an existing commercial franchise?

- Vasant Narasimhan – CEO of Novartis

A. Harry?

- Harry Kirsch – CFO of Novartis

A. Yes. Matthew, welcome to the second round. So on the corporate cost, we guided so far to USD 600 million to USD 650 million this year. Our new guidance now would be a notch down, USD 550 million to USD 600

million.

Now the biggest piece of that is actually currency because, as you can imagine, given our headquarters in Switzerland, most of our corporate costs are in Swiss francs. And the Swiss francs also weakened versus the dollar. So the corporate dollars, if you will, will be a little bit less and will be a bit lower.

If you take in constant currencies, it's probably hard for you to model on corporate costs, right? This year's quarter 2 costs were only USD 5 million lower than last year's quarter 2 cost. And of course, we do also work on corporate cost efficiencies. So I think that answers the corporate part.

In terms of the core cost on net financial results, we of course do have some income, right? We have some hedging gains, which is the other side of the currency impact. So that should also be a little bit lower. But of course, both of this is the corporate costs a part of our core operating income guidance in constant currencies. And then a bit of gains on the net financial results also versus prior year, but not so significant.

- Vasant Narasimhan – CEO of Novartis

A. Thanks, Harry. And then, Matthew, on the respiratory side of things, I think as you rightfully point out, we do have a business inhaled respiratory LABA/LAMA/ICS outside of the US, primarily in Europe and to some extent in emerging markets. And as well as we have the Xolair business outside the United States in severe asthma as well as a co-promote in the US. All those businesses remain intact. And of course, we will continue to drive them. We always do evaluate what is the right mix in the markets.

And I think with our recent – now with the transformation announcement, where we moved to a single Innovative Medicines unit in every country that we operate in, we are going through an exercise to ask what is the right portfolio – not necessarily specific to respiratory. But what is the right portfolio of medicines for us to really focus our resources on? And where can we optimize or deprioritize so that we drive the most growth out of the business and really have the most impact that we can from the portfolio? So as we get to better clarity on those decisions and if anything changes, we'll of course let you know.

- Matthew Weston - Crédit Suisse AG, Research Division

Q. Vas, I don't know if my mic is on. I don't know whether a follow-up is appropriate. But could we see those spun out with Sandoz, given that they'd fit with that kind of long life cycle ex US footprint that Sandoz has?

- Vasant Narasimhan – CEO of Novartis

A. So I'm getting in trouble with all of my IR colleagues for taking your follow-on, Matthew, but I will answer it since we've known each other for so long. Right now, our intention is not to move any of our Innovative Medicines business with any consideration with Sandoz. We'll keep Sandoz as a pure-play small molecule generics and biosimilars business.

- Matthew Weston - Crédit Suisse AG, Research Division

Sorry, Samir.

- Operator

Your next question comes from the line of Wimal Kapadia from Bernstein.

- Wimal Kapadia - Sanford C. Bernstein & Co., LLC., Research Division

Q. So just firstly, with Kisqali®, you previously suggested that adjuvant is a USD 6 billion opportunity. But I'm just curious how we should think about it. Because when you look at the epidemiology, it would suggest a

much larger opportunity in intermediate patient pool. So I'm just curious, what assumptions you're making in terms of which – actually receive the drug in this population? Because really, if you see a decent penetration, the market potential should be significantly larger.

And then just to be cheeky because we've done one round. Just on sabatolimab. Given the delay in filing due to needing Phase III OS data and the high hopes that physicians seem to have for VENCLEXTA in MDS from the VERONA trial, I'm just curious how you're thinking about the potential for the product in MDS at this point. Does it now become somewhat of a lower priority? Or do you still believe that greater than USD 1 billion opportunity you discussed previously in MDS is still feasible?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Wimal. On Kisqali® in the adjuvant setting, we do believe that with the possibility of adding intermediate risk on top of high risk, that is a significant expansion in the patient population, probably 3 to 4x what we see in the high-risk patient population.

We previously guided to, I think, USD 6 billion based on what we saw in kind of consensus outlooks in various market projections. But I mean, I would agree that if we are successful in demonstrating a meaningful benefit across that entire intermediate risk range, there could be a larger opportunity for the medicine. And we're certainly doing that work now as we move towards the final readout of the study.

So I agree. It is a significant opportunity and could be a fundamental inflection point for the company if Kisqali® is successful, and most importantly, for all of those women with breast cancer who need better therapeutics so that their cancers don't recur. But I think it's a good push, and we'll try to come back with better numbers.

On sabatolimab, I think the data that we have suggests that we need to wait for the OS data in Phase III. The opportunity for this medicine is both across AML and MDS. We do note that there is a rapidly changing treatment landscape in MDS. Nonetheless, we think that, if the medicine has a unique mechanism of action with targeting TIM-3 and could be used in combination with other agents, and if the safety profile would reasonably hold up, we do think it has that USD 1 billion potential in each of the indications.

But I wouldn't know. We need to wait for now for the full Phase III studies. And it wouldn't be prudent to put too much more on to it until we see that data readout.

Next question, operator. And we'll try to do as many as we can in the last five minutes.

- Operator

Your next question comes from the line of Richard Parkes from BNP Paribas.

- Richard J. Parkes - BNP Paribas Exane, Research Division

Q. It's a follow-up on Leqvio® in the US. Feedback we've received recently from US physicians is that they're still seeing difficulties accessing injection centers and that reimbursement is still challenging. So I just wondered whether that's just an issue of experience and lack of infrastructure or whether there are the barriers that payers are putting into place in order to manage utilization, such as requirements for specific injection centers or anything you haven't expected.
And then can I just ask a clarification? Because I think I heard you say that the final NATALEE readout was the end of next year, but I might have missed that. So if I could just clarify that time line.

- Vasant Narasimhan – CEO of Novartis

A. Yes, absolutely. So first on NATALEE, it would be in the second half of next year, which I think is what we guided to previously. Not end. I didn't mean to give a new time line. Time line is exactly as we've said previously, so no change in time line.

On Leqvio®. I think there is an element of experience and also understanding the Part B and the payer dynamic. There is 30% to 40% of patients who are in Medicare Part B fee-for-service that don't have any relevant blocks and can access the medicines. There is a set of patients where there is a prior authorization, and then there's a set of patients that do have a step edit.

And I think physicians are just getting experience seeing how different patients actually have to move through the system. I think as they get smarter about that and understand those dynamics, as offices get better and as we get better at supporting offices, we should be able to overcome those. And as I noted, we have a very high percentage of patients covered now to the full Leqvio® label.

To my knowledge, there's no restrictions on which alternative injection centers or other administration centers that can be used that would really be impacting that perception. I think it's just, if you happen to put a certain – a patient on certain insurance as the first patient through the system, you do have to work through the reimbursement hurdles and get that all set up in the office. Normal things for a US health care launch in cardiovascular. Things that we're well adept at managing, having successfully launched Entresto®. And things we're working very hard to resolve as quickly as possible.

- Operator

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

- Richard Vosser - JPMorgan Chase & Co, Research Division

Q. Just one on the LOEs that we should expect in '23. I think Promacta® is slated, but there are some formulation and use patents that might actually push that out.

And maybe similarly, just anything else like Lucentis® that we should be thinking about?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. Yes, on Promacta®, we're continuing to work to really support all – the full range of patents we have on the medicine. And I think in appropriate time, if we're successful, we'll provide an update on Promacta®. But it's something we're very focused on.

And then on Lucentis®, we do expect the biosimilar – a few biosimilar entries in Europe. I think it's important to note that, with the broad scale availability of Avastin for now many, many years, that we believe the biosimilars market has in effect already happened in Europe. So we would expect a moderate decline on the launch of the biosimilars, but maybe not what you would see with other biologics when biosimilar entry occurs. So that's how we're forecasting Lucentis® now for the coming years.
And one last question, operator?

- Operator

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

- Graham Glyn Charles Parry - BofA Securities, Research Division

Q. So just one on Gilenya®. So obviously, you've had the overturning the decision from the appeal court, and you said you're going to petition. So just help us understand time frame for the petition. Does that prevent a

launch happening in the intervening time frame? So your level of confidence that we won't see a launch this year? Or is the guidance just a guidance assumption, but that could change depending on what happens with the court?

And then just one last one. Kisqali® growth was just well above prescription growth, although, obviously, we are seeing resurgence there. Is that reflective of real volume growth? Or could it be just a sort of prescription retail versus other channels that we're seeing, and actually, the reported growth is much more in line with the real volume growth?

- Vasant Narasimhan – CEO of Novartis

A. Yes. On Gilenya®, right now, no generics can enter the market. We are petitioning the court. And we would expect to get a response from the court in the coming months. If granted, then it would be another set of months before the hearing. And then the hearing will take another set of months. As a reminder, we guided to generics entering in 2024. So really, what we look at here is, between now and that time line, when exactly the entry might happen.

So we'll know more, I think, as the court gives us feedback once we – we have yet to be – we are in the process of submitting the petition. The petition would then need to be reviewed. We either be rejected at that point or the petition would be granted and then we would then move forward from there. So that's kind of the scenarios right now on Gilenya®. But to remind again, the launch update was anyway in '24. So from a midterm growth standpoint, this is not having a significant bearing.

Also in Europe, where we were granted the patent by the European patent office, we expect that patent to be issued later this year, and we'll continue to defend Gilenya® across Europe. So a lot of things, puts and takes, I think, on Gilenya® at the moment.

And I think on your question on Kisqali®, I don't know the answer, so we'll just have to follow-up with you. But we'll get back to you on that to make sure you're clear on the volume/price dynamics. But I would say that what we see in our numbers is a strong growth in underlying demand for Kisqali® that we'd like to sustain.

So thanks, everyone, for joining the call. Apologies we didn't get to every single question. But I really appreciate everyone taking the time, and we'll look forward to catching up soon. Bye-bye.
