2023 Q2 results presentation and transcript

Presentation

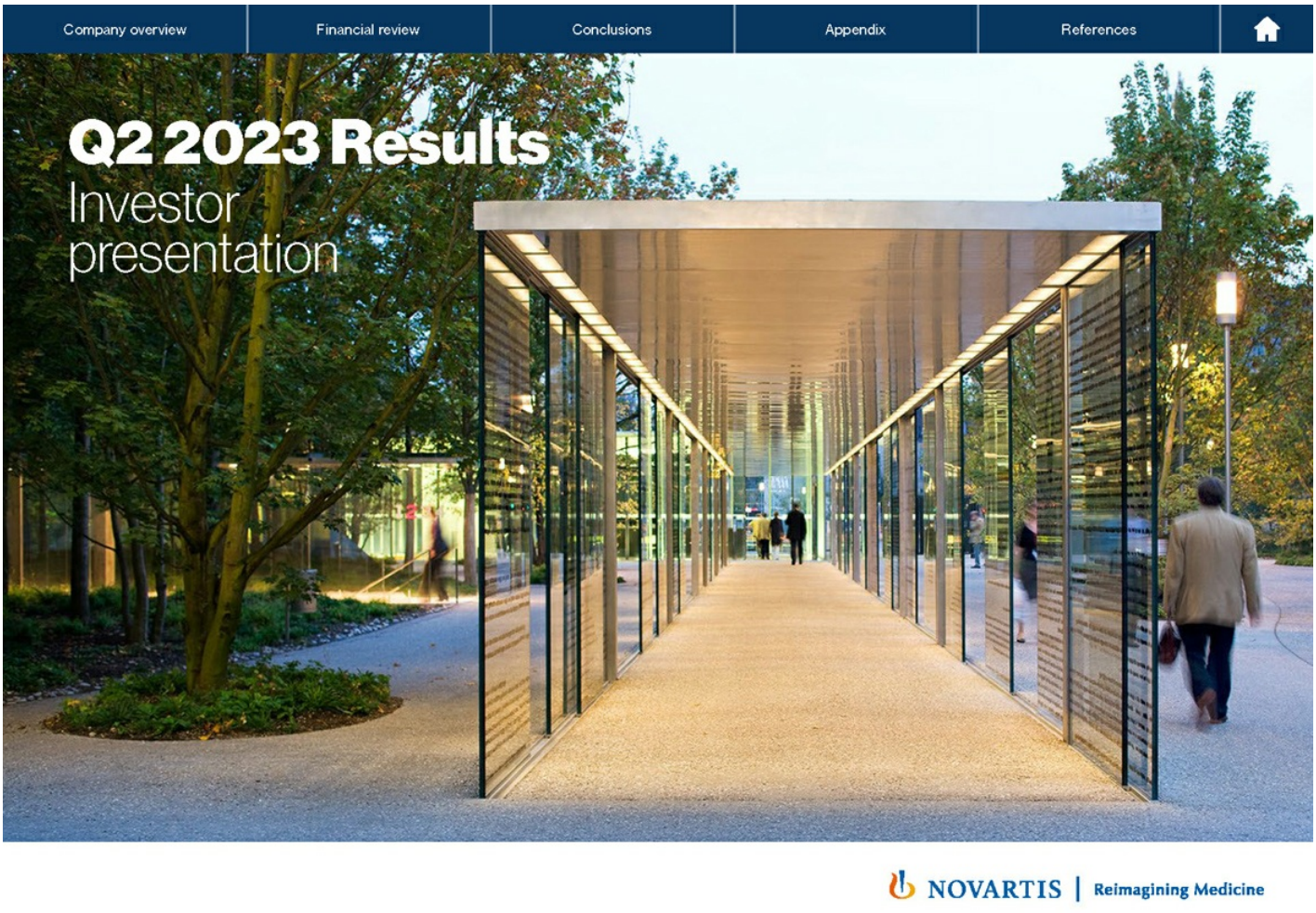
Download the interactive presentation (PDF 3.4 MB)

Download the podcast (MP3 34 MB)

Transcript

View the 2023 Q2 results presentation and read the transcript slide by slide.

Slide 1 – Samir Shah, Global Head Investor Relations



Good morning and good afternoon, everybody. I want to begin by thanking you for participating in our webcast and investor call again. Before we actually start, I'm going to read the safe harbor statement.

Slide 2

Disclaimer

This presentation contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," or similar expressions, or by express or implied discussions regarding potential new products, potential new indications for existing products, potential product launches, or regarding potential future revenues from any such products; or regarding potential future, pending or announced transactions, including the acquisitions of Chinook Therapeutics or DTx Pharma, or our divestiture of 'front of eye' ophthalmology assets; or regarding potential future sales or earnings of the Group or any of its divisions; or regarding discussions of strategy, priorities, plans, expectations or intentions, including our transforming into a "pure-play" Innovative Medicines business; or regarding the Group's liquidity or cash flow positions and its ability to meet its ongoing financial obligations and operational needs; or regarding our planned spin-off of Sandoz; or regarding the new share buyback; or regarding the impact of the decision of the US District Court for the District of Delaware on the validity of our patent covering Entresto and combinations of sacubitril and valsartan. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. You should not place undue reliance on these statements. There can be no guarantee that the investigational or approved products described in this presentation will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. Neither can there be any guarantee expected benefits or synergies from the transactions described in this presentation will be achieved in the expected timeframe, or at all. In particular, our expectations could be affected by, among other things: liquidity or cash flow disruptions affecting our ability to meet our ongoing financial obligations and to support our ongoing business activities; the impact of a partial or complete failure of the return to normal global healthcare systems including prescription dynamics; global trends toward healthcare cost containment, including ongoing government, payer and general public pricing and reimbursement pressures and requirements for increased pricing transparency; uncertainties regarding potential significant breaches of data security or data privacy, or disruptions of our information technology systems; regulatory actions or delays or government regulation generally, including potential regulatory actions or delays with respect to the development of the products described in this presentation; the potential that the benefits and opportunities expected from our planned spin-off of Sandoz may not be realized or may be more difficult or take longer to realize than expected; the uncertainties in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products; safety, quality, data integrity, or manufacturing issues; uncertainties involved in the development or adoption of potentially transformational technologies and business models; uncertainties regarding actual or potential legal proceedings, investigations or disputes; our performance on environmental, social and governance measures; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; uncertainties regarding future global exchange rates; uncertainties regarding future demand for our products; and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this presentation as of this date and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

Chinook Therapeutics and Chinook are registered trademarks of Chinook Therapeutics, Inc. DTx Pharma is a registered trademark of DTx Pharma, Inc. BAUSCH + LOMB is a registered trademark of Bausch & Lomb Incorporated.

2 Investor Relations | Q2 2023 Results

NOVARTIS | Reimagining Medicine

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

Just a couple of housekeeping points. As per usual, we'll have one question per analyst when we go to the Q&A session, and you'll have time to go back again and ask a second question. And the other point is that we aim to finish today at quarter past the hour. So it's 9:15 East Coast Time and 15:15 European Time. And with that, I'll hand across to Vas.

Slide 3 – Vasant Narasimhan – CEO of Novartis

Vas Narasimhan, M.D.
Chief Executive Officer

Company overview

NOVARTIS | Reimagining Medicine

Great. Thank you, Samir, and thanks, everyone, for joining today's call. With me today, I also have Harry Kirsch, our CFO.

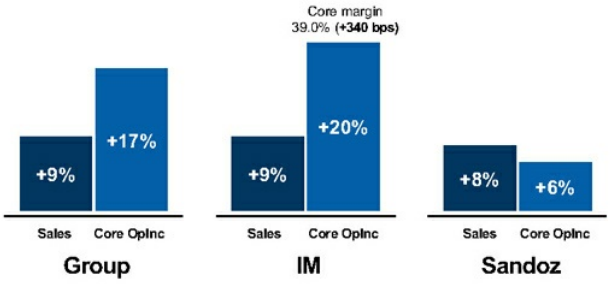
Slide 4

Q2 SUMMARY

Novartis delivers strong sales growth, robust margin expansion and raises guidance

Growth and Productivity

Q2, % cc



FY 2023 Group guidance raised[1]

Sales expected grow high single digit
Core OpInc expected to grow low double digit

Innovation and other milestones

Kisqali®
NATALEE Ph3 at ASCO

Cosentyx®
US approval 300mg AI and PFS; EU approval in HS

Entresto®
EU approval in pediatric HF, extending RDP to Nov 2026

Iptacopan
US and EU filings in PNH; US BTD for C3G

Continue strategic rationalization of development portfolio
including Chinook acquisition, divestment of front of eye assets and termination of BeiGene option agreement for ociperlimab

Entresto® US IP update
Mylan held to infringe crystalline complex patents; Novartis disagrees with negative decision by Delaware Court and will appeal to uphold validity of combination patent

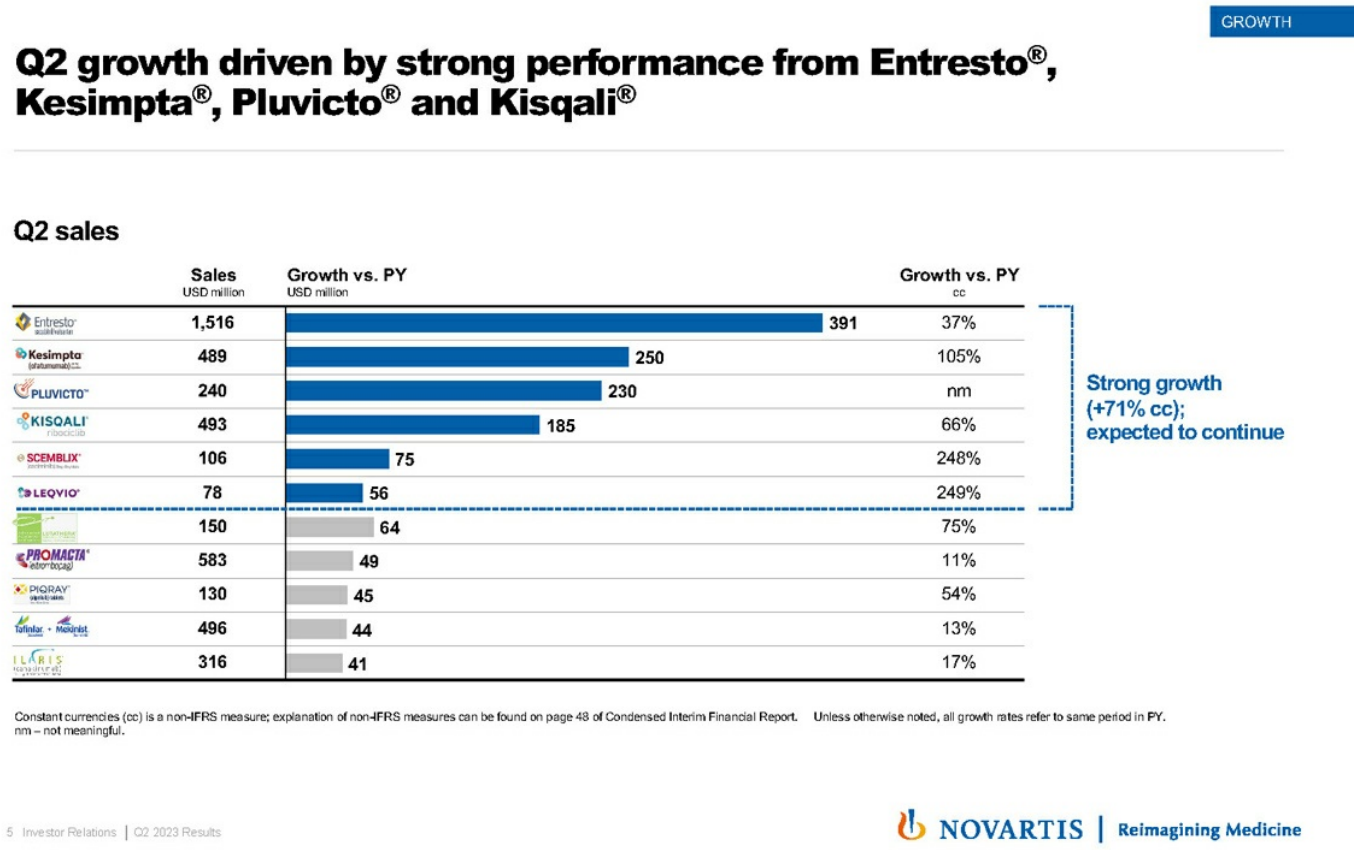
Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report. Unless otherwise noted, all growth rates refer to same period in PY. OpInc – operating income. IM – Innovative Medicines division. RDP – Regulatory data protection. HF –heart failure. HS – Hidradenitis suppurativa. BTD – Breakthrough therapy designation. 1. Assumes no US Entresto® Gx at risk launch in 2023.

NOVARTIS | Reimagining Medicine

So let's move straight to Slide 4. And as you saw in our release earlier today, Novartis delivered strong sales growth, excellent margin expansion, and we were able to raise our full year guidance. Getting into the numbers, our group sales grew at 9% and core op inc at 17%. IM sales were up 9% and core op inc up 20%, allowing us to drive our IM margin to 39%. And Sandoz sales were up 8% and core op inc up 6%. Harry will go through the guidance in more detail, but as you saw, we raised our full year guidance for both sales and core operating income.

We had a number of innovation milestones as well as other strategic milestones over the course of the quarter. And we go through those over the course of my slides. In addition, you saw that there was a ruling from the District Court regarding one of our patents for Entresto®, our combination patent. We're in the process of appealing that patent and feel our arguments are strong to ultimately prevail on appeal, though that process will take 12 to 18 months. We would note there are currently no generics that are currently approved for Entresto®. And also of note, in our assessment of recent history, there hasn't been an at-risk launch on a product of Entresto® size in at least 15 years. So we'll continue to fully defend our IP citizens petitions and other elements of our strategy to enable Entresto® to have as long an exclusivity period as we believe it deserves.

Slide 5



Now moving to the next slide. Our Q2 growth was driven by strong performance across our key growth drivers. You can see each of our key brands, Entresto®, Kesimpta®, Pluvicto®, Kisqali®, Scemblix®, Leqvio®, all delivered excellent performance in the quarter. And I think this reflects a combination of our new strategy or refreshed strategy of focus in five key therapeutic areas, as well as our streamlined organization from our transformation last year. That's delivering outstanding growth in market from a top line standpoint, but also delivering strong performance on the bottom line as well. We're going to take each one of those brands in turn in the subsequent slides.

Slide 6

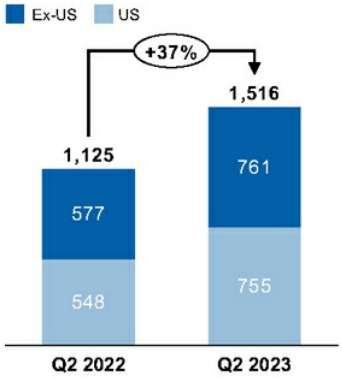
GROWTH

Entresto® delivering strong double-digit growth in all geographies

Entresto

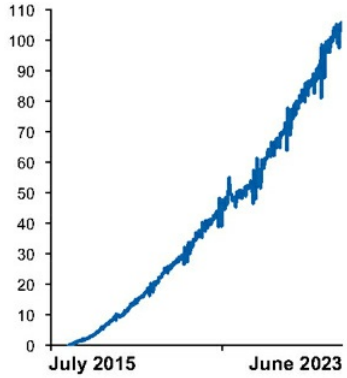
Sales evolution

USD m, % cc



US weekly TRx[1]

Total prescriptions (000)



Strong Q2 momentum

US: sales +38% cc, NBRx +17% vs PY, ~1.3m TRx in Q2[1]

Ex-US: sales +36% cc, continued strong growth in HFrEF

China/Japan: Significant contribution from HTN[2]

Confidence in future growth

Robust guidelines[3] (US/EU)

Expect further penetration in HFrEF (2/3 eligible patients still on prior SoC)

PARAGLIDE in HFpEF met primary endpoint[5]

Pediatric approval confirms **RDP to Nov 2026 EU**[4]

US IP update

Mylan held to infringe crystalline complex patents; Novartis disagrees with negative decision by Delaware Court and will appeal to uphold validity of combination patent

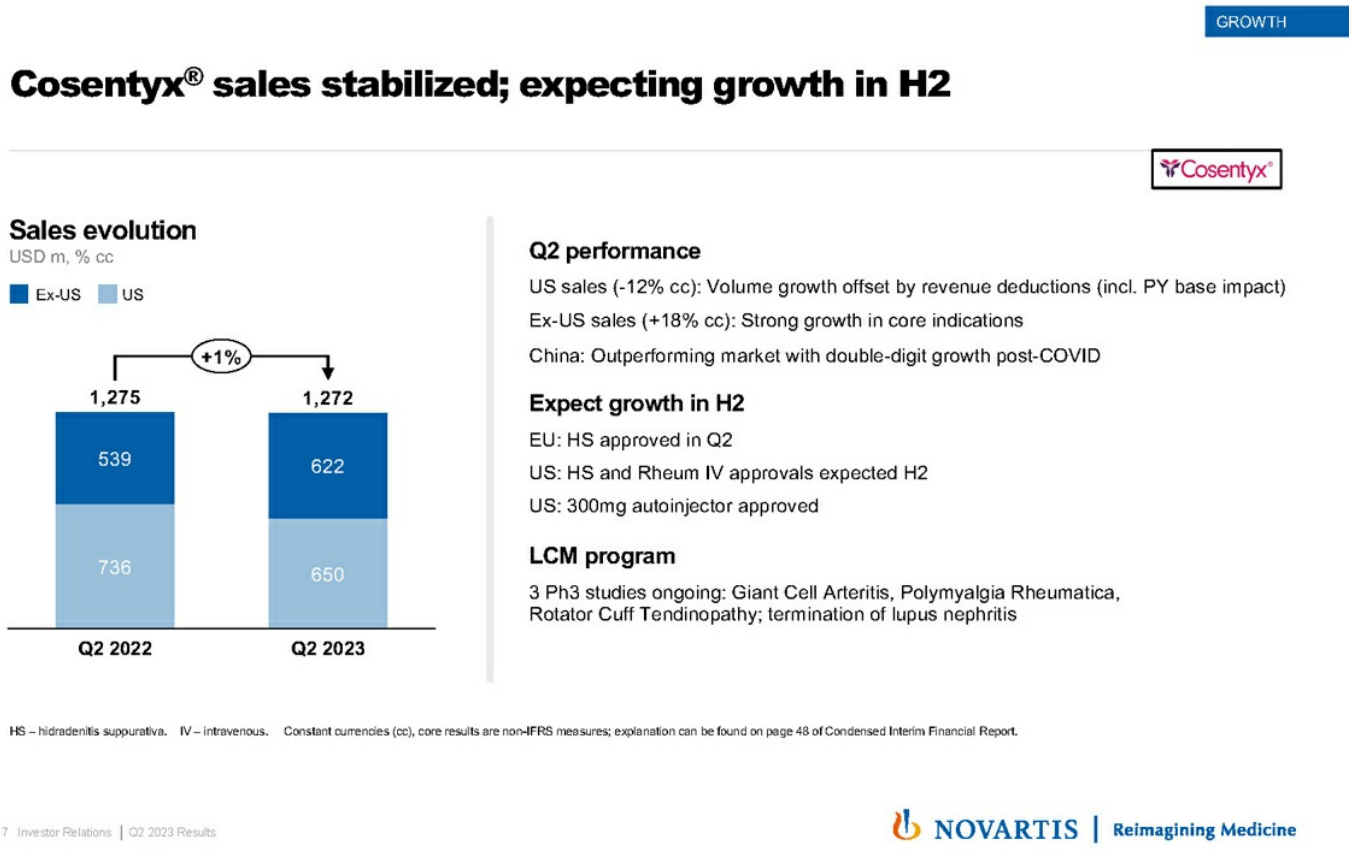
See last page for references. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report. TRx – total prescriptions. NBRx – new to brand prescriptions. HFpEF – heart failure with preserved ejection fraction. HFrEF – heart failure with reduced ejection fraction. HF – heart failure. HTN – hypertension. RDP – Regulatory data protection. SOC – standard of care.

NOVARTIS | Reimagining Medicine

Now moving to Slide 6. Entresto® delivered strong double-digit growth in all geographies. The brand grew 37% on the quarter, and you can see robust growth, both ex-US and US On the US side, our weekly TRx prescriptions continue to grow robustly, 38% sales growth, 17% NBRx growth. So really outstanding performance on the US side. Ex-US, we had 36% constant currency growth, and that's driven by HFrEF, but as well our performance on hypertension in China and Japan.

We remain confident in the outlook for Entresto® continued growth, both driven by guidelines, its HFrEF indication, but as well as continued use in the HFpEF indication. And importantly, our pediatric approval in the EU confirms that we have regulatory data protection through November of 2026.

Slide 7



Now moving to Slide 7. In Cosentyx®, our sales stabilized in Cosentyx® in the second quarter, with sales up 1%. When you dive in a little bit deeper into Cosentyx® performance, you saw US sales down 12% in constant currency. And this was a situation where volume growth was offset by revenue deductions as we outlooked in Q1. There's also the matter of the base impact we had in the previous year from the revenue deduction true-ups we took in the second half of the year, which weren't accounted in the first half of 2022, leading to a higher base last year.

Ex-US sales were up 18% across – with growth across all of our core indications. And importantly, in China, we're seeing outperformance versus the market with double-digit growth, as the China health care systems continue to stabilize. Now when you outlook to the second half, we expect important pipeline milestones with hidradenitis already approved in the EU. In the US, we expect to get approvals of both HS and R-IV formulation, which would allow us to penetrate the Part B segment with respect to Cosentyx®, with rheumatologists who continue to use IV formulations of these medicines.

And the 300-milligram auto-injector was also – we also received approval for. From an LCM standpoint, three important programs continue to progress on track: giant cell arteritis; PMR; and rotator cuff tendinopathy. We did terminate our lupus nephritis program based on a lack of compelling efficacy.

Slide 8

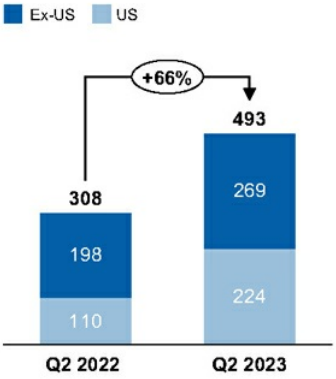
GROWTH

Kisqali® continued strong momentum globally, with increasing recognition of its differentiated profile

KISQALI

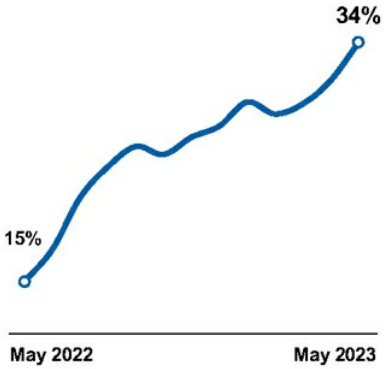
Sales evolution

USD m, % cc



US mBC NBRx share[1]

Rolling 3 months, %



Consistent efficacy

Kisqali Ph3 OS results in 1L mBC[2]

Stage IV	HR	95% CI
☑ MONALEESA-2	**0.76**	(0.63, 0.93)
☑ MONALEESA-7	**0.76**	(0.61, 0.96)
☑ MONALEESA-3	**0.67**	(0.50, 0.90)

Consistent benefit regardless of combination endocrine therapy, menopausal status, or site and number of metastases

Included in **NCCN guidelines[3]** as the only Category 1 treatment for 1L mBC with AI

mBC – metastatic breast cancer. NBRx – new to brand prescription. NCCN – national comprehensive cancer network. AI – aromatase inhibitor. 1. Of CDK4/6 mBC market, US 3 months ending May 2023 from IQVIA Breast Cancer Market Sizing report. 2. MONALEESA-2: Hortobagyi et al, NEJM 2022; MONALEESA-7: Lu et al, Clin Cancer Res 2022; MONALEESA-3: Neven et al, ESMO Breast 2022. 3. NCCN Guidelines updated as of 27-Jan-2023. Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report.

NOVARTIS | Reimagining Medicine

Now moving to the next slide. Kisqali® continued strong momentum globally. And I think this is a testament to its excellent differentiated profile. We had 66% growth across the globe driven both by the US and ex-US markets. Our NBRx share now in the US has climbed to 34% on the 3-month rolling, and we continue to see strong month-to-month growth on our NBRx share. And this is, of course, driven by data you all know well, the consistent efficacy we showed in the metastatic setting across MONALEESA-2, 7 and 3, which show that the medicine has consistent benefit regardless of patient status or combination therapy.

The medicine is included in the NCCN guidelines as the only category 1 treatment for first-line metastatic breast cancer with an aromatase inhibitor.

Slide 9

INNOVATION

NATALEE results[1] build on Kisqali's differentiated efficacy in mBC, support expansion into broad population[2] of stage II, III eBC patients

Ph3 NATALEE trial results[1,2], presented at ASCO 2023

Robust efficacy

	HR	95% CI
iDFS – total population	**0.75**	(0.62, 0.91)
iDFS – stage II	**0.76**	(0.53, 1.10)
iDFS – stage III	**0.74**	(0.59, 0.92)
iDFS – node negative	**0.63**	(0.34, 1.16)
iDFS – node positive	**0.77**	(0.63, 0.94)
RFS	**0.72**	(0.58, 0.88)
DDFS	**0.74**	(0.60, 0.91)
OS	**0.76**	(0.54, 1.07)

Favorable safety

- No new safety signals
- 400mg dose well tolerated, with limited need for dose reductions
- AE-related discontinuations (<19%) were mostly protocol-mandated due to lab findings – most frequent AEs were neutropenia and liver-related
- Low rates of Gr3 symptomatic AEs

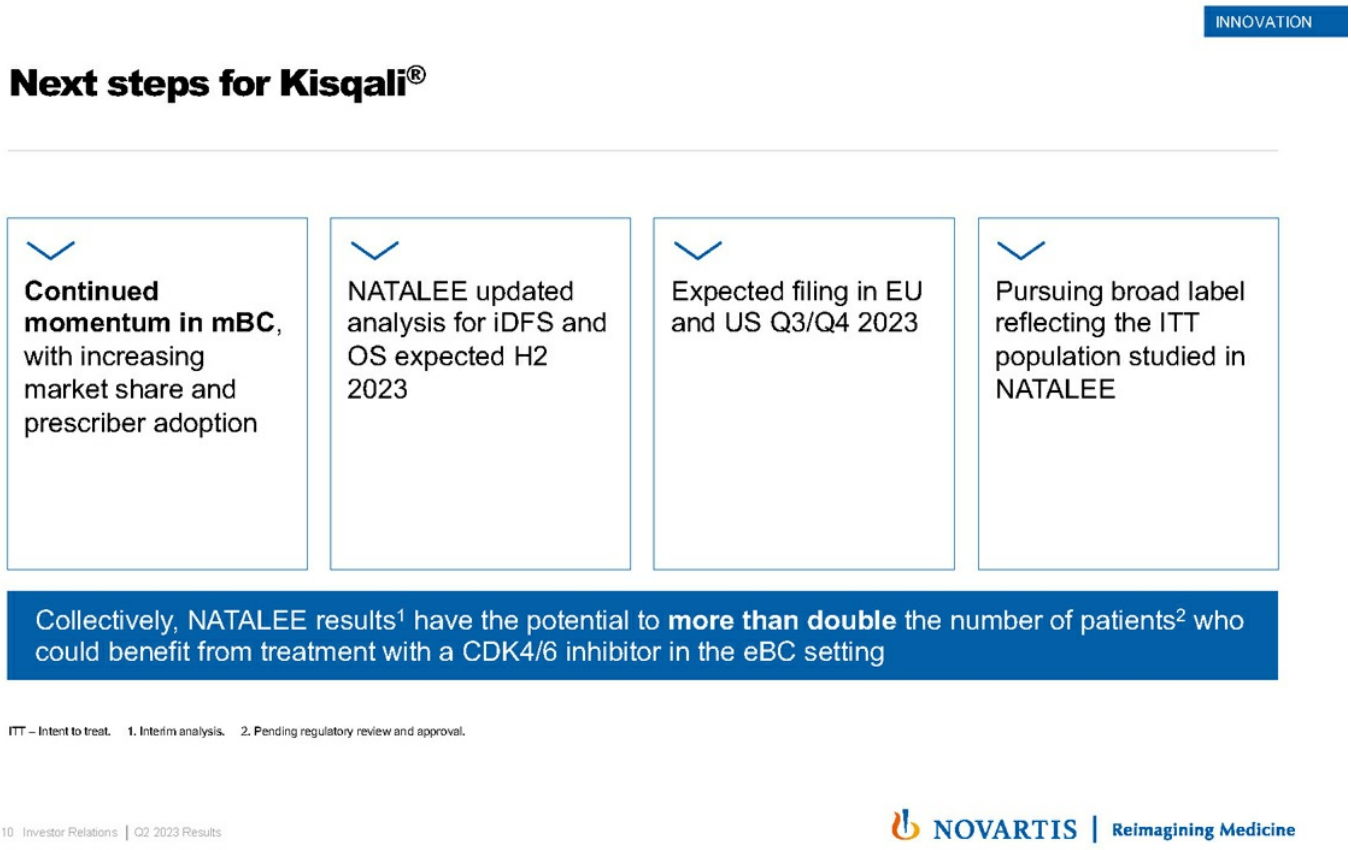
1. Interim analysis. Slamon D, Stroyakovskiy D, Yardley D, et al. Ribociclib and endocrine therapy as adjuvant treatment in patients with HR+/HER2- early breast cancer. 2. Pending regulatory review and approval.

NOVARTIS | Reimagining Medicine

Now moving to the next slide. Our NATALEE results, which we unveiled at ASCO earlier this summer, build on that differentiated profile, allowing us to demonstrate the potential benefits of Kisqali® in a broad population of Stage II and Stage III early breast cancer patients. As a reminder, we had very consistent results across iDFS, RFS, distant disease-free survival and OS. And those consistent results is what give us confidence that we'll be able to achieve a broad label in the early breast cancer setting.

Importantly, as well, we saw a positive OS trend already at this early interim analysis. Now in terms of safety, there were no new safety signals, the 400-milligram dose was well tolerated with limited need for dose reductions. AE-related discontinuations were mostly protocol mandated due to lab findings. The most frequent AEs were neutropenia and were liver related. And we had low rates of grade 3 symptomatic AEs, particularly with respect to GI-related symptoms.

Slide 10



Now moving to Slide 10. The next steps for Kisqali® will be continued momentum in the metastatic breast cancer setting, where you see strong performance across our key geographies. And we want to continue to drive that momentum as we believe Kisqali® is becoming the standard of care in the metastatic space. NATALEE update and analysis for iDFS and OS is expected in the second half of 2023.

We expect filings in the EU in Q3, and US in Q4 at the FDA, we like a greater information fraction on the OS analysis to allow us to get to the filing in Q4 of this year. And we're pursuing a broad label reflecting the intention to treat population studied in NATALEE. So collectively, we believe that NATALEE has enabled Kisqali® to have the potential to more than double the number of patients who could benefit from a treatment with a CDK4/6 in the early breast cancer setting.

Slide 11

Now moving to Slide 11. Kesimpta® also had an outstanding quarter and continues its strong trajectory, doubling sales versus prior year. Sales were up 105% US NBRx, you can see here, trending very well on the rolling 4 weeks. The TRx in the US was up 80% and NBRx was up 43%. Our B-cell NBRx share is currently 54% of the market, and that, I think, will be a key driver going forward as the B-cell therapies continue to gain a larger and larger share of the MS market.

In Europe as well, now we're seeing strong launch momentum with 24,000 patients treated. And we're confident in the continued growth of this brand, as I mentioned, both with the expansion of B-cell therapies, but also with the compelling profile versus older therapies as well as some competing overall in the B-cell class.

Slide 12

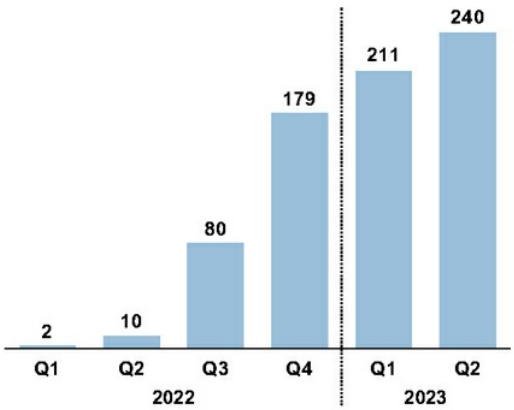
GROWTH

Pluvicto® continued strong performance with improving supply

PLUVICTO™

Sales evolution

Global sales, USD m



Strong progress in Q2

Q2 sales of USD 240m, +14% USD vs. Q1

Millburn (US) and Zaragoza (EU) sites approved for commercial Pluvicto supply in April, continuing to ramp up gradually

Actively starting new patients and onboarding new centers

Ex-US reimbursement discussions ongoing

Upcoming milestones

PSMAfore pre-taxane data presentation and filing expected in H2

Submission and approval of Indianapolis site (US)

mCRPC – metastatic castration-resistant prostate cancer. rPFS – radiographic progression free survival. OS – overall survival.

NOVARTIS | Reimagining Medicine

Now moving to Slide 12. Pluvicto® continued its strong performance. And importantly, we are at a situation where supply is no longer constraining our ability to grow this brand. In quarter 2, we saw Q2 sales of USD 240 million. Millburn was approved for the US and Zaragoza was approved for the EU as sites for commercial supply of Pluvicto®. And we are ramping up now additional lines in Millburn rapidly. This has allowed us to start adding new patients as well as adding new centers where we have goal to add over 100 new centers over the coming months to enable continued treatment for patients with prostate cancer with Pluvicto®. And we have progressed as well our ex-US reimbursement discussions.

Upcoming milestones for Pluvicto® will include the PSMAfore pre-taxane data presentation, and we expect a filing in the second half. In addition, the PSMA addition study is progressing on track as well. And we also expect submission and approval of our new Indianapolis site to further increase supply of Pluvicto®. So we would expect a continued strong performance in this brand, and we continue to outlook at Pluvicto® to exceed USD 1 billion in sales this year.

Slide 13

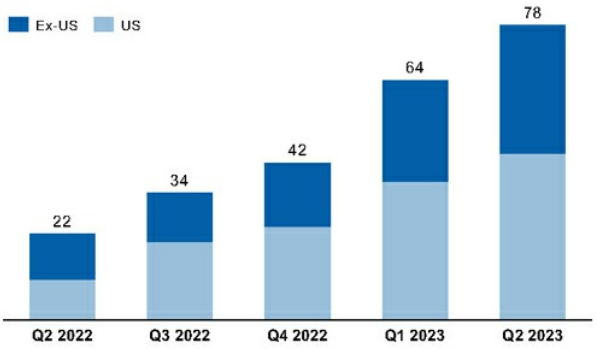
GROWTH

Leqvio® adoption expanding as we progress the launch

Leqvio® launch progressing steadily

Global sales evolution

USD m



Building foundation for acceleration

US adoption

2,600 facilities have ordered Leqvio (+18% vs. Q1)

Buy & bill 54% of Leqvio demand (+16% vs. Q1)

Early adopters driving Leqvio depth

Clinical profile

Consistent safety vs. Ph3 studies beyond 5yr follow-up in pooled analysis across 7 clinical trials[1]

Label expansion in US: indication updated to

- Primary hyperlipidemia incl. HeFH
- Less restrictive language for use for statin therapy
- Removal of several adverse reactions from safety section

HCP – healthcare professional. LTD – Launch To Date. *Leqvio® is administered initially, again at 3 months, and then once every 6 months. Novartis has obtained global rights to develop, manufacture and commercialize Leqvio® under a license agreement with Alnylam Pharmaceuticals 1. Wright RS. Oral presentation at: American College of Cardiology Annual Conference; March 2023.

NOVARTIS | Reimagining Medicine

And moving to Leqvio®. The launch continues to progress steadily as we've outlooked, and we continue to gain broader and broader utilization and adapt amongst cardiovascular providers in the United States. Sales reached USD 78 million globally. We now have 2,600 facilities that have ordered Leqvio®, which is a solid increase versus quarter 1. We are expanding buy-and-bill as the primary mode of acquisition of Leqvio® consistently now over time.

And one of our key areas of focus is to drive greater depth amongst early adopters of Leqvio®. In general, we find that once physicians reach a certain comfort level with the medicine along with their office staff, then we can reach a significant number or proportion of patients in a given office or clinic, ultimately receiving Leqvio® to lower elevated cholesterol.

We've demonstrated already, as you are aware, a consistent safety profile for this medicine. But importantly, in the last few weeks, we've also achieved a label expansion in the US, which expands Leqvio® to patients with primary hyperlipidemia and that, in effect, allows us to move into the primary prevention setting. Less restrictive language for use for statin therapy, meaning that patients do not have to be on a maximally tolerated statin to initiate Leqvio®, as well as the removal of several adverse reactions from the safety section. So this will give us an additional catalyst to help us continue to drive broader Leqvio® adoption in the US and around the world.

Slide 14

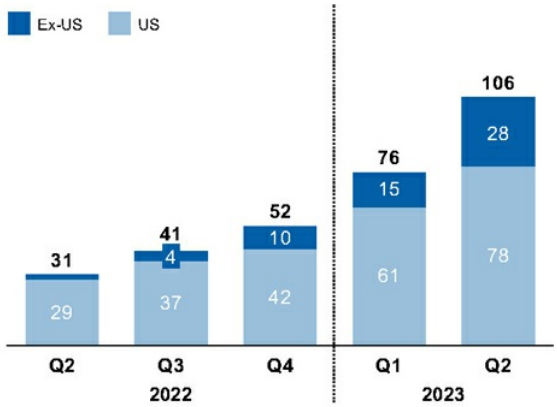
GROWTH

Scemblix® strong sales growth driven by underlying demand and increasing recognition of efficacy and tolerability benefit

SCEMBLIX® (asciminib)

Sales evolution

USD m



Q2 sales reflect strong demand from CML patients resistant or intolerant to 2 or more prior TKIs

US new patient share in 3L+ at 35%[1] ; average # of monthly prescribers +16% vs. Q1 2023

Global rollout ongoing with strong performance in Germany & Japan

Despite available therapies (1st and 2nd generation TKIs), strong unmet need remains in CML[2]

ASC4FIRST (1L registrational study) completed enrollment, readout and filing expected 2024

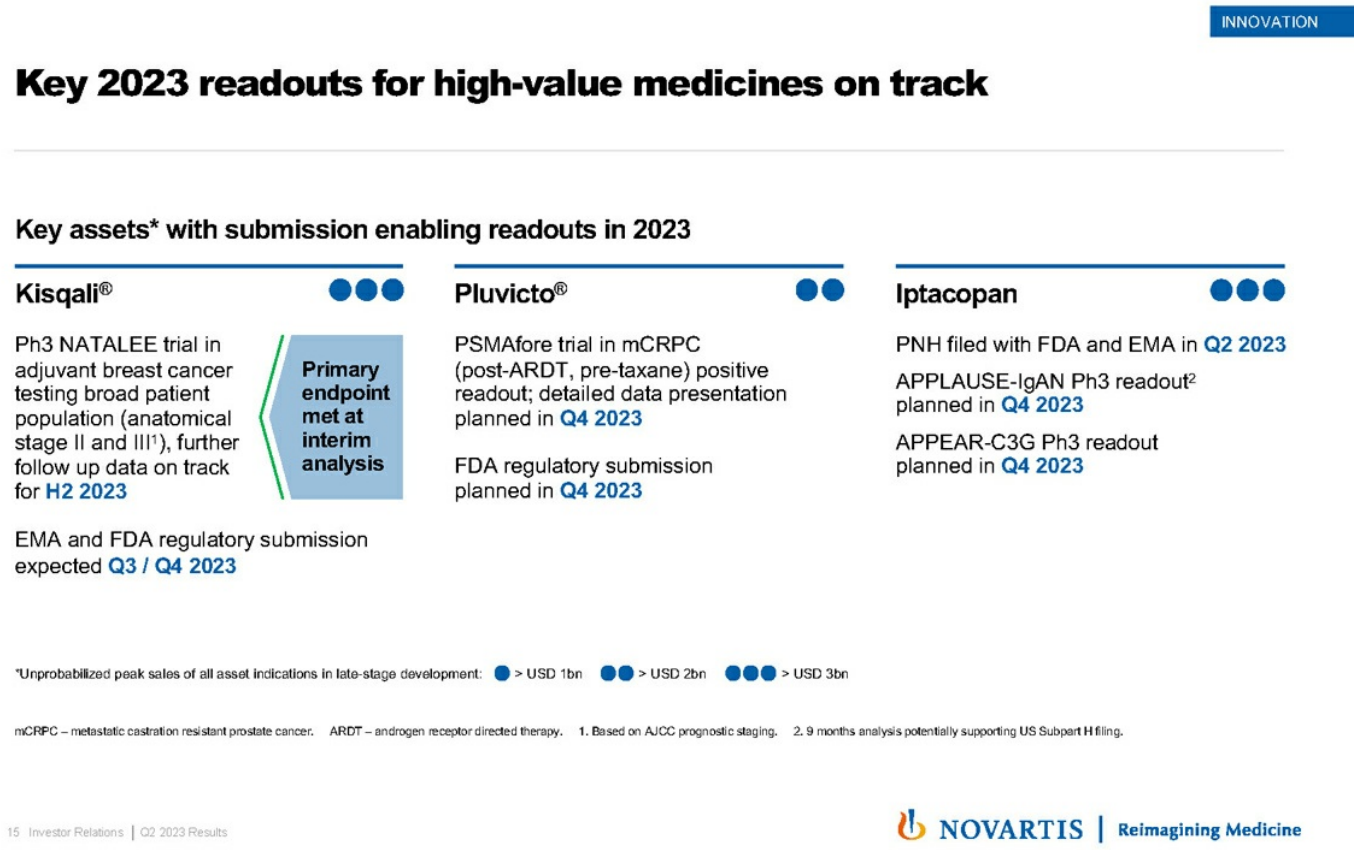
1. IQVIA: US April 2023 rolling three months 3L+ new patient start share. 2. Survey on unmet needs in CML at EHA: reveals the need for treatment decisions that balance quality of life, efficacy, and tolerability goals; Chronic Myeloid Leukemia Survey on Unmet Needs (CML SUN).

NOVARTIS | Reimagining Medicine

Now looking at Scemblix® sales. Scemblix® sales were strong in the quarter. This brand continues to outperform our internal expectations. Sales reached USD 106 million in the quarter. This is driven by our new patient share in the third-line setting, where we've reached now 35%, and we've had a 16% increase of monthly prescribers on the brand, as well as the global rollout of the medicine in Germany and Japan.

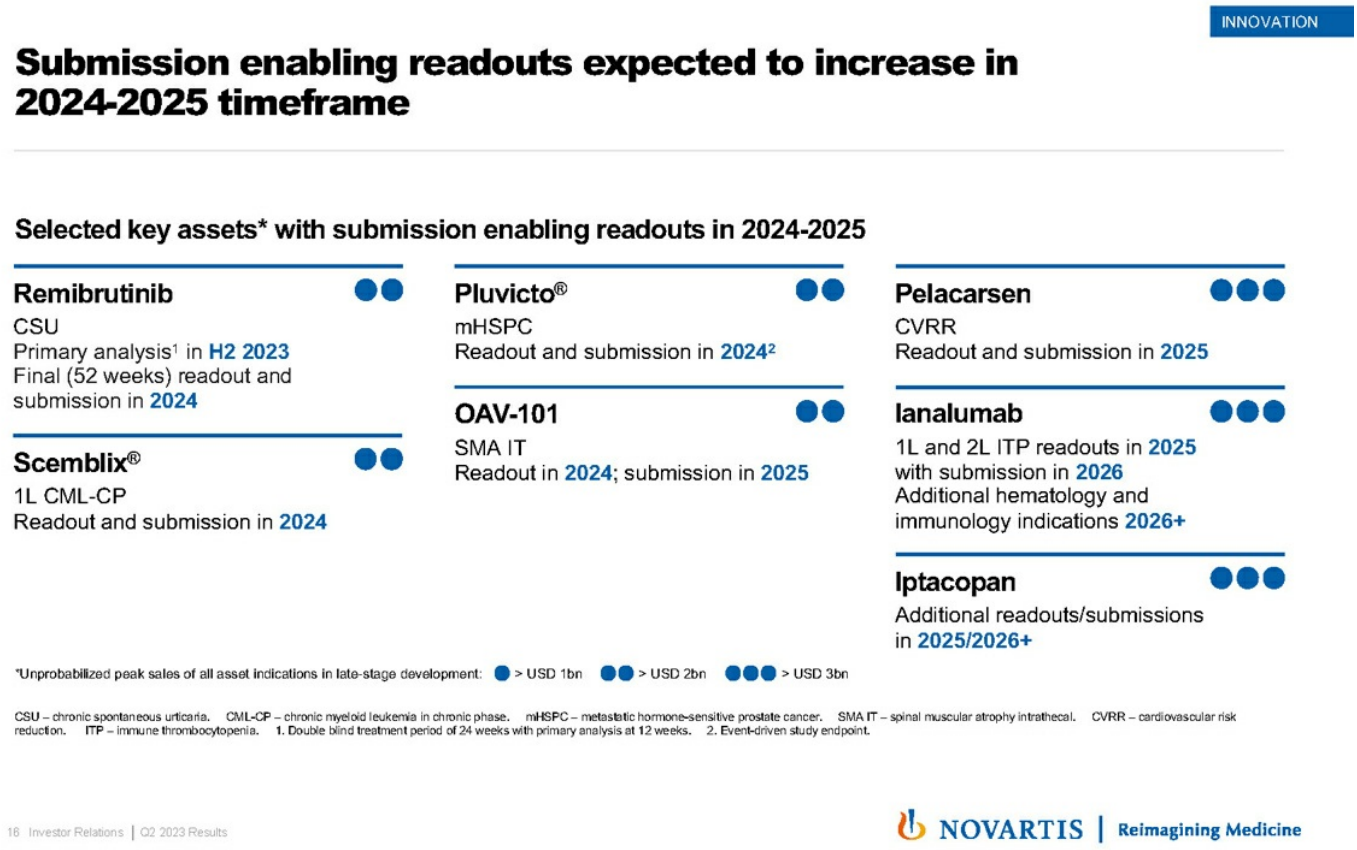
I think one of the compelling things of this therapy are excellent efficacy, but also an outstanding safety profile, which clinicians and patients appreciate. And we continue to work to advance Scemblix® data set to enable it to be used in earlier lines. The ASC4FIRST first-line registrational study has completed enrollment, and we expect readout and filing in the early part of next year. And we also continue to do additional studies to further profile Scemblix® in the second-line setting as well as in combinations with second-generation TKIs.

Slide 15



Then moving to Slide 15 and turning to our pipeline. A couple of notes here. Our key 2023 readouts are on track. That includes the Kisqali® data, which I've already mentioned; the Pluvicto® updated analysis, which I've also mentioned; as well as iptacopan, where you're aware, we've filed in both – PNH both in the US and the EU. We used a priority review voucher as well in the US. We also are on track to read out the APPLAUSE-IgAN Phase III study in quarter 4 as well as the APPEAR-C3G data readout as well in Q4 of 2023.

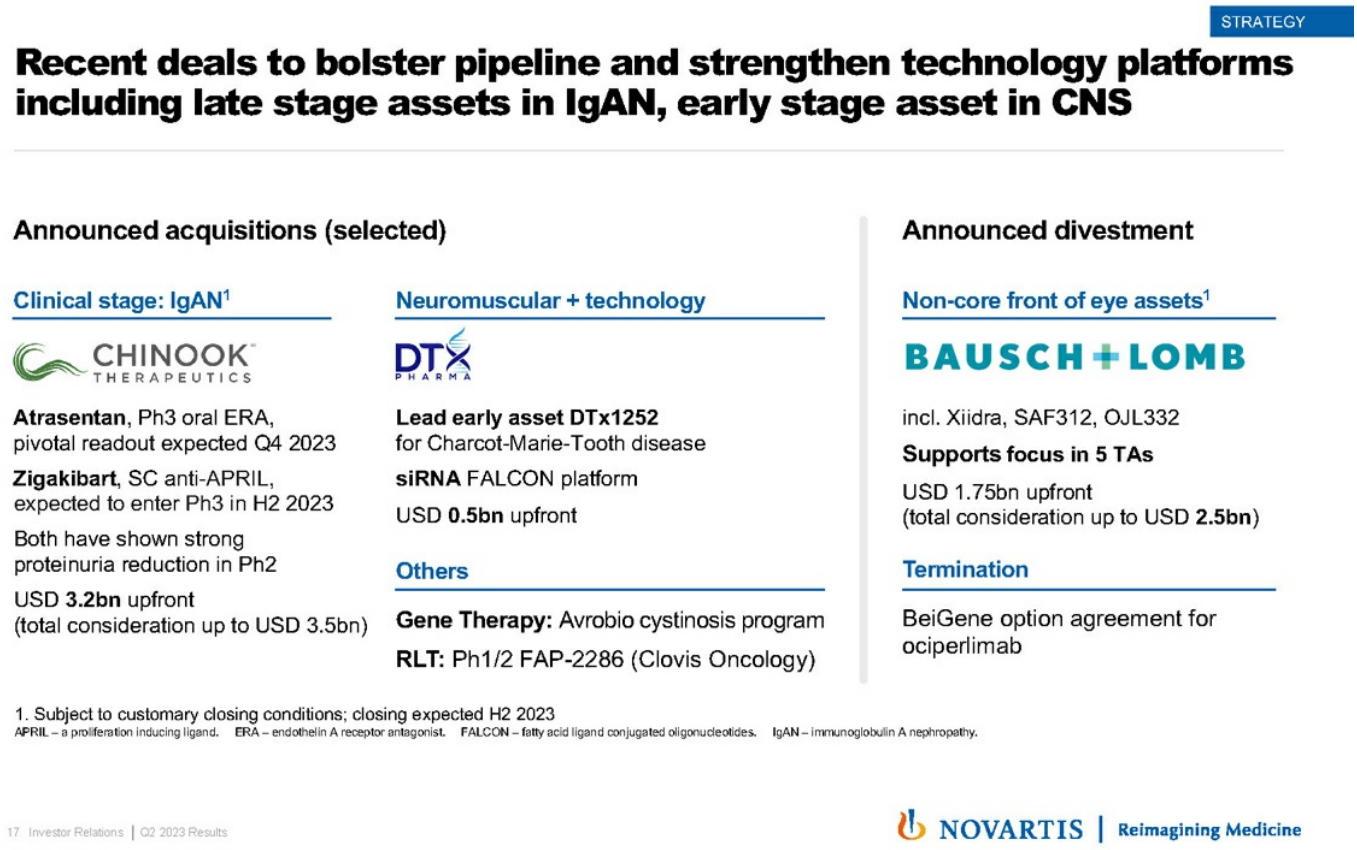
Slide 16



Now turning to the next slide. When you look ahead now to the potential readout that we have – expected readouts we have in the 2024, 2025 time frame, these also are on track. Remibrutinib will have its primary analysis in CSU, chronic spontaneous urticaria, in the second half of this year, with the final 52-week readout required for regulatory submission in the US in 2024. I've already covered Scemblix® and Pluvicto®.

Our OAV-101 gene therapy for SMA in older patients with an intrathecal administration is on track now for a readout in 2024. And pelacarsen, ianalumab and additional indications for iptacopan also all are on track, which really gives us a broad array of new medicines to enable us to drive growth in the second half of this decade and into the 2030s.

Slide 17



Moving to the next slide and just to provide an update on some of our external BD&L related efforts. We've done a number of recent deals to bolster our pipeline as well as strengthen our technology platform. We have a proposed acquisition of Chinook Therapeutics, which is currently awaiting regulatory approvals. This would bring into the portfolio two late-stage assets for the treatment of renal diseases, atrasentan and zigakibart, which is an anti-APRIL antibody. Both have shown strong proteinuria reduction in Phase II and could provide near-term launches for – in our portfolio.

We also announced earlier this week the acquisition of DTx, which is an siRNA company, that has an asset that we expect to soon enter human clinical trials for Charcot-Marie-Tooth syndrome, but also as a platform importantly, which enables the siRNAs to be directed using a lipid technology to the central nervous system, which hopefully could open up new opportunities to treat a range of diseases with siRNAs.

We also made important acquisitions of a gene therapy from Avrobio for cystinosis, a really debilitating disease without great therapies currently, as well as a mid-stage radioligand therapy targeting FAP from Clovis Oncology.

We also continue to focus our portfolio. Consistent with our overall company strategy, we announced the proposed divestment of our front of the eye assets to BAUSCH + LOMB, for an upfront of USD 1.75 billion as well as a total consideration depending on sales milestones of USD 2.5 billion. We also recently terminated our option agreement for ociperlimab with BeiGene. So with that, let me hand it over to Harry. Harry?

Slide 18 – Harry Kirsch – CFO of Novartis

Yes. Thank you very much, Vas. Good morning, and good afternoon, everyone. 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. As you will see from the numbers, it has been a very strong first half of the year.

Slide 19

FINANCIAL PROFILE

Very strong H1; Q2 continuing robust top and bottom-line growth...

Group[1] USD million	Q2 2023	Change vs. PY % USD	Change vs. PY % cc	H1 2023	Change vs. PY % USD	Change vs. PY % cc
Net Sales	13,622	7	9	26,575	5	8
Core Operating income	4,668	9	17	9,081	9	16
Operating income	2,920	31	50	5,776	14	28
Net Income	2,317	37	54	4,611	18	32
Core EPS (USD)	1.83	17	25	3.54	17	25
EPS (USD)	1.11	44	62	2.20	24	39
Free Cash Flow	3,275	-6		5,995	23	

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 48 of the Condensed Interim Financial Report.

19 Investor Relations | Q2 2023 Results

NOVARTIS | Reimagining Medicine

On Slide 19, we detailed the strength of top and bottom line performance during quarter 2 and half 1. It's really a pleasure to present results like these, which are strong across the board. Overall, we have continued the robust top and bottom line growth that we saw at the beginning of the year.
In quarter 2, sales grew 9%, with broad-based performance across our key therapeutic areas and focused geographies. Core operating income increased by 17% driven mainly by higher sales. Core EPS grew 25% to USD 1.83, faster than core operating income also supported by our USD 15 billion share buyback program, which we just finished in June.

Turning to the first half, sales grew 8%; core operating income 16%; with strong core EPS growth also of 25% to USD 3.54. Free cash flow grew 23% to USD 6 billion. In summary, a very strong first half of the year as our efforts to focus and streamline the business continue to pay off.

Slide 20

FINANCIAL PROFILE

... contributing to core margin improvements for Group

	Q2 2023				H1 2023			
	Net sales change vs. PY[1] (in % cc)	Core operating income change vs. PY[1] (in % cc)	Core margin[1] (%)	Core margin change vs. PY[1] (%pts cc)	Net sales change vs. PY[1] (in % cc)	Core operating income change vs. PY[1] (in % cc)	Core margin[1] (%)	Core margin change vs. PY[1] (%pts cc)
Innovative Medicines	9	20	39.0	3.4	8	19	38.9	3.6
Sandoz	8	6	18.0	-0.3	8	5	19.6	-0.5
Group	**9**	**17**	**34.3**	**2.5**	**8**	**16**	**34.2**	**2.4**
Novartis ex-Sandoz	**9**	**19**	**37.7**	**3.0**	**8**	**18**	**37.4**	**3.0**

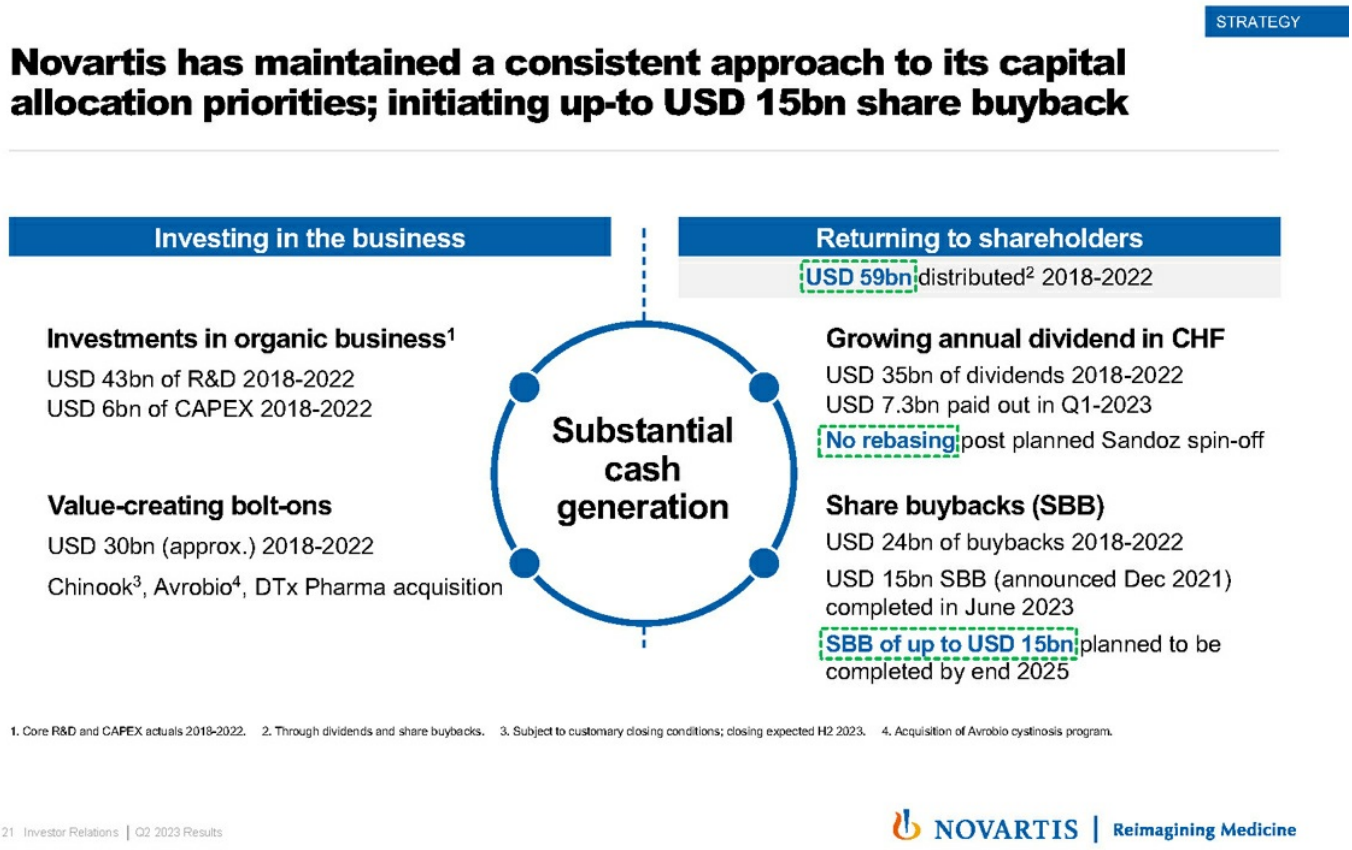
1. Constant currencies (cc), core results are non-IFRS measures. An explanation of non-IFRS measures can be found on page 48 of the Condensed Interim Financial Report.

NOVARTIS | Reimagining Medicine

On the next slide, Slide 20. I want to go into a bit more detail about the performance of Innovative Medicines and Sandoz. For quarter 2, Innovative Medicines sales grew 9%, which drove an increase in Innovative Medicines core operating income of 20%. Core margin improved 340 basis points versus prior year for the quarter, reaching 39% in quarter 2 for Innovative Medicines.

Sandoz net sales grew 8% for the quarter, mainly driven by Europe and the biosimilar business. Core operating income was up 6%, with a core margin at 18% for the quarter. As we move towards the anticipation of the spin-off of Sandoz, we have also provided figures for Novartis excluding Sandoz in the bottom row here. And you see Novartis excluding Sandoz grew 9% top line and 19% on the bottom line for the quarter. Of course, these numbers are very close to Innovative Medicines' numbers, and there was also a 300 basis points growth in the core margin, which reached 37.7%, meaning we are well on track for 40% midterm margin target.

Slide 21

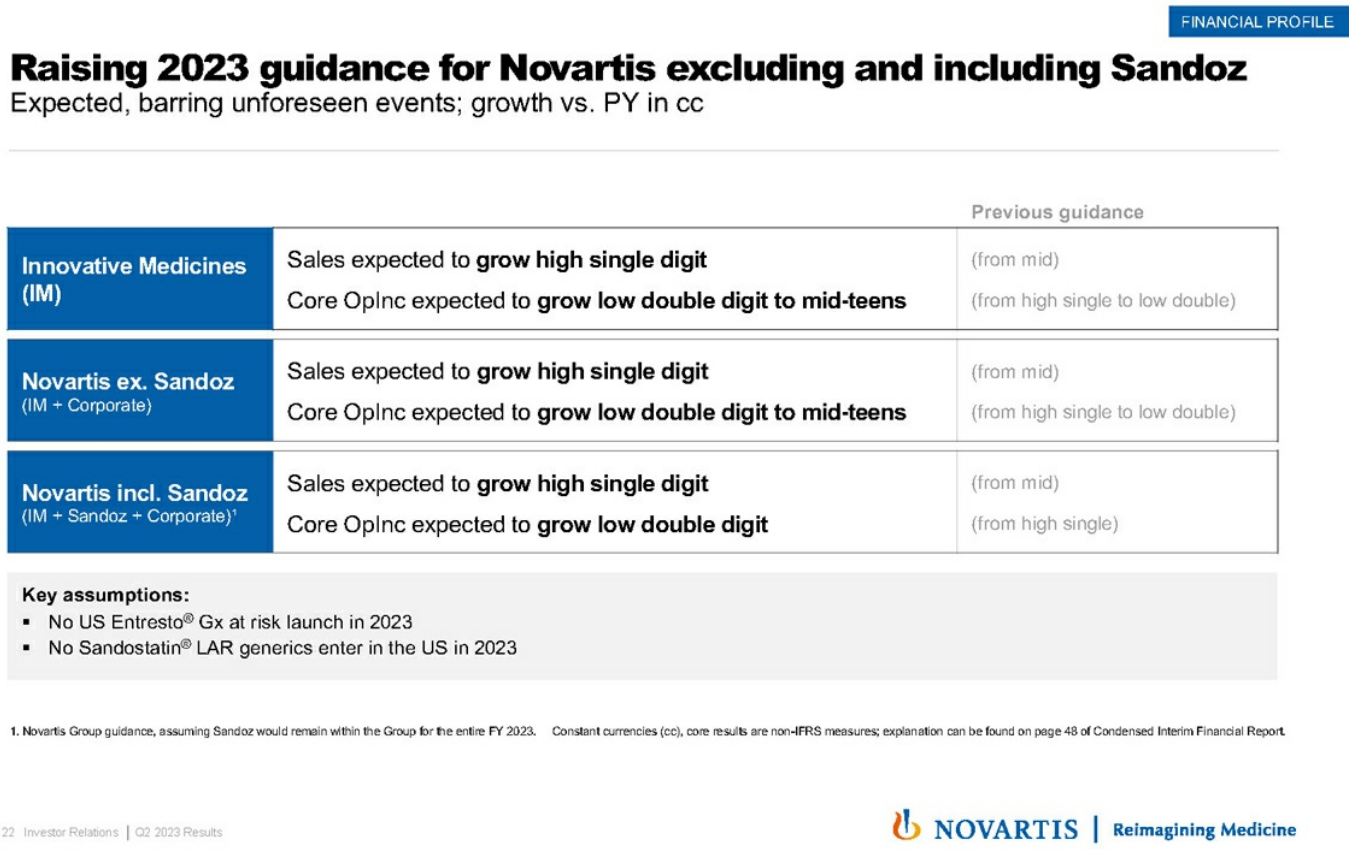


Next slide, please. I would like to remind everyone about our capital allocation priorities. As a company, we have, of course, substantial cash generation, which we aim to distribute across both our priorities of investing in the business, and returning capital to our shareholders.
In terms of investing in the business, we have one of the largest R&D budget in the industry and have spent USD 43 billion on R&D from 2018 to '22. Over the same period, we spent about USD 30 billion on bolt-on M&A opportunities.

In terms of returning capital to shareholders, we have a strong and growing annual dividend in Swiss francs per share and have undertaken regular share buybacks at, I would say, a reasonable level. Please note that the annual dividend will not be rebased post the Sandoz spin, and Sandoz will also pay its own dividend, essentially providing a further uplift of dividends for our investors.

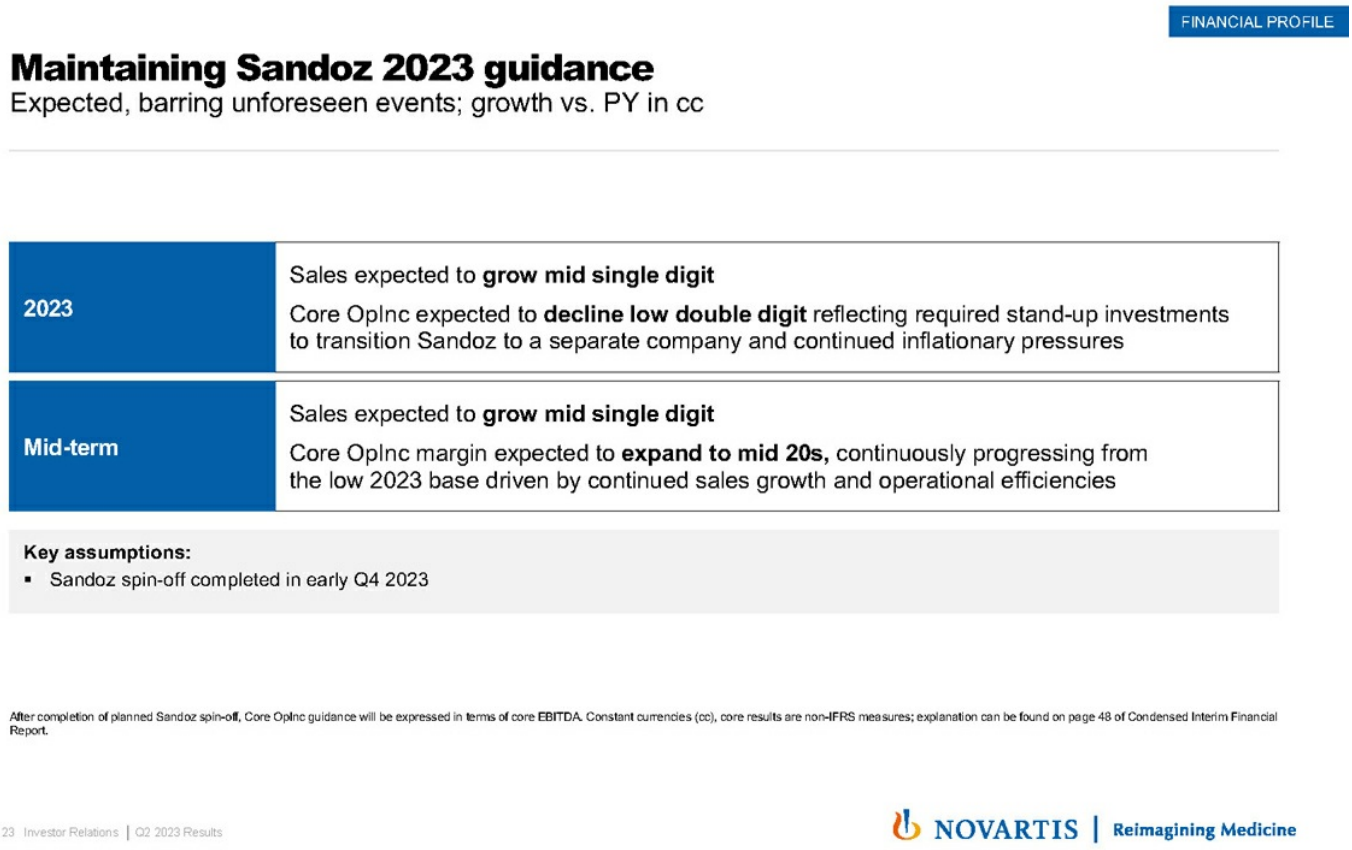
With respect to share buybacks, we have today announced the continuation of our previously completed share buyback program in June with a new up to USD 15 billion share buyback, which we expect to complete approximately by the end of 2025. Obviously, given our strong cash flows and expected top and bottom line continued growth, we continue to have the flexibility to do both share buybacks and bolt-on M&A and BD&L deals.

Slide 22



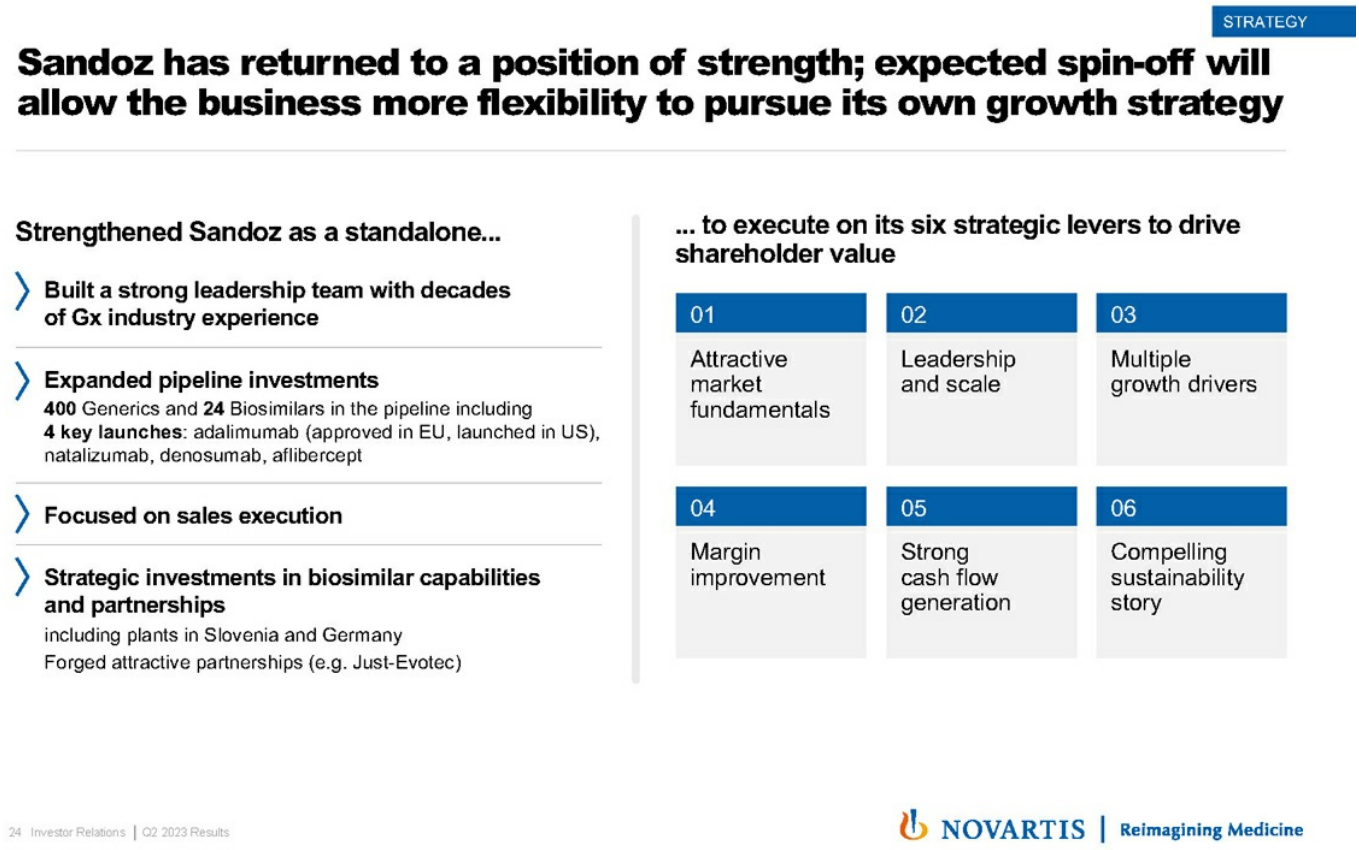
Now to Slide 22, please. The continued strong performance so far and confidence in our future growth allows us once again to raise both top and bottom line guidance for the full year of 2023. So for Innovative Medicines and Novartis, excluding Sandoz, we now expect sales to grow high single digit and core operating income to grow low double digit to mid-teens. For Novartis including Sandoz, which is a group guidance and assuming that Sandoz would remain within the group for the entire 2023, we now expect sales to grow high single digit and core operating income to grow low double digit.
Our key assumptions are that no US Entresto® generic launches happen at risk in 2023, and also that no Sandostatin® LAR generics enter in US in '23.

Slide 23



On the next slide, turning to Sandoz. Sandoz guidance is maintained for 2023. This guidance is obviously very conservative given the first half delivery, but it's also ahead of the spin-off and there are clearly upside potentials to that guidance.

Slide 24



On the next slide, please, on the assumption that Sandoz becomes an independent company, it will do so clearly from a position of strength.

First and foremost, we have built a strong leadership team around Richard with decades of generic industry experience. Second, the company has a strong pipeline with small molecule generics and biosimilars. Clearly, the sales execution has improved significantly, and Novartis has increased investments to ensure Sandoz has strong future biosimilar capabilities, including a state-of-the-art new biologics manufacturing site.

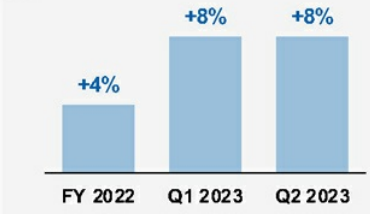
These strengths will allow Sandoz to execute on its six strategic levers that you see on the right side. I won't go into all the details here. But you have seen Richard and his team having outlined in detail for you all of these priorities during the most recent Capital Markets Days and IR roadshows.

Slide 25

STRATEGY

Sandoz delivered several consecutive quarters of growth, with a strong Q2 performance and ambitious mid-term outlook

Sales growth rates[1] in cc



Q2 performance[1]

Sales USD 2.4bn, **+8%**

Biosimilars **+13%**; Generics **+6%**

Strong ex-US sales growth driven by EU (USD 1.3bn, **+13%**)

Core OpInc **+6%**

FY 2023 guidance: Sales expected to grow mid single digit; Core OpInc to decline low double digit

Mid-term guidance for standalone Sandoz

Sales[1]
Mid-single digit CAGR

Core EBITDA margin
Approximately **24-26%**

Dividend Policy
30-40% of core net income
1st payment in 2024
for 2023 performance
(20-30% of FY core net income)

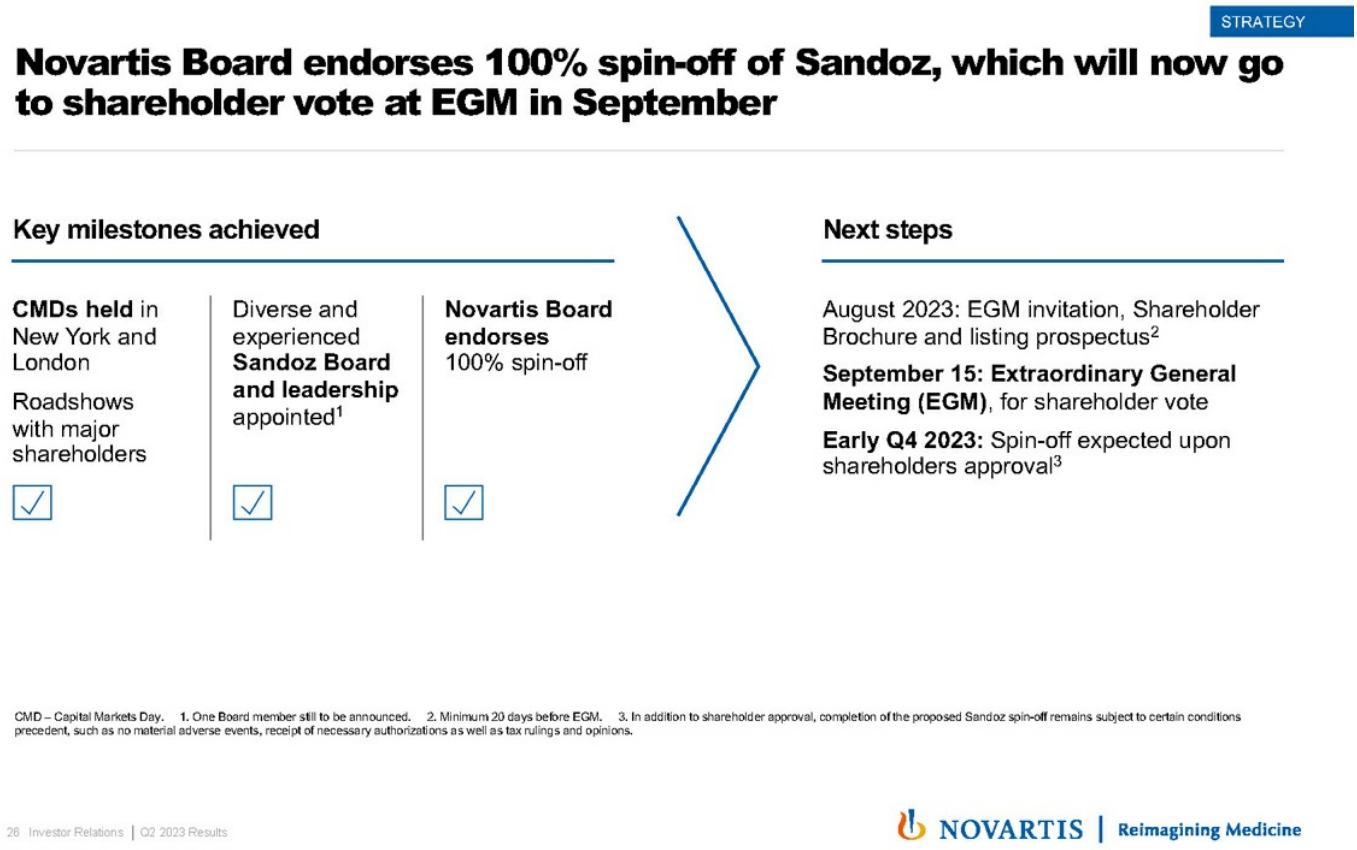
1. All growth rates in constant currencies (cc). Constant currencies (cc), core results are non-IFRS measures; explanation can be found on page 48 of Condensed Interim Financial Report.

NOVARTIS | Reimagining Medicine

On the next page, I just want to turn to the numbers for Sandoz on the next slide. And you can see that the business has performed well with respect to sales growth for the last few quarters. Looking specifically at quarter 2 performance, sales were strong, driven by Europe and biosimilars, and US has stabilized quarter-on-quarter. As expected, standup costs mean that the growth rate for core operating income are lower than for the top line.

Importantly, for the midterm, we expect solid mid-single-digit sales growth and core EBITDA margins to be in the mid-20s. And as a reminder, the first dividend will already be paid in 2024 for the full year 2023 performance.

Slide 26



Now turning to my final slide. The planned spinoff is well on track. Many of you have attended the Sandoz Capital Markets Days and shareholder roadshows. If you have not been able to participate, there will be further opportunities to do so after the Extraordinary General Meeting. The EGM will take place on September 15, and you will receive the necessary materials, which include a shareholder brochure and listing prospectus well in advance. If you and the majority of the shareholders approve the spin-off, we will also be doing post EGM roadshows in the second half of September, just in time before the expected spin-off in early Q4. And with that, I'll hand it back to Vas.

Slide 27 – Vasant Narasimhan – CEO of Novartis

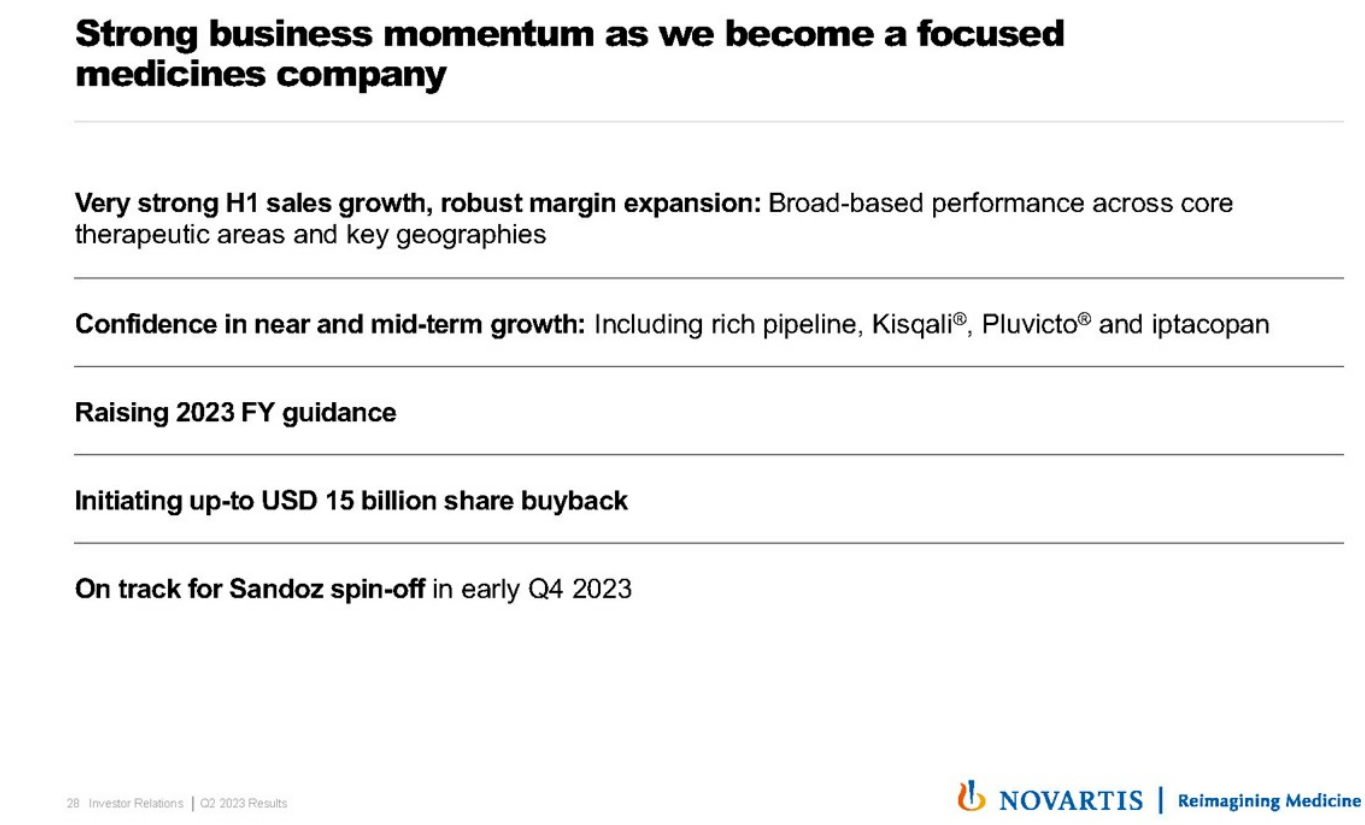
Vas Narasimhan, M.D.

Chief Executive Officer

NOVARTIS | Reimagining Medicine

Thank you, Harry.

Slide 28



So moving to Slide 28. So you can see in the quarter that we demonstrated strong business momentum as we are really now well on our way to becoming a truly focused Innovative Medicines company. Very strong half 1 sales growth, robust margin expansion and that broad-based performance was across TAs and geographies. We remain very confident in our near and midterm growth profile, including our pipeline, Kisqali®, Pluvicto®, iptacopan, as well as the continued performance of our other launch brands such as Kesimpta® and Leqvio®. We're raising our 2023 full year guidance. We are initiating, based on our confidence in our outlook and in our company, a USD 15 billion share buyback. We're on track for the Sandoz spin-off in early Q4 2023. So with that, we can open the line for questions. One question per analyst, please. Sharon?

Q&A

- Operator

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

- Richard Vosser - JPMorgan Chase & Co, Research Division

Q. A question on Entresto®, please. Could you talk about your discussions with the FDA around the citizens petition around the form of the product and whether any of the generics meet these requirements? And when we could expect an update around those discussions with the FDA?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Richard. So with citizens petitions, we of course filed them and then there isn't a formal process. So we're really now awaiting FDA's decision, and there is no time line necessarily for FDA's decisions around citizens petitions. There are two relevant citizens petitions. One is of the nature of any potential generic in our view is that the generic must be an exact match to Entresto®, which was an important consideration in the number of generics that might be able to be ultimately approved by the agency.

And the second is with respect to labeling and how the label needs to reflect our dosing titration as well as our overall indication statement for the medicine. So we'll await that. Typically, the agency will rule on citizens petitions prior to taking an action on any of the generics. And as we noted earlier that, as of right now, there are no approved or pending approvals of generics to our knowledge. Thank you, Richard.

- Operator

Your next question comes from the line of Jo Walton, Credit Suisse.

- Jo Walton - Crédit Suisse AG, Research Division

Q. Hello, can you hear me?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Go ahead, Jo.

- Jo Walton - Crédit Suisse AG, Research Division

Q. I wonder if you could just tell us a little bit more about Leqvio®. You were very confident that there would be an inflection in the second half of the year. You do have a broader label. Could you just tell us a little bit more about, say, formulary positioning, levels of reordering, how many doctors have really moved across from having tried it once to saying this is awesome and kept going, and a little bit more perhaps about the European rollout?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Jo. With Leqvio®, what we see right now is a continued expansion in the number of facilities that are ordering and the number of physicians that are ordering. On the positive side, what we see is once a physician gets beyond a certain number of patients on the medicine, roughly four or five, then they really expand their practice, and they're able – actually can drive quite a bit of depth. But then we have a group of physicians who are still at the one to two dose – one to two patient level.

And a big part of our efforts right now are to drive greater depth amongst those prescribers. Because we find once there's enough scale in a practice of understanding how to operate in Part B, that then, of course, physicians find a value proposition very compelling. In terms of coverage, we have very good coverage. We're well beyond what the PCSK9 monoclonals achieved. We're at over 75% coverage at label. And so we feel very good about the coverage. So this is really more about just going step-by-step, practice by practice and getting them comfortable with the buy-and-bill process with Part B and all of the details therein.

I think we'll continue on a steady trajectory through the second half of the year. Difficult to predict when exactly an inflection will occur, but we know well from our past cardiovascular launches, whether it was Diovan® or Lotrel® or Entresto®, that these things take time. But once we reach a certain level of scale, then the launch really takes off, and that's what we continue to expect for Leqvio®.

Overseas, we see good performance in the European markets where we primarily launched in the private market. So very good. And now in the UK, we are starting to see an uptick as the UK has rolled out some additional programs for physicians to create incentives to get their patients to goal for cholesterol. So I think that's really helping the rollout in the UK. And then looking forward, we continue to work towards approvals in China and Japan, which should further help Leqvio® growth trajectory in the medium to long term. Thanks for the question, Jo. Next question, operator.

- Operator

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

- Emmanuel Douglas Papadakis - Deutsche Bank AG, Research Division

Q. Maybe I can take one on Pluvicto®. So just a few thoughts ahead of the PSMAfore details, which you obviously headline PFS for quite some time ago in December, but you've yet to present. So ahead of seeing the details, any thoughts on whether that will directionally look similar to VISION, thoughts about how OS trends may also match and mirror that data set?

And then just a word, if we could on the supply situation, the cadence of sales for H2 and beyond. You reiterated the over USD 1 billion number, but how could PSMAfore reflect that addressable opportunity next year? And if it's not pushing my luck, we've got a competitor readout SPLASH also due by the end of the year. I'd just love to hear your latest thoughts in terms of differentiation, mechanistic or logistic.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emmanuel. So on Pluvicto®, we continue to see very strong demand for this medicine. And we're really now getting back out to actively promoting and generating demand as we've gotten our supply situation stabilized and beginning to expand. So on the VISION population, we continue to see very robust growth, and we would expect, as I outlined, over USD 1 billion of sales. Now how much larger that gets is really just a dependent on how fast we can bring facilities online and work through the logistics of getting these centers scaled and up and running.

Now in terms of PSMAfore, we outlined that we had a clinically meaningful, statistically significant readout in our PFS. We're now awaiting the maturation of OS. I think as everyone knows, the FDA is now requiring companies to have not just no detriment on OS on these readouts, but mature enough data set as well in terms of the information fraction available. That's why it's taken us a bit more time to get to that. But that will then enable us to provide the full data set later this year, both for rPFS and OS. And what I can say is we found the rPFS data to be clinically meaningful and we think important for clinical practice.

So what will that mean for demand, depending on how you – when you speak to physicians, at least the physicians I've spoken with personally as well as heard through others, a potential tripling. I mean, on the order of that level of the potential demand for the product in a given center. It's too early to say exactly the trajectory of that and it really depends on the timing of us getting the approval, which would enable them the reimbursement. But it would be a substantial, we believe, expansion of the potential for Pluvicto® in the marketplace, which puts, I think, really the importance of getting our Indianapolis site fully approved and up and running later this year. That would enable us between Millburn, our site in Italy Ivrea and Indianapolis to fully meet the demand.

In terms of the competitor, our understanding of that competitor readout is similar to PSMAfore. And I think really, this is a market that you need outstanding supply chain logistics, commercial scale, and the ability to consistently deliver for customers, not only in the US and around the world. And really, we believe our key differentiators will be experience with Pluvicto® as well as the supply chain that we've built that enables confidence in the supply. I would note as well, we're continuing to pursue Pluvicto® as well in other markets, so Japan, eventually, other markets in Asia as well as continued expansion in Europe.

So it's very exciting. It's an exciting medicine. I would take a moment as well to say we also invest on our broader pipeline within RLT, not only do we look at expansion of Pluvicto® into the pre-metastatic setting as well as biochemical recurrence, delayed castration, but as well, we have our Lutathera® programs looking at other types of cancers. We're advancing our FAP program, which we recently acquired, as I mentioned, from Clovis in a range of different tumors. And we have our (inaudible) program, which we're looking at a number of mid-stage studies as well. So a lot of things happening in the RLT space, and we continue to believe, given the infrastructure we're building and the potential to have compelling efficacy and a very good safety profile so far, with a limited number of administrations, is very compelling to both patients, providers and hospital systems.

- Operator

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

- Emily Field - Barclays Bank PLC, Research Division

Q. I just wanted to ask a question about MBL-949. I know it was updated this quarter that, that was discontinued for efficacy. But just how you're thinking about the commitment to sort of the broader cardiometabolic space inclusive of obesity? Given that you have a pretty substantial cardiovascular infrastructure from the commercial side, is that an area for potentially focused business development?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Emily. So the MBL ultimately did not have a compelling overall profile, so we're stopping that program. We do have earlier-stage efforts looking at novel mechanisms in the preclinical space in obesity and metabolism, but these are very early and I think still far away from ultimately reaching the commercial marketplace. Our focus is cardiorenal. I mean we continue to have, of course, on top of our efforts with Entresto® and Leqvio®, we have pelacarsen. We have our XXB program, which is a novel mechanism looking at hypertension and heart failure. A range of programs in the clinic now in antiarrhythmic agents, as well as we're advancing a broad portfolio of siRNAs to follow up on Leqvio® to address cardiovascular risk reduction. We hope with less frequent therapy and hitting multiple different drug targets at the same time.

On the renal side, as I mentioned, building on iptacopan, we have the proposed acquisition of Chinook as well as our continued efforts to treat a broad range of renal diseases, where we think there's a lot of unmet need and the opportunity to bring meaningful medicines forward. So that's where we will be focusing on in the years ahead.

- Operator

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

- Graham Glyn Charles Parry - BofA Securities, Research Division

Q. It's on Entresto® patent litigation again. So we understand the 938 Delaware MDL litigation that was subject to a trial in October last year is now being settled ahead of ruling. So if you could just confirm that's correct, which filers you settled with and whether the filers that were in the 659 ruling two weeks ago for MSN, Macleods and Hetero are part of that settlement?

And then how is the 938 and 134 crystalline patents being asserted against those filers that were successful in the 659 ruling that we saw a couple of weeks ago? So overall, I guess, the broader question is, is there still a scenario where generic Entresto® doesn't launch until November 2027 or later? Or do you now see that as off the cards and the latest that you could protect this being mid-2025?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Graham. So the overall Entresto® situation is complex in that each one of the generic filers had different scenarios in terms of the patents that they – we believe they've infringed and we've asserted against them. They have different approaches, which may or may not enable them to ultimately get approved depending on how FDA rules on citizens petitions. So I'm not going to get into all of the details. I can confirm that we did – as you did note, we did settle the 938 patent with Crystal and the relevant other generics. And so that matter is closed off from our perspective.

But in terms of the rest right now, our focus is on appealing the district court ruling, where we feel that we have strong grounds to ultimately prevail on appeal to continue to assert our remaining patents through the various litigations that we have ongoing, to await the citizens petition ruling. Our forecasting guidance remains unchanged at a mid-2025 forecasting guidance. We, of course, will do everything we can to extend our overall support longer – overall exclusivity longer for Entresto®.

And as I mentioned as well, there's no generics currently approved. And in terms of the history here, nobody has filed – launched at risk on a brand of this size in the last 15 years. So all of that gives us confidence on the outlook on the brand. Thanks, Graham.

- Operator

Your next question comes from the line of Michael Leuchten, UBS.

- Michael Leuchten - UBS Investment Bank, Research Division

Q. It's Mike from UBS. Obligatory question for Harry, please. The guidance implies a less of a margin gearing from the top line in the second half. What OpEx lines would be heavier as we're heading into the second half that wouldn't allow you to gear the top line as much as we saw in the first half?

- Harry Kirsch – CFO of Novartis

A. Yes, Michael, thank you for the question. So overall, maybe if we talk about Novartis ex Sandoz, right, there will be a little bit more inflation coming through on the COGS line as inventory, of course, gets used like through 6 months, if you will. Not dramatic, but a little bit there. The other one is we started to get our transformation for growth savings in quarter 4 last year.

So there's a bit harder comp. And of course, one is a bit conservative, maybe also so maybe there's a bit more upside coming. So overall, I do see that the sales continues to have this very good momentum. And then maybe a little bit less bottom line leverage, but still a very nice bottom line leverage, right? We have 340 basis points improvement. I think one cannot assume that it happens every quarter and every year. So those are the things.

And then of course, on the group guidance, that has to do with Sandoz in the second half, expecting also a little bit higher COGS line, lower gross margin due to inflation as well as some stand-up costs. That is then on the Sandoz P&L a bit more, obviously. Will it be as much as guided? Let's – we have to see that. Spin situation is a bit more volatile than normal ongoing business. But overall, I would say, especially for Novartis ex Sandoz, continued fantastic top and bottom line performance expected, with maybe a little bit less margin leverage than we have seen in the first two quarters.

- Vasant Narasimhan – CEO of Novartis

A. Thanks, Michael. Thanks, Harry.

- Operator

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

- Timothy Minton Anderson - Wolfe Research, LLC

Q. Could I just go back to Entresto®? So if generics do, in fact, launch early and at risk, how does Novartis adapt to that reality? I'm guessing you may not have significant additional cost to pull out of the organization for example, because you're still promoting other drugs in the category. So maybe you could talk about your cost levers in that worst-case scenario and then also what it would mean towards M&A strategy?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Tim. As we stated, we continue to not expect generics to launch at risk given the risk of trouble damages in such a brand of this size as well as the strength of we believe our case on appeal. That said, we feel confident that in the midterm, we'll continue to hit our 4% sales and 40% margin guidance for the company ex Sandoz, as Harry outlined. And that wouldn't require us to take any additional cost out because we had already assumed Entresto® would go in mid-2025 as our forecasting assumption.

So our 5-year CAGR outlook and 40% margin outlook already assumed that Entresto® will be moving out. So all of our current transformation programs, procurement programs, et cetera, as they continue to mature,

would enable us to still achieve those mid-term goals. Harry, anything you want to add?

- Harry Kirsch – CFO of Novartis

A. I think, Tim, you're right, the majority of the marketing and sales is, of course, also on the other growth drivers. And these other growth drivers have significant potential. We talked about a few of them. right? So I do not see that there would be a significant adjustment on the cost base because of a bit earlier Entresto® LOE. On the other hand, in this scenario, we are fully on defending our IP, and that's the focus here. And then, of course, driving the full portfolio, including Entresto® and the other great growth drivers as we go forward, and not have a distraction to the organization after having done quite a significant restructuring already. And by the way, we are ahead of our restructuring cost savings. So all of that is going also very well, which you also see reflected in the bottom line numbers.

- Vasant Narasimhan – CEO of Novartis

A. Thanks, Harry. Thanks, Tim.

- Operator

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

- Mark Douglas Purcell - Morgan Stanley, Research Division

Q. It's on Pluvicto®. I wanted if you can help us understand the importance of showing a strong trend on overall survival in the PSMAfore trial, given sort of recent rulings and precedents the FDA has taken a bit of a tougher stance when it comes to showing an OS benefit in prostate cancer specifically?
The reason for the question is we've been asked about the relevance of the PFS benefit in patients progressing on an androgen receptor pathway inhibitor being rerandomized on alternative ARPI, as opposed to being moved on to a taxane in the control arm. And therefore, you'd expect a high crossover rate from the control arm to Pluvicto® in this study. So recognizing, clearly, they've shown – already shown a strong PFS benefit with the trial powered for a 44% benefit, but how important is it to show the strong OS benefit to gain approval from the regulatory authorities?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Very good question, Mark. So right now, our trial is designed in such a way, and our agreements with FDA is that we would need to show no detriment to OS and a compelling rPFS benefit. As you likely rightly note, there will be significant crossover in the study because these patients have few alternatives at that point in time, and so crossing over to Pluvicto® after the results that we announced earlier, of course will happen. So our current expectation is to show no detriment to OS. On an upside case, we would show a positive OS already now. And then over time, of course, the OS will mature. But with FDA, we have an agreement and understanding that there will be crossover that we'll need to account for in the study analysis.

- Operator

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

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

Q. It's on Kesimpta®. So clearly, an impressive growth this quarter. But can you talk to your expectations for this product as we head into next year and beyond? In light of the new subcutaneous competition, it looks like need to be coming, I'm referring here to the recent positive data the Roche's sub formulation of Ocrevus®. So what is the risk here that you lose share to Ocrevus® as a less frequently dosed subcut well-established

option when asset reaches the market?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Kerry. I think first, we'll have to see the full data set. Because I think as you know, one of the challenges with IV administered of CD20s, whether given in a long infusion or a subcu pump short infusion is do you need to steroid pretreat and what is the level of reactogenicity and injection site reactions that you're going to see with the medicine. Overall, our expectation is that the players who are currently compete – are going to compete with one another for the market for other physicians who prefer to provide IV-administered medicines or subcu pump administered medicines in the Part B setting.

And that where Kesimpta® continues to do extremely well is amongst physicians who prefer to treat their patients with at-home administered monthly medicines, and Kesimpta® outstanding efficacy and safety profile. So we're prepared if, ultimately, there is a move by our competitors to try to move into the at-home subcu administration space. But we feel confident in the Kesimpta® profile. You have to remember this is a medicine that takes a minute to give yourself – a patient to give themselves a month, so 12 minutes a year. You don't have to have any preadministration, you don't have to deal with pumps and other technologies, which I think in this patient population is greatly, greatly valued. So we think the overall proposition is clear. We have to be aware of the competition, but we feel confident in the outlook for Kesimpta®.

- Operator

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

- Stephen Michael Scala - TD Cowen, Research Division

Q. Also on Entresto®, but regarding the new USD 15 billion share repurchase. Based on what Novartis is saying, it sounds as though Novartis has every intention of fully completing the new USD 15 billion share repurchase by year-end 2025. Even if, for instance, a generic Entresto® were to launch tomorrow, which I guess is within the realm of possibility. Is that correct? Or is the share repurchase telling us that Novartis believes the probability of a generic Entresto® launch between now and year-end 2025 is essentially 0?

- Vasant Narasimhan – CEO of Novartis

A. So Steve, on your first question, it is correct. Our USD 15 billion share buyback is independent of various business scenarios including Entresto®, but other business scenarios. It's based on a long-term view that we have adequate capital to pursue our internal investments as well as our external M&A and BD&L. We're confident in the outlook for the company. It's our growth outlook and, ultimately, where we believe our share price will appreciate, and believe it's prudent to buy back our shares over this period of time and returning capital to shareholders and also as we fundamentally believe we're undervalued versus our potential.

So those are the reasons for the share buyback. And we are also confident that, while we can't exclude, as I've mentioned many times on the call today, a generic will launch at risk, we believe we have a compelling case with respect to appealing the district court ruling, a compelling case across a range of other patents that go out to 2027 or in the case of our dosing titration patent to 2036, as well as the various citizens petitions we have with the FDA. So we maintain as well our guidance for our expectation from a forecasting standpoint that there wouldn't be Entresto® generics in the US before mid-2025.

- Operator

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

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

Q. So my question is a quick one. Just on the BTK, can you potentially update us on if FDA has made any request of your preliminary data or of your ongoing clinical trials just with regard to potential risk of liver injury? You know the agency is reviewing the overall class more broadly, and this has been a stated differentiating factor. Just didn't know how long the FDA is requiring or potentially requesting Novartis study the product to kind of disabuse that potential risk.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Seamus. So consistent with what I think they've asked other sponsors, we do have enhanced liver monitoring in our multiple sclerosis programs and I have to double-check, but I think also in our CSU programs. To date, we have not seen any liver signals nor have been placed on any kind of clinical hold. We continue to believe that this is not "class" specific to the BTK target, but specific to the design of individual molecules in the space. And if you look at – as we've noted, I think, in the past and you've seen, our chemical structure is quite different than the chemical structure of the other BTK inhibitors being pursued either in neuroscience or in other indications, which is why we think it has the unique profile that it does from a safety standpoint.

So we're looking forward to the initial efficacy readouts in CSU in the second half of this year, which hopefully will enable us to file in CSU and get a first label in immunology for remibrutinib, and then following that up with multiple sclerosis as well as other immunology indications over time.

- Operator

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

- Naresh Chouhan - Intrinsic Health Advisors

Q. Just one on Hyrimoz®, please. Just trying to get a feel for how we should think about the sales trajectory over the next kind of 18 months given the importance for Sandoz. Should we – given it's – we've the 6 months of this year, should we expect a fast launch this year? Or will you need to negotiate the formulary position for 2024 before we get a better feel for where this can go?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Naresh. The right now I think it's early days on the Hyrimoz® launch. There have been multiple competitors entering, Sandoz is also entering. I would expect a slow ramp for this medicine as we continue to get strong positions with payers as well as get the infrastructure up and running to launch. But over time, we do believe this will be a meaningful growth contributor to Sandoz US and, ultimately, global growth in overall biosimilars business outlook. Let me hand it over to Harry in case he has anything to add.

- Harry Kirsch – CFO of Novartis

A. Thank you. No, overall, too early, Naresh, to talk about now peak sales and other things, right? The launch is just starting. And as Vas said, we get on plan formulary positions. And Keren Haruvi and the US team are, of course, have prepared and now pulling through that launch. And over time, the Sandoz team is expecting that it becomes a good growth contributor.

- Vasant Narasimhan – CEO of Novartis

A. Very good. Thanks, Naresh.

- Operator

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

- Peter James Welford - Jefferies LLC, Research Division

Q. It's just in general on returning back to capital allocation. Just when we think about the USD 15 billion buyback. I mean last time you did a buyback of that magnitude was obviously following the Roche disposal. Now you're doing another one again based on the underlying cash flows. But I wonder if you could just talk about whether we should read into this anything about further needs or further desire to slim down the portfolio like you did with ophthalmology, and whether or not there's any divestments that's sort of related to that? And how far you are on sort of the process of that sort of prudent focus on the core therapeutic areas?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Peter. I'll cover the focus, and I'll let Harry take on capital allocation. So we've done a lot, as you know. I mean if you go back five, six years, between the exit of the consumer health business, Alcon, Roche stake, now the proposal on Sandoz, alongside that streaming down to – streamlining down to five therapeutic areas, exiting areas like liver as well as diabetes and now front of the eye, really, I think we're in the right place in terms of the therapeutic areas we're in.

There may be one-offs that we still need to do in terms of streamlining, but nothing major that we would foresee at this point in time. And really, our goal is, post the Sandoz spin, is to focus on driving the pipeline, driving the strong operational performance you're seeing and hopefully exceeding the 4% sales growth, and driving to that 40% company margin as a new Novartis ex Sandoz by 2027. From a capital allocation standpoint, Harry?

- Harry Kirsch – CFO of Novartis

A. Yes. Peter, overall, of course, we do our mid- and long-term liquidity planning, right? So you could say this is simply a continuation of a very responsible capital allocation application. On the other hand, you can be also, in a very pragmatic way, from the Roche stake, we have about USD 6 billion left. There will be a certain debt push-down to Sandoz, and that pays already for the majority of the USD 15 billion. On top of that, of course, we have and expect continued very good cash flows.

And of course, in that planning, we always have still flexibility for executing our bolt-on M&A and BD&L strategy over the years. So all of that is simply a normal continuation of our capital allocation strategy, built on a very strong balance sheet. As you may know, our net debt is just USD 15 billion. So it's below 1x EBITDA. It's a very strong balance sheet there. We have strong cash flows. And from that standpoint, I think it's just a logic way to continue share buyback at the same time, of course, a growing dividend in Swiss franc per share for the Novartis ex Sandoz. Not rebasing after Sandoz spin, and then Sandoz will pay another dividend on top of that.

So I would say it's a logic extension of our capital allocation that provides us a lot of still flexibility on M&A and BD&L. But we focus on bolt-on as always.

- Vasant Narasimhan – CEO of Novartis

A. Thanks, Harry. Thanks, Peter.

- Operator

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

- Andrew Simon Baum - Citigroup Inc., Research Division

Q. Question for Vas on how you protect Leqvio® from IRA-related price negotiation in the Medicare patients. Now I'm assuming, given the duration of exposure around, the magnitude of MACE reduction is going to massively exceed that for Repatha® and Praluent®, and you're probably going to get a significant fatal MI benefit as well. If those assumptions are correct, how protective you think it will be when the clock strikes after nine years and you have price negotiation?

I'm asking partly because you just opened the VICTORION-1P trial, which is another large and expensive trial. So that's the first part. And the second part is just for VICTORION-1P, what percentage of that trial population in the real world, do you think, is outside the Medicare patient population, and therefore immune from the impact of price negotiation?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Andrew. All very good questions. So our overall strategy with Leqvio® and I say this with two important caveats. We don't know yet exactly how, as you know, CMS is going to be looking at data sets and how they're going to ultimately transact the price negotiations. We'll understand more, I think, over the coming years. And then second, we continue to advocate for moving the 9 to 13 as an industry and as a company. And also more specifically until that big move happens, also advocating that siRNAs and related therapeutics were never intended to be part of the 9-year portion of this ruling. And there is bipartisan legislation that's been tabled at least in the Senate trying to correct that – those issues.

So two elements of our story. One, as you rightly point out, is data. We believe that V2P, given the longer follow-up that we'll have versus the PCSK9 monoclonal antibodies, so we can hopefully show a very compelling cardiovascular risk reduction. Theoretically, that risk reduction could be in the 25% to 30% when you look at the model outcomes, which we think would be very compelling and hopefully deserving of a price premium if and when the negotiations then happen.

V1P would give us another data leg. Now it's important to note, we don't need V1P anymore from labeling standpoint because we've already received the label from FDA without any limitations on – in the label referring to the lack of outcomes data. So we actually have a very optimized label. Nonetheless, we think generating that data will be compelling. I don't have the exact figures, but I would say a vast majority of those patients would be – primary prevention patients would be below 65 years of age. And so that also is another leg.

Second, we are advancing combination programs of combination siRNAs. So 2 pro 1 is a common – working towards combinations with HMG-CoA reductase but also looking at are there ways to extend as well the intervals at which Leqvio® would ultimately have to be given. So all strategies, we're looking at as well to protect Leqvio® in the long run in this situation. So I think a lot will be seen in the coming years, but clearly something that's high in our minds to make sure we can protect this medicine. As a reminder, its patents go up to – between 2036 and 2038, so we would have a long runway if we can navigate IRA.

- Operator

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

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

Q. Coincidentally, it's also on – again to Jo's question and also touching on Andrew's. Given the strong progress you're making on the number of facilities, the number on board for buy-and-bill, I just wonder if you could give us a bit more detail on (inaudible) facilities and with prescribers. What's driving in that physician inertia from getting people from putting a few people on to four, five plus? Is it related to the profile of the

product? Are people waiting for more data? Is it buy-and-bill? Is it Part B? If you could just give us a little bit more color on what's stopping that move. Was it simply there is a lag time between people coming on board and becoming multiple prescribers?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks, Simon. I think the biggest topic is just helping physician offices, inclusive of the physician understand how to navigate the Part B buy-and-bill system. I mean we still have a surprising number of physicians who ultimately file for reimbursement for Leqvio® on the first two doses under the pharmacy benefit. And under the pharmacy benefit, they will either get rejected or go through a lot of hassle, and then that ultimately frustrates them.

So we're really focused now on educating physicians as best we can and physician offices that you need to set up a separate pathway, buy-and-bill is a different approach. And once they actually get that experience of both having the patient get on the medicine, ultimately, there is no co-pay for many of these patients depending on the insurance that they're in. There's net cost recovery for the physician. So many benefits. And then when they get through that journey, then they expand very quickly from two patients to eight patients to ten patients to twelve patients.

We're losing physicians because of that initial step of misunderstanding pharmacy versus medical, how to actually procure under buy-and-bill. I would say, frankly, we underestimated that challenge, but that doesn't change our conviction when we see how – when physician offices do convert, how large and big they grow. It gives us the conviction that if we can get through that hurdle of getting enough offices to fully understand that there is a big runway for this project – product coming out of that. And so that's the work we still need to work through over the coming months.

- Operator

Your next question comes from the line of Eric Le Berrigaud from Stifel.

- Eric Le Berrigaud - Stifel, Nicolaus & Company, Incorporated, Research Division

Q. Actually, the question is how to reconcile the second in a row raise in the full year guidance, the midterm guidance, because after the second raise in 2023, you will end up '23 by growing probably 8% to 9%, i.e., double the expected range of growth for the four to five coming years. So how should we think about this? There are basically two scenarios. One, growth is very much front-end loaded and the end part of the period will show slow growth or you're just very conservative. You're surprised yourself by the strength in the business this year, and you might be surprised also by the strength in the business for the next four to five years.

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks for the question. I think it's a very valid point. I mean overall, right now, we want to see, obviously, the continued trajectory on these brands. Clearly, if Pluvicto®, Kisqali® in early breast cancer; iptacopan, Leqvio® inflection; Scemblix® and particularly if Scemblix® first-line comes, certainly, we have the opportunity to outperform that 4% sales growth given the outlook that we have. I mean, right now, we maintain that outlook based on what we see today. But I think certainly, our aspiration is to do better. And I think it really comes down to the outlook on those handful of brands. And if they continue to perform the way they have, there's certainly an opportunity for us to do better than what we've expected last year. Harry, anything to add on your side?

- Harry Kirsch – CFO of Novartis

A. I think, of course, the 5-year CAGR, right, is harder to lift than a 1-year. But – obviously. On the other hand, of course, from our financial planning standpoint, the Entresto® contributions to the current growth would not be very much at the end of the five years because of our mid-'25 forecast assumption, right, the outlook was to '27. So it's a technical detail that the Entresto® contribution at the end of it would be lower. And that's why we also outlined at the time when we gave the 4% CAGR, if we are able to hold on to Entresto® in the US longer, that this 4% CAGR would get to a 5% CAGR. So we are in that range at the moment. And as Vas says, if Pluvicto®, Kisqali®, Kesimpta®, Scemblix® continue to outperform like this, we certainly see the potential for overperformance.

- Operator

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

- Rajesh Kumar - HSBC, Research Division

Q. If I may, looking – just looking at the acquisitions you've done, you've announced today or you announced in the quarter. Could you run us through how you're thinking on what type of or what stage of assets you would acquire have changed, as we have an uncertainty around IRA and also a lot of your peers are also looking to acquire? So that part of capital allocation, if you could provide us with a bit more color, that would really help.

- Vasant Narasimhan – CEO of Novartis

A. Yes, absolutely. I mean generally, you see us moving to mid-stage and earlier. And as we've always guided, the bolt-on range or smaller deals with Chinook, as you saw, it was in that USD 3 billion range, so I think very much in line with what we've guided. We are carefully looking at assets in terms of potential IRA impact and ensuring that we think we have opportunities to either manage the IRA impact or avoid the IRA impact, certainly with conditions like Charcot-Marie-Tooth, cystinosis.

These are areas where you wouldn't be impacted by IRA as best as we currently see those patient populations.
Certainly, on Chinook in terms of those renal assets, again, we believe that given the patient profile, overall largely manageable with respect to IRA. So that's certainly on our minds. But I think the biggest thing for us is we want assets that are in our core therapeutic areas or in our core platform technologies that have an adequate risk reward, where they're derisked from the basic science, but still there's an upside that we believe we can deliver based on our capabilities. And we don't want to overpay for very large deals where assets are fully valued and it's difficult for us to find upsides Novartis is contributing, and therefore, difficult to create value for our shareholders.

- Operator

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

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

Q. Just one last. Just been a lot of discussion obviously about the Entresto® LOE, but there's also possible a couple of smaller products that could face generics over the next few years, I'm thinking Promacta® and Tasigna®. So just wondered if you could update for us your latest thinking on expected first generic launches to those two drugs in various territories.

- Vasant Narasimhan – CEO of Novartis

A. Yes. I mean both with Promacta® and Tasigna®, there's no change to the previous expectations. We

obviously are continuing to prosecute with respect to Promacta®, our various patents, and seeing if there's a way we can have longer exclusivity on Promacta®. But other than that in each of the geographies, there's no change from our prior guidance on Promacta® or Tasigna®. Next question, operator, and this will be our last question.

- Operator

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

- Graham Glyn Charles Parry - BofA Securities, Research Division

Q. Great. We just get a follow-up in. So it's on data timing. So PSMAfore, do you think you can make ESMO with that data, let's say, 4Q, that's just into 4Q or are you thinking something later? And then on NATALEE, you talked about some additional updates later in the year. Presumably, San Antonio Breast Cancer Symposium would be a good forum for that. And given that the hazard ratio on overall survival was there approaching borderline statistical significance, and when you look at the event rate in that trial now, is there an opportunity to see a statistically significant OS benefit this year if we sort of – if you continue to predict event rates in line with what you've seen to date in the trial?

- Vasant Narasimhan – CEO of Novartis

A. Yes. Thanks Graham. I think on both of those conferences, those would be our aspirations. Of course, we have to get the data and ultimately get accepted to the various congresses, but that's certainly in line with our current aspirations. With respect to the OS benefit, it is certainly possible given that we were at 0.76. I think it really will, of course, depend on the event rate and ultimately, what we see. But I think there's at least the possibility that we get to a statistically significant OS benefit. And then when we look at the competitor OS benefit, we hope that we can demonstrate something that's compelling on that front to build on our broad benefit that we already saw in the iDFS in Stage II and Stage III patients.

So thank you all very much for joining the call. I really appreciate it. We continue to plan on delivering strong performance for the second half of the year, executing on the Sandoz spin, getting the share buyback moving and updating you with, hopefully, exciting clinical trial data over the course of the second half.
I really appreciate your interest in the company, and we'll keep you updated as we continue to progress on our journey. Thank you again.
