Novartis AG

Analyst/Investor Day - Novartis AG

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Event Participants

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Graham Parry, Holger Blum, Anja Pomrehn, Victoria Lambert, Matthew Weston, Marietta Miemietz, Harry Thomas Sephton, James Vane-Tempest, Frances Cloud, Florent Cespedes, William Hamlyn, Max Herrmann, Richard Parkes, Simon Baker, Unknown Analyst

Samir Shah Executive

Great. Can everybody hear? So good morning, everybody. Thank you so much for making your way here to the London Stock Exchange for our Capital Markets Day for Sandoz, and thank you to the people who are listening on the web, too. I apologize for some of the conditions here.

It's rather warm in here so do feel free to take off your jackets and things if you need to, and we're trying to fix the air conditioning here.

So a great pleasure to have the whole Sandoz team here with us, and we'll be getting on with the program very shortly. Just a word or two. This slide, which is Slide 4, for the people on the web, goes through the agenda itself. And we've actually divided the day up into 4 sessions. The first session after I finish will be with Gilbert Ghostine, the Chairman-Designate; and Richard, the Chief Executive Officer for Sandoz.

We're going to actually be talking then about business strategy, the investment proposal, et cetera. Following that, in the second session, we'll be talking about the commercial aspects of Sandoz, and we'll have the 3 business leaders going through that. In the afternoon, after a short lunch break, we'll be talking about operations, in particular with Pierre Bourdage, Claire talking about development and regulatory and Glenn talking about all the operational improvements, which we'll be making within Sandoz. And then we'll go on to the final section with the financials and then a wrap-up from Richard.

As you see from the agenda, we've allowed plenty of time for questions and answers after each of those sessions, and then we have some breaks in between after that. Now the

objective of the day is to introduce you all, if you don't know the Sandoz management, to the Sandoz management. We want to introduce Sandoz as a stand-alone company, its strategy, what its growth drivers will be. Obviously, a part of the day, we hope will be to explain to you and that you actually get across the benefits of Sandoz as a stand-alone company and to discuss the financial framework and guidance for the Sandoz over the short and mid-term. And of course, most importantly, it's an interaction with us to address your questions that you may have on Sandoz.

Before we start, I just wanted to read you the safe harbor statement, and that is the information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These results 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, its most recent quarterly results on Form 6-K that respectively were filed with and furnished to the U.S. Securities and Exchange Commission. Just before we start, an introduction to the Sandoz management and Richard will go through in a little bit more detail.

We've mentioned Gilbert, the Chairman-Designate; Richard, Chief Executive Officer; Colin Bond is the Chief Financial Officer; then you have Rebecca, Keren and Francois, as a commercial lead for their regions; Pierre Bourdage, the Chief Commercial Officer; Claire, who is the Chief Scientific Officer; and Glenn, Chief Manufacturing and Supply Officer. One word for housekeeping. When you do ask a question, you will have a mic, which will be floating around. Please do state your name and your institution before you actually ask the question.

And with that, I'd like to hand the call to Gilbert, our Chairman-Designate. Thank you, Gilbert.

Gilbert Ghostine Executive

Thank you very much, Samir. Good morning, everyone. As you could see, I took the tip of Samir and I removed my jacket because here, it's even warmer than you in the back. We're very excited to host you here today. This is our second CMD.

We had the first one in New York last Thursday, and we're extremely pleased to have this high level of engagement with you today. As Samir mentioned, my name is Gilbert Ghostine, and I'm privileged to have been offered the opportunity to be the Chairman-Designate of this outstanding company, especially in its transformation journey into a stand-alone company, obviously, further to Novartis Board approval and shareholder approval.

Today is an extremely exciting day for us. Why? Because we were bringing you into -- under the tent, sharing with you more insights about why Sandoz is an outstanding company, what have we built in terms of muscles to allow us to be there and at the same time, I think the most important thing, you will get exposure to an outstanding leadership team that Richard leads. And this will give you a very high level of confidence into our ability to deliver against our ambitions. As a company, Sandoz, we are very proud about our past, but we're even more excited about our future.

And you will hear from the speakers later today, why is that? I had the opportunity to join Sandoz earlier in February this year, and I was extremely impressed with the entrepreneurial

spirit in this company and how everyone is proud and excited to be able to take control of our own destiny and at the same time, to build our legacy for the future. What became also very evident, and you will hear it from Richard and from our other colleagues on the exec, everyone at Sandoz is very proud to be in generics. This is an industry that we understand inside out. We have a huge legacy in this industry.

And at the same time, we are very confident on what we are going to create into the future. What got me excited to joining Sandoz is primary the mission. This mission into shaping health care, bringing affordable medicine to underserved population, and all of this coupled with our significant value creation opportunity. And today, I would like to focus on what makes Sandoz a unique company and the value-creating opportunity that we could deliver for our shareholders and also stakeholders. Now let me turn to the brand.

The brand Sandoz is really unique, unique in -- it's with heritage, extremely credible in Switzerland, its home market, and also internationally. And this credibility that the brand had locally and internationally is driven by trust. And trust is earned every single day with the work, with the trade, with the retailers, with the science organization in order to build credibility. And this is the level of credibility that Sandoz has built with the trade in the pharma industry and most importantly in giving access to off-patent medicine to patients and consumers. And the brand has an amazing integrity.

Most importantly, you know what build us this level of credibility is our strength in science, our constant innovation and our ability to build a very strong pipeline to keep transforming our industry and having a positive impact into the future. Now looking at our history, and the Sandoz legacy started back in the late 19th century by its creation in Basel. And since then, it has been hitting significant milestones. We are proud that we were the first company to launch oral penicillin back in 1951. And at the same time, we're extremely proud because we were the first company to launch the first biosimilar in 2006.

And back in 2005, we've cemented our leadership in generics with the acquisition of Hexal in Germany. But it's not only our past because we have leveraged our heritage. But most importantly, what we are doing here, we keep building on strength. And what we have done as a company over the last decade, we have been creating and establishing significant building blocks into strengthening our position into the future in terms of M&A, strategic transformation opportunities, partnerships and also, most importantly, the investment into our pipeline, which gives us a very high level of confidence into the future. And you will hear from Richard and you'll hear from our colleagues later during the day, when you have a pipeline of 400 genetics and 24 biosimilars, it gives you an idea of why we are confident about our ability to create value into the future.

And also our leadership in biosimilars is very evident. We have established our leadership and credibility in this space. We lead in 6 out of the 10 biosimilar markets in the world, and we have the credentials. Having launched so successfully biosimilars in the past, it gives us even a higher level of confidence into our ability to win bigger into the future. Basel will keep being our global headquarters and our home, and we have confirmed this a few weeks ago.

And at the same time, we are a major player in antibiotics in the world. This is also an area of strength for us, and we are the most vertically integrated player and the only player in the

West that has manufacturing facilities for antibiotics in Europe and into the Western world. Now let me move to the rationale of the split. With our leadership position at Sandoz in generics and biosimilar, we are in a very different point along the bio -- the big pharma value chain compared with the innovative medicine of Novartis. There are very limited synergies between these 2 businesses, and that's where we are very excited about the future.

Thinking about the future, the way Richard, the Executive Committee, me and the Board are looking into the future Sandoz, we're looking into a fit-for-purpose organization where we will be more focused behind our business and bring these specific skill set that is required for our industry. This would require greater agility and nimbleness and flexibility, and this is the business model that we will have. You saw from the financials and the press release that we have issued last week, that also we have a big ambition around value creation in terms of profitability and most importantly, in terms of cash generation. So that's mainly the journey that we are on, and this is why we are excited about what we have today. And we are confident that we will become the world leading and most valued generics and biosimilars company in the world, and this in terms of long-term value creation but most importantly in terms of impact on society.

Now my first task as a Chairman was putting together a Board. And you could see that we managed to put together a very strong Board, and a truly world-class Board in line with the Sandoz ambitions. As you could see from the screen, the Board of Directors that we managed to attract had their careers into the largest health care companies in the world and at the same time, the largest FMCG companies in the world. And when I look at the Board that we have put together, 60% of the members of our Board would have been or are today, CEOs or CFOs, 50% of them would have worked in the health care industry, 50% of them would have worked in the FMCG industry, 40% are female, 100% are independent, and there is no overboarding whatsoever. We have started as a Board, our work, to be ready for the spin.

Obviously, subject to Novartis Board and shareholders' approval, but we will be ready in due time to make sure that we deliver against our shareholders' expectations. Now moving to my last slide, and before I hand it over to Richard, I want to express my appreciation for our fruitful collaboration. Richard and I had the opportunity to get to meet each other back in December. And since then, we've been joined to the hip. I feel proud that as a Chair, we have a CEO for Sandoz that is one of the best CEOs in our industry, seasoned, understands the industry inside out, proven CEO, have been working in the genetics industry for the last 20 years and at the same time, it didn't waste time.

Since he has been appointed in 2019, he has put around him a world-class executive team with over 200 years of pharma and generics experience. And you will have the opportunity to get exposed to them during the day, and then you will understand why we feel this level of confidence about our ability to deliver against our 2028 ambitions, and not only the 2028 ambition around our ability to deliver every year along the line of our 2028 ambitions. Thank you very much for listening to me, and I will hand it over to Richard. Richard, over to you.

Richard Saynor Executive

Good morning, everybody. It's a pleasure to be here. Before I sort of take you through the slide deck, I just want to reflect, I mean, clearly, this is an incredibly exciting moment for me

personally, taking what I think is a truly remarkable company to the capital markets and into an independent life outside Novartis. But also that reflect about Sandoz. Sandoz is also a unique company in its own right.

It's pretty much the only global generics company that wants to be a generics company. And we're a leader in that field, both in generics more molecules and also biosimilars. What I'd like to reflect this morning is a few things, clearly who we are and the journey that we've been on to get to this point, delivering sustainable growth. And then why Sandoz is such an exciting and interesting investment proposition going forward. We have very 1 clear, simple purpose.

We ultimately pioneer access for patients. Our job is ultimately to democratize biologics, bring medicines to patients all around the world. And our vision along that way is to become the most valued and valuable generics and biosimilar company in the world. Today, we serve over 500 million patients, and we have a social impact of nearly $200 billion in terms of cost saving and impact to government and health care systems, something that we are incredibly proud of and really propels and sustains us going forward. I've got a few numbers on this slide, but we operate in a market today that's worth about $200 billion.

Sandoz had about $9.1 billion of sales in 2022. We're a clear European champion, and you'll hear from Rebecca a little later on. We have an incredibly strong and device pipeline, over 400 small molecules in our development plans and 24 biologics in partnership and in development. That's one of the deepest and broadest pipelines in this industry. We serve over 100 markets, and you'll hear from Paco a little later on a lot of those markets where we launch biosimilars in markets where the originator couldn't even be bothered to launch.

And as Gilbert said, we're led by an incredibly strong management team with decades of experience in this industry and leaders in their own right. So 2022 sales, $9.1 billion, roughly split 20% in biosimilars and 80% in generics. The generics business grew at about 3%. But clearly, the biosimilars business grew at 9%. And that's continued to accelerate.

If you look 5 years back, that was approximately about 15% of our sales. So clearly, the strongest growing element supported by one of the broadest pipelines. So we have currently 8 biosimilars launched and in market in Europe and around the world, and we're seeing a strong increasing contribution of our biosimilars going forward. And clearly, we'll explain that a little bit more later on. And when you double-click and look at the split of those businesses, today, roughly half our business comes from Europe, growing at about 6%.

International, 27% of our business, consistently growing at 7%. And then North America stabilizing. And again, you'll hear from Keren later today about her journey about, again, $2.1 billion of sales split between Canada and North America. Clearly, strong leadership in Europe, capturing high-volume, high-value returns across international and then a strong stabilizing North American business. I'd like now reflect on the journey that we've had over the last few years.

Clearly, we focused on building an incredibly strong leadership team. We've aligned the vision of the organization around our purpose, our access for medicine, ruthlessly focused on sales execution whilst expanding our pipeline. We've invested in our internal capabilities and forged highly attractive partnerships with external players. So as said, a very strong and broad

leadership team with over 200 years of generics and pharmaceutical experience, not all of it on me. But clearly, very, very capable and leaders are in their own field, and it's a real pleasure to be part of this team.

Ultimately, we are proud to be a generics company and don't understate that. That's driven a lot of the energy and the focus of the organization. It allows us to attract talent and retain talent and at every level of the organization, from Gilbert down to every part. And we've really shifted and focused our culture around that, a generics mindset, being entrepreneurial, being quick moving, agility, accountability all to the single vision to become the world's leading and most valuable generics and biosimilars company. So over the last few years, what have we done?

Well, clearly, we've prioritized winning share. And clearly, again, when you hear from Rebecca, Paco and Keren, we'll see how we're winning against the competition and taking share. We've invested in our capabilities over the last few years to restabilize and reenergize the pipeline, particularly in the U.S. We've executed accretive M&A and BD&L. We've done more M&A and BD in the last 4 years than we did in the previous 10.

And we've discontinued and stopped non-core activities to our business. And the results have followed, so we had 6 straight quarters of growth. We've advanced our leadership position in Europe outperforming the market on every metric. And we've accelerated our growth in international and stabilized our business in North America. There's a lot of numbers on this slide, but I'll take you through this.

Over the next 5 years, we expect to double the launch contribution for the assets that we launched compared to the previous 5 years. We have over 400 small molecules in our pipeline. We have 3x the number of biologics in our pipeline that we've expanded over the last 4 years with now 24 assets in partnership and development. And we assume at least 50% of the value of the launches coming from the next 5 years will come from biosimilars. And the molecular value coming off patent in that time is about $340 billion.

So a significant opportunity, an incredibly strong pipeline and an expansion heavily towards biologics. And in the short to mid-term, 4 major launches. So ADA, natalizumab, denosumab and aflibercept all planning to launch in the U.S. and in Europe or locally ADA we've already launched in Europe. So excited about the short to midterm prospects and driving our mid- to long-term prospects by expanding and driving our pipeline.

We're also investing heavily in our strategic capabilities. We recently announced a $400 million investment in Slovenia. This is on a plant that is already part of Sandoz, but we'll expand and build a state-of-the-art biologics manufacturing facility, which should be on stream by mid- to end '26. And we're expanding our biologics development capabilities in Munich where we currently have a lot of our developments at the plants already. We're also leveraging our partnerships.

Obviously, we recently announced a partnership with Just - Evotec Biologics. This gives us a world-class technology platform to develop, manufacture and bring assets to the marketplace. We partner with Polpharma Biologics, and clearly, we'll continue to have a partnership relationship with Novartis. And again, Claire and Pierre will take you through that.

This means also we have -- actually, we are the partner of choice when you think about it from an industry point of view.

We have the technical capabilities, the medical, regulatory and scientific capabilities, the manufacturing know-how and the commercial footprint globally to extract the maximum amount of value. So we are the partner of choice to many of the development and partnership companies in this space. So we'll continue to expand by leveraging our scale and technical capabilities and commercial power. And then think about going looking forward, clearly, the generics market is highly attractive in terms of its fundamentals. I want to spend a little time looking at that.

Clearly, we have leadership in scale in key geographies, particularly Europe. We have numerous growth drivers with the portfolio that we have balance between small molecules and large. We have clear plans to grow both the top line but also expand our margin along the way, driving strong free cash, all of this supported by a very strong compelling sustainability story. So if you look forward over the next 9 years, the generic and biosimilar market, we expect to more than double. So from about $200 million today to over $400 million.

Also worth noting, given demographic trends, challenged health care systems, growing numbers of loss of exclusivity, we see a strong trend towards biosimilars. So clearly, the biosimilar sector will grow more quickly than the small molecule sector, but is equally balanced between the two. So we think we're in a very unique position, having a strong biologic pipeline that extract some value here but also underpinned by a strong small molecule pipeline as well. Out of all of the slides, this to me describe Sandoz. So I think, just forgive me, let me explain it.

The top right-hand corner are mainly the biologic peers. So either originators deciding to get in the space to offer portfolios against their own assets, particularly in the U.S., all the Korean players trying to develop biosimilar capabilities. But what they tend not to have is anything in the small molecule space. And then on the left-hand side are the traditional generics companies, heavily indexed on small molecules, lower cost of development, but highly fragmented. So if you look at the top right, roughly 5 players account for 80% of the market.

The biologics business is already heavily consolidated, and we're currently ranked #2. On the left-hand side, highly fragmented. Development costs, to develop a biologic is 5 to 10 years, $100 million to $200 million. To develop a small molecule, 2 to 5 years and $2.5 million to $5 million. Sandoz has this unique position that we have the strength and capability in both.

That gives us leverage in the market. It means that we drive free cash that allows us to invest over the medium and long term and balance those 2 things. And it gives us a real edge in terms of our ability to compete, our ability to develop and our ability to launch and extract value. And then when you look at our scale, this is the IQVIA data. Clearly, we are the leading player in Europe, significantly larger than any of our competitors and a very stable dynamic region, consistently growing and profitable.

We have a strong North American business. And again, Keren will take you through that. and then a dynamic international business, competing in key markets and are really focused. And again, Paco will take you through the journey there. I'm also particularly proud of this slide.

Sandoz was the first company to launch a biosimilar. We launched it in Japan, in Europe and in North America. Biosimilar was human growth format. Today, 15 years later, we are the #1 provider of human growth globally, consistent growth, attractive margin expansive and continuing to grow. So I'm incredibly proud of the journey that we've been on.

And then when you look at our rankings for all of the major biologics market, we're generally ranked certainly in the leadership position the majority of those markets. So very strong. And in Europe, we're consistently by far the largest biologics player. So very excited. Clearly, 4 launches coming up in the U.S., 3 into Europe and we see a strong opportunity to continue to grow and expand in the international markets, bringing biosimilars frequently where the originators have not launched.

And we think about the drivers of growth over the next few years. Our guidance is to deliver mid-single-digit growth between now and 2028. That's excluding any incremental M&A. We do a low level of M&A about $100 million a year, but that tends to be more BD&L. And historically, that's always been the run rate that we've operated at.

So clearly, we will drive growth over a number of levers. Clearly, the sales execution journey focused on where we've been going over the last few years, maximizing the significant opportunity that we see from biosimilars, driving a much stronger product mix and leveraging our strategic partners. So we become the partner of choice for many other developers and other companies, ultimately expanding the depth and breadth of our pipeline, driving and supporting our growth over the mid-term. And then from a margin point of view, clearly, we'll set up the company this year with about, I guess, an 18% to 19% margin. A lot of that dilution, due to the onetime setup costs of the company.

Clearly, Sandoz has never been an independent business. So there are things that we needed to build into the organization, and that's really incorporated there, and Colin will take you through in more detail in terms of this. Glenn will also spend more time in detail in terms of how we will execute some of these things, but it gives you a frame. So our guidance again here is to deliver margin expansion from 18%, 19% in 2023 to 24% to 26% by 2028, really driven across a number of drivers, volume and mix as we launch more biosimilars and they have a stronger impact on our business. By simplifying our network design, clearly, as we step out of a large big pharma company become a lean generics company, we see significant opportunities around a number of levers, network design, focusing our integration in terms of our supply chain, continued operational excellence and building a strong agile procurement organization.

That will deliver about 350 basis points and then 150 from organizational efficiencies. So a good example, we have actually like 1,500 shared software platforms between Novartis and Sandoz. We don't need 1,500 shared software plant folks to run a generics company. So it's a major opportunity to simplify, rewire the company and turn it into a much more lean and focused generics company. Driving that, we'll more than double our free cash, delivering a sustainable EBITDA cash conversion, increasing our EBITDA to cash and then think about our working cash.

So we'll have very clear capital allocation priorities, investing in our organic business, returning capital to our shareholders. And I'll talk about that in a moment, and Colin will

expand further. And then only after those things, thinking about deploying value-generating BD and M&A to support our strategy and grow our business. We intend -- and this is very important for us. We intend to have a very prudent capital structure spinoff.

Our goal will be to have an investment-grade credit rating, which is, again, pretty unique in this industry with a net to core EBITDA ratio of around 2 to 2.5 in terms of our debt. Again, Colin will take you through that, but it's important that we want to maintain optionality with a very strong balance sheet going forward. This is really a summary of the top level guidance. Top line sales growing -- maintaining our momentum mid-single digit between now and the '28 guidance, expanding our EBITDA from high teens to mid-20s by 2028 and a dividend policy paying out 20% to 30% of percentage core net income. The '23 payout will be for the full year not just for the partial year, and we'll expand that dividend payment to 30% to 40% by 2028.

All of this is supported by an incredibly strong sustainability story. We talked -- Gilbert has already introduced you to our Board, but we have a very strong culture in terms of governance and framework as we step out of Novartis with a world-class Board building and supporting as we go forward. Access is core to our business. That is the very focus. That's actually the reason for being is democratizing biologics and serving patients all around the world.

As we step away from Novartis, we already have a strong framework in terms of environmental responsibilities, and we'll give guidance in terms of those specific commitments next year when we publish our annual report and have our AGM. And as an organization, we champion diversity, equality and inclusion. And we'll spend more time later on today looking at those key metrics. So in summary, attractive market and growing heavily indexed towards biologics. We're a champion in leadership and have scale.

We have a broad deep pipeline, 400 small molecules, 24 biosimilars, one of the leading portfolios in the industry. We have a clear plan in terms of margin improvement over the coming years, which will deliver strong cash flow generation. All of this supported by an incredibly strong sustainability story. Thank you so much, ladies and gentlemen. Happy to take your questions.

Richard Saynor Executive

Who's got the mic? Samir, would you do the honors.

Graham Parry Analyst

It's Graham Parry from Bank of America. So thanks for the intro, and thanks for spending time with us here in London. And first question really is just around the biosimilars market going forward. It's obviously a key part of your growth. But to what extent do you see the IRA legislation in the U.S.

as a disincentive to develop biosimilars or for that matter first to file generics, given that essentially in the Medicare population and government pay markets brings forward price reduction and reduces the market size ahead of loss of exclusivity? And then secondly, on the pricing environment for generics in the U.S. and Europe. Just can you run through your

thought process on what's assumed in the guidance and how you see the outlook for that over the mid-term?

Richard Saynor Executive

Okay. Thank you. I'll comment a little bit more top level on the biosimilars Graham, if that's okay. And then Keren will talk about it specifically when she comes and does her presentation on the U.S. business.

So I don't want to steal her thunder, and then we can address some of those specific ones. I guess, look, I view this slightly -- clearly, our focus is very much as a European company. So we're investing our pipeline with a European lens. Every product we've developed, all 8, we've filed, we've launched and we've ended up in a leadership position in Europe. So in a sense, then the U.S.

becomes accretive on top. It's not necessarily all focused on the U.S. Now clearly, it's a significant opportunity. It's still the largest market in the world, but we see this much more holistically that's a balance between Europe and the U.S. And then the impact of the IRA, I guess, at top level is puts and takes.

And I think there's clearly some areas of opportunity. We'll see how else it goes. But I think Keren will get more into the details. Pricing assumptions, we've assumed about a 5% price erosion. That's generally historically what we've seen.

So when we look forward in terms of our growth assumption, we assumed about plus or minus on a global sale. Clearly, U.S. at times may be higher, maybe lower, Europe. But I think generally, we've assumed about a 5% price erosion in our planning assumptions.

Holger Blum Analyst

It's Holger Blum, Patinex Management. A question on the market side. You spoke about 8% growth in targeting off the market, and you're targeting mid-single-digit growth. Is it regional or timing differences of the forecast horizons? And maybe looking backwards, if we see Novartis 10 years or Sandoz 10 years ago, it was similar size, close to $10 billion, close to $2 billion of operating revenues and no growth basically in the reported numbers.

So did the market part not play out? Or was it more company specific? And what are your lessons you take home?

Richard Saynor Executive

No, it's a good question. Further, I mean the growth figures because we use IQVIA data are gross and not necessarily net. So don't necessarily take into account the gross to net effect. So you always get a slight variation between the gross figure because, effectively, IQVIA attracts list price times volume. That's just how the data works, but then we look at net pricing.

Also don't get -- along that journey, Sandoz has consistently divested significant chunks of its business. So whilst it's not necessarily -- while it may have grown underlying, it's chosen to divest. And when you look at the last 4, 5 years, actually, Europe's consistently grown.

International has consistently grown. The challenge has been in the U.S., particularly really around and then post the Aurobindo decision.

So clearly, 5 years ago that we made the decision to potentially divest this, the U.S. business or large chunks of it to Aurobindo.The FDC didn't let that go through. And at that point, we effectively dismantle the development organization and the pipeline organization. So then you had a very strong negative washout in terms of the third-party deals that we had, low margin but delivering top line and a lack of pipeline. I think then the focus over the last few years is to start reenergizing that pipeline, stabilizing the business.

And then Keren has done a phenomenal job now getting that business stable. And now we're in a position to launch more biologics than we've ever launched in the U.S. that will deliver strong top line and bottom line growth.

Anja Pomrehn Analyst

Anja Pomrehn, Mirabaud Securities. Richard, you stated at the beginning of your presentation about Sandoz being the preferred partner for your customers, given the scientific technology research capabilities that you have. Now you stated later in the presentation, you are looking at M&A to add on. So my question would be, what are you still missing that you would be looking in terms of M&A? And then the second question, you say it has to be value added.

And what -- how would Sandoz define the value added?

Richard Saynor Executive

No, thank you. It's an important question. I mean, clearly, as I look here at the moment, I wouldn't anticipate any transformation or large M&A over the next few years. Clearly, our priority is to invest organically in our business, make sure we have the right manufacturing footprint. And the pipeline that we have, the growth we plan to have comes from -- inorganically from the business and pipeline that we have.

The only M&A I would anticipate doing in the short term is really sort of more increment, tiny BD&L deals, stuff that we do routinely anyway. As I look at our biologics pipeline, there's very little, I would say, we could go out and buy that would be attractive. Maybe some technology platforms in the medium and long term, and Claire will talk about that, but in the short to mid-term. I guess my partnership point is a lot of the development partners that we go to, Polpharma is a good example, where they have an asset but don't really have the depth and breadth of experience, either working in the market. And natalizumab is a complex asset on many fronts.

And again, Claire and Keren will talk about that. But what we've been able to bring to Polpharma is our technical capability, our regulatory capability and our commercial capability, and they're effectively then is a strong partnership. And other partners that we talk to, we give them global scale. So it means that then if they sign a deal, it's a single global deal. We have technical capabilities that can help them, support them, particularly in the development phase.

So in a sense, no other company can offer that. Either they're purely commercial, but they

don't offer technical or we offer the technical and development. So it's more of a unique partnership. And that's really to me much more of a focus over the next few years rather than big M&A in that space.

Victoria Lambert Analyst

It's Victoria Lambert from Berenberg. My first question is just, could you talk us through the main variable remuneration linked KPIs for management? Are any of these expected to change following the spin-off? And then my second question is just Sandoz has an extensive geographic footprint. Are there any geographies or regions you're looking to exit or divest from?

And would you use these proceeds to pay down debt?

Richard Saynor Executive

Clearly, we're working with the Board and Gilbert in terms of what the remuneration policy would be for Sandoz and its executives. Again, that will be published later on as we then separate as a company. So it's not really appropriate for me to comment. But clearly, as we're in the Swiss governance, it will be extremely transparent and in the normal framework. In terms of our footprint, I would say we're pretty much where we are.

There aren't any markets that we would necessarily think about exiting, which also then leads on to your debt question. And what's important is we're not going to leave with that significant amount of debt. We'll end up with lead. We have a relatively modest level of debt, keeping our investment-grade credit rating, which means that we've got freedom to operate to invest rather than necessarily selling down assets to pay off debt. So again, that position Sandoz extremely well as we spend gives us optionality in terms of our growth and allowing to invest in our business rather than have to raise cash to move forward.

Okay.

Matthew Weston Analyst

It's Matthew Weston at Credit Suisse. Two questions, if I can. Richard, we heard for years that Sandoz was critical to stay within the Novartis family, but we always heard that from Novartis. What I'd be very interested in is what you think the most significant thing you'll lose from leaving the Novartis family will be. And then the second issue is what's the most critical shared service, like business critical, that you need to build in-house that at spin you'll be taking from your parent?

But what time frame do you want to build that?

Richard Saynor Executive

That's a question no one's ever asked me, so thank you. What would I lose? It's a great question. Thank you. I think really that's a good question.

I think, look, Novartis has been a very strong parent over a long period of time, and I think all credit to them. I don't think we'd be in the biosimilar business if they not had the vision and the long-term investment. And I think what they've given us is that capability. But I think where

we got to a point now where we have a sustainable growth plan and momentum in the business, we're creating 2 strong companies. Clearly, Novartis now.

Sandoz was pretty much the only remaining non-core asset as part of Novartis. This allows Novartis to continue its journey to become a world-class science-based pharmaceutical company, and it allows Sandoz to become a world-class generics and biosimilars company. And philosophically, the 2 businesses want very different things in terms of capital allocation, approach to IP, all of those things. So I think that's clear. And then in terms of separation, I think mainly the IT tech systems.

I mean we touched on the 1,500 share platforms. We'll have a TSA for about 2 years in terms of managing that. So if you think about, Sandoz has always had its own supply development. Commercial was always mainly independent on Novartis. But the back-end support services around tech, particularly, were shared.

So those will be the areas in terms of building and separating, and that will take a little bit of time. Clearly, we set up our own financial reporting, medical regulatory, the things that we have to have on day 1 that are separate from Novartis, but we have some time then to migrate. And then I want to use that as an opportunity to rewire the company because, again, they're not necessarily fit for a generics company. So it's a great opportunity to simplify and focus the business.

Marietta Miemietz Analyst

Marietta Miemietz, Primavenue. Just a clarifying question on your guidance for the mid-term. How do you think about inflation in that context? How do you think about the effect of inflation on price growth and margins? You said you have baked in 5% price decline because that was the historic average.

But that was obviously in a much, much lower inflation environment than we're currently seeing. So if basically current inflation levels persist, would you think you can just add all of that to the top line, avoid the price declines and maintain your margin? And I also wanted to clarify whether the $100 million in sort of routine M&A you do every year, is that already baked into your mid-term guidance? Or should we basically add like 1 percentage point of growth every year just from the routine M&A and then there would be more of these transformational M&A at some point?

Richard Saynor Executive

No, thank you. I mean, Colin will spend a bit more time talking about inflation and the assumptions in the plan. Now the $100 million is already baked into the assumption that we will do that. We've done that historically in the last few years outside the big transactions, whether Aspen or GSK. They tend to be local BD&L deals or whatever.

So we've assumed a level to maintain that, particularly in international. And then inflation, clearly, we've seen a spike beginning of this year, like the whole of the industry. Some of that we've been able to transfer and pass on to payers. We're now seeing that washing down. So we've assumed normal levels of inflation really from '23 onwards.

But again, I think Colin got a couple of slides that will address that specifically.

Harry Thomas Sephton Analyst

Harry Sephton from Credit Suisse. On your first comment that you made that you're the only generics company that wants to be one, why is that? We see all the generics companies focusing more on specialty portfolios, given they've had pressures on their generics margins for many years. What makes generics a more attractive industry for you than it does for them?

Richard Saynor Executive

I think, first of all, our scale in Europe that is unique. I mean, really, every other competitor doesn't have that kind of scale. I guess I'm not going to comment on specific competitors. But if you look at the industry large, generally the issue is around the U.S. And then it's really finding ways to stabilize the decline.

So whether then it's a mature brands portfolio that then can't really extract growth or trying to recover an IP portfolio that offers the opportunity for higher margins. But I think then specialty is something -- certainly differentiated 505(b)(2)s or it can be a tricky road.

And also what we're not good as an industry is creating therapeutic sectors. We're extremely good at converting markets, but we're not good. And so in a sense, what's important to me, we play to our strengths. There's a significant opportunity, $400 billion of product coming off patent, more and more in biosimilars. That's already a highly consolidated area.

We see strong growth in biosimilars. So if you look at our biosimilar business grew strong mid single digits last quarter, but we've not launched a biosimilar in Europe for 3 years. It is still throwing off 8%, 9%, 10% of cash 3 years after launch, which is just phenomenal. I showed your Omnitrope, 15 years after launch, it's now the #1. So to me, that's why we want to focus on that space.

It's an unmet need. We're at scale. We have a unique capability and ultimately a unique purpose.

James Vane-Tempest Analyst

It's James Vane-Tempest from Jefferies. Two questions, if I can, please. You talked about portfolio simplification to help margins. How many divestments are planned in that? And how material is it to that element?

And the second question, you talked about the doubling the contribution of launches over the next 5 years compared to prior. Where are we with that today as a proportion of the business to help us get a sense of contribution?

Richard Saynor Executive

Okay. The portfolio is more -- not necessarily divestment. And again, when Glenn talks to you today, we have, I think, 700 third-party suppliers who supply a lot of our assets. There's a significant opportunity to consolidate that and simplify it to look at the portfolio of SKUs, so that's like 28,000 SKUs in our business. Again, a number of those are relatively low margins.

So I think there's an opportunity to simplify that portfolio. I'm not so keen to take products out of the market. Ultimately, it's part of our purpose in terms of making sure those medicines are supplied, but there are significant opportunities both to consolidate our suppliers and get more strategic partnerships to drive that. And sorry, your second part of your question was on pipeline. So I think we guided probably about $3 billion plus will come over the next 5 years, of which more than half would come from biosimilars.

So clearly, we see double the opportunity from the previous 5 years in terms of the value of that pipeline. But also then the quality of that pipeline, we anticipate to come or stick predominantly of at least 50% from biosimilars.

Frances Cloud Analyst

Frances Cloud from Pharmacloud. This is actually not a question for you, Richard. It's a question for Gilbert about the Board composition. So Gilbert, you had a very unusual opportunity really to build the Board of a large company from scratch, not many people get the chance to do what you've just done. You need to really think about how you want the Board to be composed.

So I'd be very interested to hear how you feel these individuals are going to contribute to Sandoz's ambitions. I mean you characterize generics as nimbleness, agility and flexibility, which I completely agree with. And I'd also say that in many ways, generics is quite antagonistic to big pharma or at any rate, it seeks weakness in big pharma and exploit it. And it's also quite a risky industry in many ways, certainly from a regulatory perspective and a litigation perspective. So when I look at your Board of these very heavyweight and impressive individuals, I see a lot of big pharma expertise, but no generics.

I see a lot of big industry expertise, but not necessarily industries that I would superficially feel would characterize by agility or risk taking. But you, of course, have seen the people, which I have not seen. So maybe you can just talk a bit about what you feel these individuals are going to bring to the party.

Gilbert Ghostine Executive

Thank you very much. I appreciate you asking this question. And it helps me reflecting on this one and sharing with you the journey. First, it's amazing about the Sandoz franchise, how powerful is the franchise and at the same time, how compelling is the mission. That's why we managed to attract very high-caliber people.

Just to give you an idea, we started with a long list of 500 people, 73 of these people accepted to join the Board. I ended up interviewing 22 to choose 9. So we went through a very selective process in order to get where we stand today. What was critical for us is we have done an exercise, mapping up what are the capabilities that we want. And we have to take into consideration that when you look at the generics business, we are at a crossroad of FMCG and pharma.

And that's why we've looked at what are the capabilities that we need.

Generic capabilities, we have them. We have over 200 years of generic expertise on our

executive committee, and you will get exposure to them later on, and you will be impressed by the knowledge they have. We have 50% of our members who have deep pharma expertise that will be able to contribute at the Board level. And the other 50% are coming from big FMCG companies that could support us along the transformation journey. What we have also another element that we have taken into consideration is how are we going to operate together?

Because like you said, it's once of a lifetime opportunity to set up a Board from scratch. And that's where we focus on culture, attitude, behaviors. And what is critical for us, and this is where I have a very high level of confidence, that we will move very quickly from being a team of stars because this is what we have today to becoming a star team as a Board to be able to support management and at the same time, deliver against our shareholders' value creation aspiration and make a significant impact to society. Because let's not forget these 3 elements: availability, accessibility and affordability. And they are core to the mission that we have today at Sandoz.

Thank you.

Florent Cespedes Analyst

Florent Cespedes from Societe Generale. A quick question on the operating profit margin improvement that you expect in the coming years. Could you elaborate a bit on which are the main drivers and which are the elements which are not yet in place where I see vertical integration or procurement optimization? It should be part of your business as usual. So could you give us a little bit of color on this?

Richard Saynor Executive

Yes, sure. I mean if it's okay with you, Glenn and Colin will spend quite a lot of their time giving you much more detail in terms of those activities. So the margin plans that we have are very well prepared. We know where to go for those margins. Clearly, it's split between mix, efficiency, simplification and purchasing.

But again, Glenn will take you through that and hopefully give you the color that you're looking for specifically. So if you bear with me, we'll just pause that.

William Hamlyn Analyst

Will Hamlyn, Manulife Investment Management. I want to go back to Harry's question on you being the only generics company that wants to become a generics company. Because I think when the spin-off was announced, the concern was that you would get the same multiple as all the U.S. generics companies because, to be frank, it's a pretty horrible business. And so I was hoping for some indication of kind of why operating in Europe is a much more fundamentally attractive business proposition than that of the U.S.

and what those differences are.

Richard Saynor Executive

Fantastic. Great question. And Rebecca will take you through a lot of those details. Let me

take a step back. The paradigm in this industry always assume that being first to market and the cheapest means you always win.

And if that's true, then the Indian players would dominate Europe. But they're nowhere. I think they have something like a 6% share of the direct. So something else is going on. And really, to me, that's our relationship with our customers and the market and scale.

And scale is a difficult thing to build because there's not enough margin in individual assets to invest and build that scale. I guess, because of our history, because of the acquisitions, because of our portfolio, we have scale. We have a $4.5 billion business. We're leaders pretty much in every market in Europe. You go to Germany, it feels very German.

If you go to France, it feels very French. So we're very closely aligned to our customers and the payers in that environment. So when we launch assets, we don't need any more incremental scale to extract that value. And then what you see really, since I've been in the company, Europe has consistently grown quarter-on-quarter. We've expanded on 1 share.

And when we launch assets, particularly biologics, even if we're not first to market, we end up a leader in that position. So it's really quite unique. It's 40 markets. If Austria is up, Switzerland is down. If Switzerland down, Holland -- so it gives you a very dynamic framework.

Clearly, the regulatory framework is harmonized, but the procurement and reimbursement mechanisms are all completely different. And so they're never really going to harmonize. So having that scale is truly unique. So I guess the question to me is, okay, well, what makes us different, I think, really 3 things. Clearly, Europe, we have an unparalleled biologics pipeline.

We're currently ranked #2. We will regain our leadership position given the launches that we have. We have a strong international business. And we have, at scale, U.S., but it's not a drag on our business, and we have an opportunity to extract significant value going forward. And lastly, we don't have significant amounts of debt.

So we have a growing business. We've grown 6 straight quarters. We have minimal debt strong biologics leadership in Europe.

Max Herrmann Analyst

It's Max Herrmann from Stifel. Just to understand a little bit more about biosimilars and your plans there because, obviously, you've highlighted that it's going to be your key driver to growth, and you've talked about $3 billion of incremental business and half or more than that coming from biosimilars. And obviously, there's more product launches in the U.S. So I'm just wondering how that balance is going to be between Europe and the U.S. for the biosimilars.

I take what you said about the sort of small molecules being predominantly a European business.

Richard Saynor Executive

Yes. I mean, clearly, I mean, Europe, we already have 8 biologics launched in the market. So there's always that scale that will continue to grow and expand market share, but at a more modest rate now given the age. Out of the 4, 3 of those we would intend to launch in Europe.

adalimumab, we've already launched in Europe anyway.

And clearly, the U.S. presents a very big opportunity. Now Keren will take quite a bit more time taking you through the individual assets. Clearly ADA, I think the last time we looked at potentially 11 players in the low-dose formulation, 2 players in the high concentration formulation of which we won. So I think we're well positioned, but it's a $20 billion LoE.

It's the largest we've -- the industry has ever seen. But it's going to be interesting to see how that evolves. And so we'll take some time looking at that. And then clearly, we saw a couple of other assets. natalizumab, we don't see any real competition in that space.

Technically quite challenging, but we're excited about that as a potential, similarly with denosumab and aflibercept, and Pierre will take you through some of those. Just trying to give you a bit more color in terms of that split. But clearly, in dollar terms, the U.S. presents a significant growth opportunity given the size of the market and the number of launches that we have. But Europe will get more sustainable growth given the portfolio we launched.

We have no more questions, then I would suggest we break for coffee and get out of this slightly warm room and then come back. We will stick to -- well, unfortunately, we'll stick to the time on the agenda because, obviously, it's a live webcast as well. So people stay connected. So if we'll be back in as in line with the agenda. So thank you so much for your time this morning.

[Break]

Richard Saynor Executive

Okay. Thank you so much, thank you for coming back. Okay, what I'd like to do now is delve into the commercial part of our business and think about how we've driven and supported that. We broke into 3 chunks. So Rebecca will come to stage first, talking about our European business.

Rebecca has deep experience in the generics industry, over 25 years working in pharma and 16 years in Sandoz working in numerous markets and now leading and driving Region Europe. Really about 50% of ourselves, as said, come from Region Europe. We're #1 in generics and biosimilar and a leader in the majority of markets we operate in and really capitalize on our footprint and portfolio, and I think it goes back to some of the questions we picked on earlier on. After Rebecca, we'll hear from Keren. Keren, again, has a deep experience here.

She came out with Teva originally and was Head of BD and M&A for Teva, and then join Novartis as Head of M&A and then has led the U.S. organization and re-driven the transformation that she'll take you through, stabilizing the business and focusing and driving our growth. And then lastly, Francisco or Paco as we call him, deep experience, 35 years in the pharmaceutical industry. He covers a very wide geography, basically Asia, Middle East, Africa. Really focusing on targeting and growing our business, bring very aligned around the specific markets we want to operate and then leveraging our portfolio.

We're particularly proud of the fact that we've launched biosimilars in markets that the originators have not even bothered to launch. So I'm very proud in terms of our access

agenda, but also a very strong business agenda. So I'll hand the floor to Rebecca. Thank you.

Rebecca Guntern Executive

So good morning, everyone. It's a great pleasure to be here with you today. London is actually part of my region. And my name is Rebecca Guntern. I'm 16 years in the company.

And since 4 years, I'm the President of Region Europe. So the last 4 years have been truly an exciting journey. And together with Richard and my colleagues in the Executive Committee, we've been working hard on our ambition to become the world's leading and most valued to generic and biosimilar company. Today's presentation here in London, of course, is a key highlight and a great opportunity for us to get you equally excited about our equity story, but equally more how we're going to drive value in the future. In my role, focusing, of course, on reaching Europe.

Before I'm going to share with you how we have built a success in Europe and how we're going to drive value in the future, let me start to say that I feel truly proud to lead Sandoz in Europe. I do have an amazing and highly capable team. And with over 1 billion packs sold, there is almost no other company who impacts the lives of so many Europeans today more than ever. And that's also why we feel proud to say that we take care of Europe, and we're truly passionate about what we're doing every day. So let's have a look at Sandoz in Europe at glance.

Sandoz in Europe is a true commercial champion with a clear market leadership in a growing and attractive market of the size of $65 billion. We do have a strong foundation and brand heritage, and we have a commercial presence in over 40 markets. Critically, we're a top 3 player in over 80% of the markets we're operating in. This gives us a huge scale and strong and unique footprint. And together with our broad portfolio coverage but also leading go-to-market capabilities, this translates into a very powerful commercial platform, led by a very experienced and highly committed leadership team.

The business has delivered sustainable profitable growth over the last couple of years, accounting for 50% of the total Sandoz turnover at $4.5 billion annually.

Looking at the future, we will build further on our strong foundation and leadership position to continuously deliver growth in the Region Europe. But let's go now to the market. The market is sizable, it's attractive and it's growing. Important, the off-patent industry plays a very critical role in Europe, being the backbone of the European health care system. We account for 70% of all medicines dispensed at 30% of expenditures, and we have dramatically increased access to medicines for patients in Europe, namely in core therapeutic areas like diabetes and hypertension by over 100%.

We do expect, as you can see here, the market to continuously deliver growth, fundamentally driven by 2 main factors. First, loss of exclusivities. We do see an LoE value of over $100 billion in small molecules and biosimilars over the next decade. And what you can also see on the slide is that we see a shift and a higher shift into biosimilars, now accounting for 15% of the total market, moving to 30% by 2031. Sandoz in Europe is in a very strong position to capture and capitalize on this market opportunity, driven by a broad LoE coverage and strong pipeline.

Second growth driver is volume growth, fundamentally driven by an aging and growing population, but also cost containment measures, which will accelerate and drive further generic and biosimilar penetration. So what is our position? We have heard already from Richard. We have a strong position in Europe. We are a commercial champion in Europe.

Let me say that we're the undisputable market leader with 11% share in Europe. And we do have a very broad foundation, being the leading company in 6 out of the top 10 largest European markets, namely, to give you a couple of examples, Germany, Spain, Italy, Netherlands and the Nordics. What you also can see here is that we are the only top player. We have a very balanced portfolio contribution between generics and biosimilars. And this is a key differentiator, which will enable us to capture the future LoE value, very important on biosimilars, but also offers a very attractive value proposition to our customers.

We have been outperforming the market over the last 3 years, which is reflected in the Evolution Index of 104. And we have doubled the gap to our second-largest competitor from moving from 2% to 4%, driven by strong and above market performance in biosimilars, but also first to market launches. Biosimilars. I think that's the most important slide of Region Europe. Biosimilars in Region Europe is a true success story, specifically if I look at Sandoz.

Sandoz was the first company to launch a biosimilar back in 2006 with Omnitrope. Today, we're the leading biosimilar company with 8 commercialized product being ranked #1 in 5 out of 8 products. And what's truly impressive is the fact that besides a very competitive landscape of anywhere between 4 to 11 competitors per brand, we're still delivering year-over-year growth. And we have further expanded our leadership position across the markets. We're leading in over 85% of the markets we're operating in.

Richard has already shared the example of Omnitrope. This is also true for Europe. We're a clear market leader with 38% share, and we have further expanded this leadership position over the last 12 months, gaining 6 percentage points. But I would like to draw your attention to another example, which is Hyrimoz. Hyrimoz launched back in 2018.

Sandoz is now the #1 in over 20 markets across Europe. We have doubled our volume share over the last 3 years, now accounting for 30% of the total market. And this translates into year-over-year growth. In 2022, Hyrimoz grew by 23% in terms of net sales. And this is what is truly exciting is the fact that there is a great opportunity in biosimilars to expand the market by treating more patients and by treating them earlier on.

And by even opening markets with biological treatments like you would see in CEE. Important, of course, now we do have the commercial capabilities to do so, including contracting and pricing excellence but also pull through when it comes to share of voice markets. And this has enabled us where you can see here to move from 22% share in 2019 to 27% share in 2022. We have doubled as much the share or twice the share of the second largest competitor. And of course, this gives us a lot of confidence based on the strong past performance that we will drive value, and we will successfully launch next for pipeline assets, targeting an LoE value in Europe of $4 billion.

So what is our financial profile? We are operating in 2 business segments, generics and biosimilars. And we have doubled the biosimilar business over the last 5 years, now

accounting for approximately 30% of the total business. In 2022, the business grew by 6%. We saw strong volume growth in biosimilars, plus 17%, and in generics, plus 7%, back on a post-COVID recovery and strong market demand.

We have been able to capitalize on this market growth, further expanding our leadership position in Europe by 60 basis points. So I think the core question here in the room must be, what are the key success factors in Europe, how do you drive this performance continuously sustainability over the years. So I do see fundamentally 2 key drivers. The first one is the commercial platform. The second one is the leading go-to-market capabilities, and this in combination make us a partner of choice in Europe.

So what are the building blocks of the commercial platform, which I like to call the hardware? I do see 3 main elements. First, geographical footprint. We do have a very unique footprint in Europe, present in 40 markets, on legal entities in 32 markets, which gives us, of course, huge scale and which is important in the off-patent industry. Second, with over 2,500 sales representative, we have one of the largest field force in Europe, even beyond the off-patent sector, which is important to drive prescriptions at physician levels.

Third, portfolio. With over 900 products, we have one of the broadest portfolio among competitors in Europe, which is important to address customer needs. And because of the combination of those elements, we consistently rank among the leading companies across major markets in Europe. And beyond this hardware, the platform, we know how to play on it and we know how to win. And we know how to win across market archetypes.

And this brings me to our software, our leading go-to-market capabilities. So talking about our leading go-to-market capabilities, this really covers all elements which are important for a successful commercial execution. And we do have a strong track record and proof points when it comes to commercial execution in Europe, starting with market access. You think about Europe as 1 region. But let me tell you that we have 14 markets, 14 markets with different pricing and reimbursement policies, and we need to really understand them to enter the market.

And we know how to drive market access in Europe. We have been frontrunners when it comes to shaping policies and the market environment to ensure sustainability of the industry. We have been leading in defining criteria beyond price and tenders, but also introducing gain-sharing models when it comes to biosimilars, like, for example, in France and in Spain. We know how to launch a product, being first to market in 70% of all products we're launching. And this, in combination with our broad LoE coverage, this is truly the core skill set of any off-patent company.

Last but not least, once launched, we know how to sell. We know how to sell across market architypes. In tenders, we do have a high win rate. And we're winning many tenders not only because of price, because of product features, because of supply, because of the product quality Sandoz is offering. Talking about share of voice, we are leading when it comes to face-to-face share of voice.

Again, I mentioned it before, important to drive prescriptions at physician level. And last but not least, when it comes to pharmacy substitution, we do have a broad and strong access to

pharmacy networks, which is important to ensure broad distribution and a fast uptake of our products launched. So both the platform and on top, the leading go-to-market capabilities truly differentiate us from our local and global competitors. And very hard to replicate in the way Sandoz has built them over decades, being a very trusted brands for payers, for patients and for customers. So putting it together, I have talked you through now how we have failed a success in Region Europe.

And I'm very confident that we're well positioned to continuously deliver growth, as presented by Richard and as outlined here. In essence, it is a continuation of our growth strategy, building on our strengths, on our strong foundation doing more of what we have done successfully in the past, namely relentless focus on commercial execution. To leverage our unique footprint and scale, we want to maximize our pipeline, which is attractive with $20 billion over the next 5 years, leveraging our first-to-market capabilities. We will see a shift in product mix into higher-margin biosimilars. Of course, we're going to build strategic partnership to leverage our commercial platform.

And on top of that, we will continuously invest in the breadth and depths of our pipeline. So what is important to remember when you think about Region Europe? First, we are a true commercial champion in Europe. We're operating in a very attractive and growing market with a market proximity and a reach, which differentiates us from our competitors. We do have an outstanding track record when it comes to commercial execution and an ability to win across market archetypes, something my experience tells me is absolutely key to win in Europe.

So with those core strengths, a highly committed and capable team and a clear plan in place, we're really well positioned to continue the success story in Europe and to continue to deliver sustainable profitable growth in the future. And with this, I hand over to my colleague, Keren Haruvi, President, North America.

Keren Haruvi Executive

Thank you, Rebecca. Good morning, everyone. Great to be here. I joined Sandoz in 2021, and it was a special opportunity to join a company where my personal and professional why are coming together. My personal why, it's all about people and making difference and impact in people life.

And here with Sandoz, as you heard this morning, it's a unique opportunity to make a huge impact on patient lives every day. I'm proud and privileged to lead this organization. I was thinking on how I'm going to share with you the journey that we've been through in North America. And I was thinking of a book, and my book has 3 chapters and each chapter has 1 key takeaway that I wanted to take from my presentation. My first chapter, we stabilized the business.

My second chapter, we have the right team and strategies in place. And my third chapter and most exciting one, we are ready for our upcoming biosimilar launches, and we are entering our growth phase. Before I go into my book, let me share with you a bit more information about the market that we operate. So the North America region is $75 billion and includes 2 countries, the U.S. and Canada.

As you can imagine, with the dynamic and size of the U.S. market, most of my presentation

today will focus on the U.S. The market is growing and anticipate to grow 10% in the next decade. And as you can see, tremendous growth from biosimilars, 24% growth anticipated from biosimilar, driven by loss of exclusivities, $172 billion of loss of exclusivity. This is a tremendous opportunity for patients.

The access in the U.S. for biosimilars and the market formation is in its early days. And this is a huge opportunity to provide patient the access to biologic drugs that otherwise they would not have access to, given the price level in the market. From a small molecule perspective, the market is also growing significantly. As you can see, a 6% CAGR, driven also by loss of exclusivity.

The market in the U.S. is very interesting in the generic front. 90% of the prescriptions filled in the U.S. are filled by generic. So from a volume perspective, huge access.

This account for 3% of the overall U.S. health care expenditure. This is why it's so critical for the economic of the United States. We are uniquely positioned to continue and play and win in both generics and biosimilars, and that's why I'm excited from the opportunities ahead of us. I'll start here with Canada, and then I'll move to my chapter 1 in the U.S.

We have a phenomenal business in Canada run by a very experienced and committed team. We continue consistently to grow our share. We grew our share in the last 7 years. And we are very close, as you can see, to close the gap to be #1. We were the only company in 2022 that was growing in the market.

Now going to the U.S., and this is where Chapter 1 begins. We stabilized the business. This is the evidence that we stabilize the business. As you can see, there are 2 companies in the U.S. that were able to grow share last year, and I'm very proud that we were one of them.

We had strong sales of $2.1 billion, 80% coming from generics, 20% from biosimilars. And the business overall declined, minus 2%. As I said, we stabilized the business. As Richard mentioned before, this business came a long way. After the decision to divest, there was solid and derm portfolio in 2018.

There was 2 years that the business was under transaction, I would say. The FTC ended up not approving it, and we reintegrated in the business in 2020. As you can imagine, it takes time to build a pipeline, and we did a phenomenal job to do that. But we didn't want to wait for the pipeline to kick in, which is, again, I will share with you more how we are now ready for the pipeline. But we wanted to grow share in the environment that we had.

And I'm very proud on how we did it. And that's actually where Chapter 2 begins. We have the right team and strategies in place. So let me start with the team. As you can imagine, you cannot turn around a business without having the right team in place.

The one thing that I'm proud of the most is the culture and the people that are working in our organization. And I would say, fighting even there every day to win share. Now the team is phenomenal, but there was a lot of other things that we needed to change and do differently in order to be able to grow our share in the market. Again, there are many activities, but I'll try to focus on 3 key pillars: the first one is commercial execution. We were thinking what we can do in the market in order to grow our share.

And as I said, pipeline was about to come, but not yet. The one thing that we did, we looked at our portfolio. We have a very broad portfolio in the U.S. We looked at each molecule, and we said, "Do we have a competitive advantage, either from a price, cost, supply perspective?" If we did, we act on it. If we didn't, we put it aside.

So focus, relentless focus on our portfolio. And as you can see, it worked very well, and we were able to grow our share. The second thing that we did is focusing on our launch excellence. As I said, we have very exciting launches around the corner, and we wanted to make sure that we are ready. We have a very skilled and committed team that continue to perfect, I would say, the launch process.

But what they do very well, they have their ability and capability to launch to each one of the channels in the U.S., retail, hospital and bio. Second thing is building -- rebuilding our customer relationships. And the one thing that I joined the U.S. I heard all the time, the perception was that price is the only thing that matters. And I can tell you, it's not.

Relationship with your customer, building this trust, being able to have not just a pleasant conversation but also sometimes a tough conversation made a huge difference for us. Again, it's not something that you do in 1 day, and we'll continue to do it and improve it, but we are very proud on how we rebuild our relationships. Now as I said, price is important, but what really matters, and you heard it also from Rebecca, it's quality and supply. I'm very proud of our quality heritage that you heard a lot this morning from all the presenters. But supply and what Glenn and his team is doing every day, it's where I'm proud the most.

We had 100% supply reliability in biosimilars since we launched into the U.S. Our first product who launched into the U.S. in 2015 in biosimilars, and we never had any issue. And this is something that I'm so proud so to say, and I can tell you, this is a real differentiator in our industry. And last but not least, our pipeline.

Again, the lifeblood of our industry. There's the price erosion in the U.S., the only way to offset the erosion is to launch products. Worked very hard with Claire and her team to rebuild this pipeline, both in small molecule and, of course, in bio. We doubled our NDA submissions, and we will continue to do that. We have 70% of our portfolio is first to file either shared first to file, exclusive first to file, but opportunities to be first to file and first into the market, which is very critical in the U.S.

And last but not least, Chapter 3, and this is the exciting part of our journey. We are ready for our biosimilar launches, and we are entering our growth phase. In the U.S., there are 2 channels where you can sell biosimilars, the medical benefit and the pharmacy benefit. And I would look at them as if I would say 2 different markets with very different dynamic. Our 4 launches, which cover $30 billion of loss of exclusivities are in both channels.

I'll start with our exciting around the corner launch, adalimumab, which is into the pharmacy benefit space. This is the largest ever loss of exclusivity, $18 billion loss of exclusivity into the pharmacy benefit channel. This is an opportunity for us as an industry to write chapter in history. We're just coming off our launch meeting. And if I could translate the energy and excitement and what we can bring to patients, it was just incredible.

Now as you heard before, and I'm sure you are well aware, this market is going to be very

competitive, but we feel very comfortable that we have everything we need in order to win in this market. Now the 3 things that I want you to focus is, one, our formulation, our high concentration citrate-free formulation, which is the best one for patients. The second is our experience and leadership outside the U.S. As you just heard from Rebecca, we're leading in Europe. We're leading in Canada and in many other countries.

This translates into the 120 million patient days of experience of transitioning patients from the brand to the biosimilar. And that's critical. As you know, those are chronic patients that needs the support. You don't just send them another device and wish them good luck. You need to train them.

You need to support them. And we have a lot of experience to continue and do that. And last but not least, as I mentioned, supply. We have the supply reliability to supply into the market, which is very critical. Now as I said, the other 3 biosimilars are coming into the medical benefit space.

This is where most of the experience already exists in the U.S. The biosimilars in the medical benefit showed that there is biosimilar access into the U.S. with 80% market share after 2 years more or less, that's the time frame that we see in the market of the launch of biosimilars. We are very proud. We were the first company to launch biosimilar into the United States.

We launched in 2015 after the BPCIA pathway was introduced, our own Zarxio and we're still holding leading position. The 3 biosimilars that are coming, as you can see here, you don't have a specific launch dates. So I just want to give a bit of a framework there. All of them are subject to FDA approval and clearing the IP landscape in the United States. As you are well aware, this is a very complex framework, and we're working hard with Ingrid and our phenomenal team to make sure we're doing it successfully and very confident on where we are in the process.

On each one of them, I want to share a few anecdotes. I'll start with natalizumab, which is the biosimilar to the reference product, Tysabri. This is an opportunity for us to be first and maybe potentially only one in the market. As you heard from Richard, it's a complex product. There are some safety, a REMS program around the brand.

We feel uniquely positioned to continue and support this patient and make sure we bring this product in the safest way to patients. The second one is denosumab, which is the biosimilar to the reference Xgeva and Prolia. Xgeva is in the oncology space, which as I just shared with you. We have tremendous experience with our current biosimilar portfolio. And Prolia, we're going to leverage our expertise with adalimumab in the market.

And last but not least, aflibercept. We're going to file both the vial and the prefilled syringe. This is another opportunity to support patients in this very complex opta specialty setup. Again, as you can imagine, when you inject something into your eyes, you want to have the company that would be able to be there and support you, and we're definitely this company. So as you can see, very broad portfolio in many therapeutic areas, which will allow us to capture the opportunity to serve patients into the United States.

So to my cliff notes of my book, we will continue to execute. As I said, focus on our in-line

portfolio is key in order to continue and gain share, and we'll do that, of course, maximizing our launches with a tremendous opportunity from loss of exclusivity perspective both in biosimilars. As I mentioned, $30 billion of loss of exclusivity with the 4 launches that I shared and $53 billion in small molecule, which will improve dramatically our product mix from the 55% that we currently have to 70%. We'll continue to leverage our partnerships. We don't care where the products are coming from, if it's internal or external.

As long as we can give patients the product that they need at the right time and at the right cost, that's what we are striving to do. And last but not least, of course, the lifeblood of this industry, we'll continue to invest in our pipeline to make sure we bring more innovations to patients.

So just to summarize the 3 key takeaways that I want you to remember. We stabilized the business. We have the right team and strategy in place. And we are ready for our biosimilar launches, and we're entering our growth pace. Thank you.

Can't wait to update you with our next chapter. And with this, Paco, over to you.

Francisco Ballester Executive

Good morning, everyone. It is my pleasure to introduce Sandoz international region. But before that, thank you, Rebecca, for sharing with us the outstanding performance in Europe and also the outstanding footprint that we have and caring for the turnaround of the business in U.S. I think that was really great. Thank you.

So let me move to the presentation. So in the next 10 minutes, I'm going to share with you what is international region and what we have been doing in the last few years, what is the present and which are the plans for the future in international region. International region is covering beyond Europe and North America, so basically the rest of the world. My name is Francisco Ballester. I'm known as Paco, that's a nickname.

I have been working in the industry for the last 35 years. Novartis, 32, most of the time in innovation. And in the last 11 years, working in generics. I'm super proud about the contribution we do around the world. I have been working also in mature markets, developing markets and emerging markets.

So I have a broader experience in geography, but also the type of markets in the different geographies of the world.

International region. Let me share with you about the international region, but I wanted to review about what we did 5 years ago. We didn't have international region in the world because it was a combination of geographies, clusters, countries or subregions in the different parts of the world. So we combine them. And at that time, 5 years ago, we made 3 decisions.

Number one, to focus on people and culture and to set up a winning spirit and a winning culture. Number two, we set up a very lean, efficient team above country in order to make sure that we were going to operate with the standards of generics, making fast decisions and be consistent around the world. And the third one, we defined 5 strategic pillars that I'm going

to share with you in the first slide, but also will be covered in detail during the rest slides in my presentation. The first decision we made from the strategic point of view is focused on specific countries. So at that time, we moved from 120 countries to 26 focused countries where we operate today in international.

The second is that we decided that operating the country was not enough and was just the first move before we wanted to go in our strategy. So we decided to operate in a specific segment within the different geographies to make sure we were putting the resources and focus and doubling down in the most attractive segments within the specific geographies. The other one we decided is to streamline and reduce the portfolio. We did it because we moved from some geographies out. The second decision is, obviously, as I mentioned before, we exit some segments within the specific countries.

And the third one is that we consolidated and harmonize some of the SKUs, as I will share in a couple of slides later. Then the fourth element is focusing on launches. We did focus on launches, doing more launches better with best-in-class excellent launches around the world and expanding our first-to-market launches in the different geographies of the world. And the very last one was just a blend, a combination of leveraging our global portfolio, basically dedicated to Europe, but we maximize it in different geographies where we have decided to play. And the second one is operating through business development and license.

So contracts with third parties, either to bring portfolio in or eventually to move to distributors some of our products in specific geographies. The combination of all of this has been giving us $2.5 billion revenues in 2022 and 7% consistent growth over the last 4 years. Market is $68 billion in the countries we operate. And that is equal to North America or it is equal to Europe, so comparable in size. Growing 5%, and that is based on economy, it's based on population, it's based on aging population and it's based on expansion of health care coverage.

As you can imagine, in many of the countries that we operate in international, the health care coverage what it's doing is basically introducing generics in the market. It's more focused in generics versus innovation. So it is an outstanding opportunity for us. I mentioned before about the specific segments that we are focusing in different geographies. When I was talking about segments, a perfect example that is according to our strategy in the division but also it's a perfect example for international is biosimilars, but also other complex products and other specific segments.

It's going to grow between 4 and 5x faster than the standard market. So we are focusing on the pockets of faster growth opportunities in different geographies of the world. Segments, you remember what I mentioned about segments. This is just illustrative. It's not in detail.

In fact, it's a matrix and it's a cube. It is more detailed than what you see in the screen. But conceptually, we are working on substitution INN pharmacy market, that's one. But the details of that one, we decided we go to pharmacy chains or distributors or individual pharmacies, and we use a different level of promotion if we decided to play that market. The second one, we have the opportunity to do share of voice, but the share of voice is either through hospital specialty or we go to GPs, depending what we decide.

But we don't do all. We do what is most attractive based on the future growth of the specific segment in the geography. And the last one is tenders. But again, to be specific, tenders in some countries is national, others are regionals, others are province or you have just series of hospitals. So we decide where to play in order to make sure that we are successful in the long term.

Beyond this, we have also a hospital business or we have OTC. So we decided the specific segment within each country. And in each country, we say 1, 2 or 3.

Overall, as I mentioned before, $2.5 billion revenues in the last few years, growing 7% in a consistent way, and this has been based on the strategic pillars I mentioned before. And going back to details, focus on the most attractive countries and segments, implementing an efficient satellite model. And that is because beyond the 26 countries I mentioned from 120 to 26, we have another 26 satellite markets where we are not present, but we operate in these 26 markets through distribution agreements with third party. We don't dedicate resources, but we operate with our products in these geographies. The products, SKUs and portfolio that we manage in these geographies, it is in a very similar regulatory environment, and they are similar or identical to the products we have in the other country that is supporting the satellite country.

So with these 3 decisions, reducing countries, reducing segments and focusing on this satellite approach, we have reduced significantly our portfolio in international. And as a consequence, we are significantly more reliable in supply. We can supply more and paying off of the resources we put in the share of voice or the tender market around the world. Then the other example that I mentioned is focusing our launches and first-to-market. You will hear from Claire later today that in the first-to-market, we were pretty relevant.

We were less than 10% a few year ago. We have been moving to 25%, and we -- our aspiration is to deliver at least 50% first-to-market in international in the next few years. So we have been doubling down every year in first-to-market opportunities in the different geographies, creating a huge difference for patients and a huge difference for our market. Every time we do a first-to-market, we have been comparing the different models because we had the opportunity as we were not doing it. And it's 3 to 4x more value, top line and margin, when we do first-to-market versus when we come late.

So it's obviously no brainer. And I will cover that later in the presentation in the last slide before conclusions, which is the inorganic. We have 2 examples of inorganic activities in the last 2 years, and I will share with you the details and why we did it. Two business case examples of how we grew in the last 4 years in international. These are not the fastest growing, but they are sizable.

They are within the top 5 countries in international, and I wanted to share with you the case study.

One is Australia, growing 50% year-over-year in the last 3, 4 years. And the other one is Brazil. In Australia, we move from very local portfolio and not launching many products for the previous 8 years to launch significantly beyond, launching 7 products or more in the last 3 years every year.

The second one beyond launching more portfolio and being first to market more frequently, we went to key accounts, and we were able to gain significantly more number of key accounts in the last few years because, obviously, we were offering first-to-market and more attractive proposal for the customers. And the last one is biosimilars. Biosimilars, we prepare launches, and we did it exceptionally well versus what we were used to do in the past launches in the specialty business in Australia. The case of Brazil. Brazil, a few years ago, we were focusing only on pharmacy.

And from focusing on pharmacy, we went to pharmacy plus branded generics and specifically antibiotics. And also, the third leg in Brazil was focusing on biosimilar launches. And we did it in a partnership with the government, which is a 10-year supply agreement. With this 10-year supply agreement, we have in a country that eventually could be not predictable or reliable, we have just the opposite. We are predictable.

We are growing. We are consistent. And we know how much to supply to the market in the next few years. And it's planned the volume, but also the pricing. So it's super attractive for us.

And we have signed already a few of them, and we are planning to continue with the model in the next few years. The 2 inorganic example I shared with you before. One is Aspen. Aspen Japan business was acquired, was put together with our business in Japan, and that was an efficient smooth integration. But the most important is the message about why we did it.

We had access to the hospital channel to anesthetics in Japan, and that give us the opportunity to launch our new future complex pipeline in Japan in order to create access to patients with the pipeline that will be coming in the next few years. Second example is GSK cephalosporin antibiotic business in different parts of the world. This is perfectly fit with our strategy. Antibiotics is part of our core business, number one. Number two, will help our production manufacturing with volumes for the future.

And number three, obviously, the accreting synergies in our antibiotics portfolio in the rest of the world. And beyond that, the acquisition is branded. And as a consequence, being branded is significantly attractive for the patients. Remember that in international and most of our markets, decisions are made by individuals, patients, day by day in the pharmacy for themselves, for their -- or their families. And as a consequence, it is obviously significantly more attractive to be branded.

And also, we have the opportunity to leverage our brand that is very solid and consistent around the world. Conclusions. Why I'm confident that we will continue growing in Sandoz, but in international region in the next few years? We have the right team and the right culture, as I mentioned at the beginning. We have selected the right countries and also direct segments within the countries.

Number two, we are prioritizing launches and doing them more frequently first to market, creating significantly more value, top line and margin. Number three, focusing on the mix, more complex products and more biosimilars. And as a consequence, creating significantly more margin. So we are doing margin expansion in the next few years. And then we have been the partner of choice.

As I mentioned to you, we have been bringing portfolio to us and also distribution out some

products to third parties in different geographies. We have been the partner of choice, and we are planning to continue being the most attractive partner because we are in the right geographies for any partner in the different geographies and continents in the world. And the last one is leveraging our global portfolio. We didn't do as good. But now with Claire, Pierre helping us to develop more products more frequently and also first to market, we are able to leverage this local portfolio in a more efficient way in international, creating access for patients and value for shareholders.

And with this, I will hand over to Richard for Q&A. Thank you, Richard.

Richard Saynor Executive

Rebecca, Keren, do you want to join us? Okay.

Graham Parry Analyst

It's Graham Parry from Bank of America. Just actually a question on -- you talked about obviously scale and the reliability being kind of key to the market. You also touched on the pharmacy chain distribution. I wonder if you could expand on that further. It's obviously quite fragmented in certain markets.

So if you could perhaps help us understand the dynamics of that and how Sandoz is differentiated there? And then on the U.S., what is it do you think you need going forward from here to become #1 player again in the U.S. on the generics ex biosimilars segments of the market?

Richard Saynor Executive

Rebecca, do you want to take the first one and then Keren?

Rebecca Guntern Executive

Yes. So on the pharmacy network, I mean, on the 3 market archetypes, there are different elements which are really important to win. If you think about the pharmacy, the broad portfolio is the one single piece, which is super important. First to market in all the 3 archetype is absolutely important. The pharmacy wants to partner with a couple of suppliers, right?

They don't want to work with 10 or 15 suppliers, and that's why the breadth of portfolio plays an absolutely important role. And that's where we are leading, right? We have 900 products. It's a very broad portfolio across all therapeutic areas. We even have a couple of OTC products.

So it makes us truly attractive for pharmacies to partner with us. And then, of course, the share because, fundamentally, if you go in a pharmacy, the brand heritage, Sandoz is a well-known and trusted brand. So pharmacies want to work with someone, which has trust quality in the market. So this is a huge advantage for Sandoz across those markets.

Richard Saynor Executive

Keren?

Keren Haruvi Executive

Yes. Thanks for the question. Look, the one thing, as I mentioned, the lifeblood of our industry is pipeline, right? But I would say it's not just to have the pipeline, but it's having the right pipeline. And as Richard mentioned, we will not position ourselves as the cheapest out there.

So when you launch to the market very late, we believe that the opportunity is probably less for us. So it's less looking at the number of launches, but it's more what do you launch? We are very focused, and you will hear much more, of course, from Pierre and Claire on complex generics, opportunities that bring us first to market. As I mentioned, 70% of our pipeline is going to be first to market. So that's where we are focused.

We already have a lot of complex generics in the market, and you see the sustainability with those albuterol. We have many of them, but albuterol is one, therefore [amoxitol] and other.

Richard Saynor Executive

I wouldn't -- also, I wouldn't aspire to be a leader in small molecule generics in the U.S. I would aspire to be a leader in biosimilars and complex. So I think it's important we separate the two.

Richard Parkes Analyst

Richard Parkes from BNP Paribas Exane. A couple of questions probably on the U.S. market. Firstly, on the HUMIRA. You've obviously one of the few with the high-dose citrate-free formulation.

I think there's a clear benefit there for patients in terms of the less injection site pain. But how do you leverage that with payers? Is it going to be more of a just volume play? Or do you think you can defend your price by able to offer payers kind of more rapid uptake with the citrate-free formulation. So just how do you leverage that?

And then secondly, when you look at the success that Sandoz has had in Europe versus the U.S.? Are there like a few things that you would -- you think looking back should have been done differently and that you can learn from Europe? Or do you think it's just -- the market is just more competitive?

Keren Haruvi Executive

Thanks for the question. For the first one on HUMIRA, we are definitely having the conversation with payers, and it's very important. Most of the market already shift to the high concentration. So it's important that when you transition patients, you don't kind of start a journey again for them. So we do see it as a unique proposition, and we will work on them.

We'll continue to work with them on that. To your second question, I think the one key -- it's a very different market, as we alluded to, but I think the one key learning is this focus on the customers and be close to your customers, which, as I said, the perception in the U.S. was that it doesn't matter, and it does. So I would say this is the Q1 that we really focused on in the last year and made a huge difference for us.

James Vane-Tempest Analyst

It's James Vane-Tempest from Jefferies. Three questions, if I can, please. Firstly, how is the business managed? I mean you presented by region, but how solid is it by product group? And how does that benefit from either procurement, revenue synergies or is there internal competition for capital to expand?

My second question, Rebecca, you mentioned 70% of the INN of first-to-market. Does that differ by the centralized or decentralized procedure? And how much IP risk are you prepared to take in Europe? And my final question on international. You mentioned 26 direct and 26 indirect.

As you look out for your mid-term guidance, could that ratio change over time?

Richard Saynor Executive

If I take the first one, then Rebecca and then Paco. I mean you'll hear from Pierre a little bit later on. So we don't think about the vicinity in terms of the regions and how we allocate resource. We don't think about it as franchises or different because, in a sense, the synergy is the whole business, not buyer versus retail. So really, it's down to the individual markets and then the regions to do that.

And we find that by far the most effective way so that we get that customer intimacy and the relationship in the market. And I think Pierre will take you through in terms of how we think about the portfolio and then leverage that at scale in terms of capital allocation. Rebecca, do you want to talk about Europe and particularly around IP.

Rebecca Guntern Executive

Yes. So first of all, on the DCP versus CP because there was first a question on regulatory. We really define -- I mean, on biosimilars, it is just CP, right? There is no DCP. So when it comes to small molecules, and Claire can then also add later in her presentation, it really depends what is giving us a more competitive advantage, right, in terms of timing.

So I cannot give you to say, well, we're always going to go for DCP or we want to go for CP. It really depends on the dossier and the competitive landscape. But this said, we're managing it really well because if you think that when 70% of the products were first-to-market, of course, regulatory strategy is a key pillar, but it is also supply. There's many elements, which needs to work end to end to be at end first-to-market and to win, right? I mean this is a cascade.

And then on the second one on the IP risk, I believe we take decent risk appetite when it comes to IP. We have a fantastic example, which is apixaban, which we have launched first to market in Netherlands and in U.K., very successfully but, of course, there's going to be most probably even greater opportunity once we are an independent company to look how we're going to drive the IP landscape.

Richard Saynor Executive

Paco?

Francisco Ballester Executive

Yes. Related to the number of countries we are operating in 26. We would eventually reduce 3,

4 countries, move to distribution because they are subscale versus what we are planning to do in the future. This has been already decided and executed, and it was not public until a week ago. So that's why it was not part of the document, but it's already planned and decided.

So that's basically our long-term journey, reducing 3 or 4 countries, which is already executed.

Richard Saynor Executive

Broadly the book that we have is directionally what we would want. We wouldn't want directly and change it significantly.

Francisco Ballester Executive

We -- just to clarify, we were operating under the umbrella of Novartis with a legal entity. And as a consequence, we were over there. The threshold of a scale, but operating independently. These 3, 4 countries are the reason why we are now moving to distribution.

Matthew Weston Analyst

It's Matthew Weston at Credit Suisse. Two questions, please. The first on the U.S. and specifically adalimumab on the growth opportunity. What we've seen in the past in the payer channel is that rebating by the originator has been extremely important dynamic.

So I'd be very interested as to what you think as Sandoz is the actual proportion of the adalimumab market that's going to be competitive for biosimilars in the first couple of years of launch where the payer is not going to go with HUMIRA and take a big rebate check where you can actually compete. And then the second question is one for Paco, it's about Russia. I recall that Novartis historically had a very strong position in Russia. I'm afraid I don't know whether that's true for Sandoz. But I'd be very interested to understand, are you still selling in Russia?

Or are you donating for humanitarian purposes? What portion of your business was it? And are you able to get the cash out of that region?

Richard Saynor Executive

Okay. Keren, do you want cover?

Keren Haruvi Executive

Yes, sure. So as you noted, indeed, that's how the market operates and the pharmacy benefit, but we do believe that there is a significant opportunity there. I think the question, as you said, is not if but it's when the market would open. AbbVie was communicated everywhere that they still have a preferred formulary position in the market in 2023. So for me, having biosimilars in parity with the innovator would be very hard to compete.

We do believe that in the next 12 to 18 months, the market will open up, and open up for me will be displacing HUMIRA. So payers will displace HUMIRA, and you will have only biosimilars in the formulary. So again, we are well positioned to wait. Once the market is formed, we are confident we can lead mainly from the 3 reasons I mentioned in my presentation.

Richard Saynor Executive

Perhaps if I take the Russia question, I mean, it's not -- I mean, it's less than 10% of Region International in terms of sales. I guess our Russian business really had 2 halves, 1/2 was OTC and 1/2 is sort of critical medicine. The critical medicine business, it's a supply business. We continue to supply. Clearly, it's important that Russian patients still have access to critical medicines.

The OTC side of the business, we made the choice not to drive media spend, particularly obviously that would involve sending money to state media. So really, that business has declined. We knew that was going to happen. We made that decision over a year ago. So in terms of impact to the business, it's washed out now.

But clearly, we made the choice that it wasn't appropriate to put money into state media. So we're very clearly, but continuing to support the business, but it's not a critical swing in terms of growth or drive it to the region or to the company.

Florent Cespedes Analyst

Florent Cespedes from Societe Generale. A question first on the U.S. operations. Could you elaborate a bit on how you see the impact from the IRA in the coming years, given the fact that some products will be already under pressure from the pricing negotiation? And second question for the international operations.

How do you see the opportunity for external growth acquisitions on some specific countries? Is it a tiny opportunity? Or is it meaningful way to leverage our existing portfolio to acquire market shares in some countries where you don't have a specific presence.

Richard Saynor Executive

Thank you. Keren and then Paco?

Keren Haruvi Executive

Thank you. So the IRA is a very complex topic. And I would say it's early days. This final guidance of CMS is not out there, so we are still, of course, assessing and monitoring closely. I would say for the generic and the biosimilar industry, it's -- there are pros and cons into this.

And generally speaking, and as I mentioned in my presentation, we see our role in reduced pricing. So the law itself, we appreciate what the government is trying to do. Let's remember, this is only for Part D and Part B product in the Medicare space. So also from the impact on the overall business. We need to remember that.

Look, again, we do believe that the best way to reduce price is competition, and then we do a phenomenal job as an industry, as I mentioned, the 90% volume with the 3% overall [elser] expenditure. So we do believe that the IRA wants to continue and support our industry. There are a few things in the law that you already see this. One of them, which is very critical for us is this 2-year special rule that they made that if there is a biosimilar that meet some conditions to get into the market, they will not negotiate the brand. So this is exactly to allow us to actually reduce the prices in the industry.

So that's one very positive note. We are still working, of course, with CMS. So what are the conditions that needs to be met. And the second thing is about reimbursement, the increased reimbursement for biosimilar in the inflation-based rebates from ASP plus 6 to ASP plus 8. So you do see that they understand what our industry is trying to do and to support it.

As I said, of course, there are some uncertainties coming from the law and will continue to work closely.

Francisco Ballester Executive

So in international in terms of acquisitions, as Richard mentioned before, we're not planning to do big acquisitions. We are not planning to do acquisition of companies, but we are planning to do acquisition of assets. There are some attractive assets basically focused on specialty complex and branded. That's where we can create more value, and that's where we are focusing now. And then the regular inorganic activities to BD&L agreements with multi-country in order to have a simple approach across the geographies.

And when we do this multi-country distribution agreements with those distribution need or licensing agreements, we basically create agreements of 5 or 10 years agreement in order to make sure we bring the portfolio that so far was not planned to come to international through our internal development, which now we are doing it more often. So we will continue doing this inorganic BD&L activity until we get the products in-house, which we will in the next few years.

Marietta Miemietz Analyst

Marietta Miemietz Primeavenue. Are there any markets, regional markets that you would say are just structurally completely unattractive because they're just completely price-driven and don't really appreciate all of the other factors that Sandoz has to offer? I'm kind of thinking about China with the VBP. Does it ever make sense for you to participate in something like that? And in that context, I mean, how confident can we be that other countries won't go down that route?

I mean, I remember 10, 15 years ago, China hardly had a generics market. I mean brands continue to flourish like right even after patent expiration, just because of that trust issue that's come up so much because patients wanted the brand are not some generic they didn't trust. Now China has basically done a 180-degree turn. So in terms of like other markets like Europe, as they come under more economic pressure, do you think that they're going to say, well, we don't have the scale of China and our experience in the past with contaminated products and so forth from cheaper suppliers has been so horrendous that we just continue to value the relationship with Sandoz and the reliability very highly? Or do you think that there's a risk that some of these markets will just basically streamline everything and go to something like the value-based procurement and the lowest bidder wins, and that's it.

So any perspective there?

Richard Saynor Executive

Yes. First of all, I'll take that. I mean I don't think we can't -- we don't compete in China because

of price. Let's be clear. I think it's the environment.

So we have a fairly modest business in China. It's not a strategic market. But it's not a price issue. I mean, fundamentally, we don't believe it should be core to our business. It's hard for us to leverage against state owner operators in that market.

I can't think of a single MNC generic company that successfully built a generics business in China. I'd also put India in that framework. It's not about price, but it's not our skill set to try and leverage against local Indian players and create hundreds of disparate little brands in that market. Clearly, it's an interesting market, but it's not core to us, and we wouldn't focus on it. Do I see that washing into Europe?

No, for a whole bunch of reasons. I mean the reality is this isn't a price argument. We already supply roughly 80%, 90% of the volume of between 10% and 20% of the cost. So we're part of the solution, not part of the problem. The beauty about Europe is you've got 40 markets that all have very different reimbursement and customer frameworks.

And we're able to compete even in markets like the U.K., which you could say are probably one of the most brutal commodity markets in the world. So I just -- I don't see it evolving that way. Ultimately, it's about the portfolio clearly going up the value chain in terms of biologics and complex, but also having a broad and deep portfolio to deliver your relationship with customers and payers. But it's clear where we can compete and where our strength is and clear where we don't want to compete and just adds complexity and risk.

Rebecca Guntern Executive

And if I can just add one point, specifically looking at the biosimilars. We will go away and we see more and more markets like France, 60% of the tender criteria are not price driven. We see this in Finland. We do see the same in Spain. So we see more and more markets understanding there is something else than just price, which is product features and which is services, quality of the product.

And I'm very optimistic that this is going to really give us a lot of sustainability in the industry. And even in Germany, which is a tender market, we're #1. We're even #1 when it comes to tenders. So there must be something else than just price. And this is what I presented is this market proximity and really knowing how to play.

So I'm pretty confident we're going to see sustainability in Europe.

Francisco Ballester Executive

If I may add this trend, we don't see this in many countries in the world. As I mentioned before, 60-plus percent of the products are branded generics and out-of-pocket. And in this trend, we don't see the power -- the financial power of the countries to move to big tenders across the country because they don't have the financials to do it. So we think that it's going to be continue purchasing power of individuals and branded generics. So with this context, it is pretty unlikely that it happens like the example you mentioned in China.

Keren Haruvi Executive

And in the risk that you will have the longest answer on earth, but I just want to say on the U.S., I think the pandemic really helped everybody to see that just counting on price will not get us to where we need to be, and that's why I'm so optimistic on the dynamics of the market going forward. Price is important. It cannot be the only thing to drive. And supply, at the end of the day, this is the thing that if patients don't get the product at the end of the day, the price that they were able to get doesn't make any difference. So I do see those trends also in the U.S.

Simon Baker Analyst

Simon Baker from Redburn. Firstly, a question for Rebecca. Just thinking about sources of growth within Region Europe. One that wasn't talked about was the general increase in generic penetration. There used to be a very wide spread between Greece at the bottom, Germany and the U.K.

at the top in terms of generic volume penetration in market. How much of that is a driver for growth? And how much can you influence generic penetration within European markets? And then moving on to Keren. Going back to the point about price being not the only determinant.

It rather felt like after generic user fees came in and the market was flooded with additional competitors, that's exactly what it was about. So is that a fair characterization of where the market was? And have we seen effectively retrenchment from the days when it was all about price? And in a sense, this relationship rebuilding is not just Sandoz with the customer, it's the customer with Sandoz. And then a final question on the U.S.

market. It looks like the skinny label is dead after the Supreme Court refused to hear an appeal on Glaxo-Teva. Is that material to Sandoz in any way?

Rebecca Guntern Executive

So let me start maybe with the volume question and how important is also the increased penetration in Europe. When I showed the market, right, the market is expected to grow driven by 2 factors. The first one is loss of exclusivity, which is the pipeline. And the second is one is volume. And there, you have the population.

But of course, it is also driven by cost containment measures, which will further drive generic and biosimilar penetration. And depending on the market, right, we see markets where we still have a huge opportunity to really accelerate the use of generics, being it in Belgium, just to give you an example, being it also in France and Italy, by the way, which are the bigger markets in Europe, there is still a lot of space for generics to drive volume and bring savings to the government's back, right? And biosimilars, it's absolutely the same. And if you think about markets in CEE, in Poland, to give you an example, which is not so far away from here, only 0.5% of the entire population gets access to biologics.

So it's a really huge opportunity for us to bring there to the patients, treatments, which are much more cost effective. So there is an opportunity when it comes to volume acceleration and penetration of generics and also biosimilars. And it's part of the growth agenda, by the way. It's part of the commercial execution to really leverage then our scale and strong footprint and portfolio, of course.

Unknown Executive Executive

I think on the biosimilar, also important to note, because clearly, we're still growing this business. In Europe, we've not wanted to biologic for 3 years and it's still growing very strongly. And a lot of that is because when we launch a biosimilar, say, [indiscernible] Point in Poland, it's a third or fourth line treatment, patient waiting 5, 10 years to get an asset. When the price comes down, that gets further in the treatment pathway.

So you expand the market significantly in a way that a small molecule generic just doesn't behave. So this is a very different kind of dynamic with biologics, given the relatively high price point. When you democratize it, you can expand the market significantly, but still at a much more attractive margin than small molecules. Keren?

Keren Haruvi Executive

Thanks for your question. First of all, look, I think the prices did go this way, and look at where we are now, the prices are low, and we are the highest ever drug shortages in the United States. I think there is definitely the acknowledgment that there is a sense of urgency to fix what we currently have. So that's one.

And if you look also from a kind of a pipeline perspective, what we call the NCs in the U.S., you used to see 16, 20 filers. Now you see much less. So definitely, you see a different trend in the U.S.. On your question on the customers, look, the consolidation that happened on the customer base, there are 3 key customers in the U.S. in the wholesaler side and on the payer side.

And there are like around 240 manufacturers. So it's not a balanced, I would say, view.

And yes, also from their perspective -- and again, I don't want to talk on their behalf, and definitely ask them the question. But as you can imagine, deal is to with 240 manufacturers, it's not an easy task. And each one of them has very different supply chain, quality, et cetera. So we do feel that it's not just that we want to build those relationships. It's going both ways.

And I do believe that the only way to fix and to solve the drug shortages in the market is changing in the price points. You do see a lot of companies exiting the market either through bankruptcies -- we also -- what's happened in the last 18 months in the U.S. -- or because of lack of supply. Or people that are less interested to compete in these markets because they don't have the scale and the infrastructure that we have. The size that we have in the U.S., for me to bring products into the market, I have already the infrastructure.

So it's just launched the product and get the profits out of it versus investing in order to bring the product. Of course, in the biosimilar space, it's a bit difference in where -- and when I need sales force, of course, we will do those investments.

Unknown Analyst Analyst

And skinny label?

Keren Haruvi Executive

I didn't capture the question. Sorry.

Unknown Analyst Analyst

So I guess, that's skinny label, this is GSK, [Corec.]

Keren Haruvi Executive

So what the impact, you asked? Can you repeat the question?

Unknown Analyst Analyst

Is there a material impact on the U.S. business?

Unknown Executive Executive

It looks like the ability to carve out labels has been blocked because the Supreme Court is refusing to review that decision. So skinny labels are dead. So not specific to that case, but in a broader sense, do you see that as a particular issue for Sandoz?

Keren Haruvi Executive

I would say, in the big picture, no. Of course, there are areas that we could benefit out of it. But in the big picture, no, we'll continue to work with the new framework.

Unknown Executive Executive

Thank you. Frances?

Frances Cloud Analyst

Frances Cloud, Pharmacloud. Just a couple of questions about branding. In Europe, and I guess also in international, what percentage of the products you sell are actually sold under the Sandoz brand? I mean, as the primary brand as opposed to, let's say, Hexal, a Sandoz company. And when you're looking at your future launches, do you have a plan to harmonize everything as Sandoz?

Or will you continue to run with multiple brands?

And then just a question about operating and branded markets. Because there, I guess, in truly branded markets, the sort of economies of scale thing, if you like, is less important because you're competing more against local players. How do you give enough independence for your local managers to enable them to compete across a range of products that may be unique to that market and not have any synergies with the rest of Sandoz?

Unknown Executive Executive

That's quite -- I mean, we don't -- I guess I don't -- we don't break the business out like that. I mean clearly, there are markets where Sandoz is the brand, but it's more a patient brand rather than a prescribed brand. And I guess then, your second part of the question, do we want to harmonize the company? I mean, at the end of the day, no. In Germany, we're known as Hexal.

And why would we want to change what is an extremely well-recognized brand in Germany for

the sake of rebranding? In Switzerland, we're known as Hex Sandoz.

So -- and then clearly, depending on the market, it has a strong brand, where brands matter. I mean clearly, in Central and Eastern Europe and a number of other markets, it's the product brand that matters. And there, it's promoted. And the same in international, clearly, with some of the antibiotics and a lot of product, we'll promote them as brands as originator would promote them. So it's more about the product brand.

And actually, I think one of the successes -- but actually the success for all of the markets in the regions is trying to get that balance right between leveraging global scale. And we bring global scale in terms of our development increasingly around the portfolio, and Pierre will talk you through some of that. But then being local when we need to be. So ultimately, in many ways, the most important role in the company is the General Manager in a market. Because clearly, if you go to Greece, it's different to going to Germany, and we need to adapt to that environment.

So you've got to give the GMs enough flexibility to build their frameworks around that.

I've always said actually being a GM in the generics industry is much harder than being a GM than the originator industry. In the originating industry, somebody in Switzerland tells you your price point, your patient tower, your branding. In the generics industry, you've got to think about everything in your go-to-market model in your market. So it's very much more different, but key to our success.

Unknown Executive Executive

Now we have a privileged position in the context of the independence of Sandoz with our brand. Because using the digital platforms under the digital capabilities that we have been building in the last few years, we can leverage this Sandoz brand across the world in different countries. And this is an opportunity beyond the geographies, which we were not able to do strongly in the last few years. So this harmonizing portfolio, launching the same product in the world, being first to market simultaneously, and also at the same time using these digital capabilities is helping us a lot in the next few years.

Unknown Executive Executive

Okay. I think we're about time now. So we'll have a break for lunch now for 1 hour. Thank you so much for your questions. We'll have time for more questions later on in the afternoon.

So thank you, everybody. Thank you so much.

[Break]

Unknown Executive Executive

Thank you, everybody. Thank you for coming back. Okay. Now we're going to dig into the end-to-end capabilities, to delivering our portfolio and our efficiencies going forward. So I'm going to introduce you to Pierre, Claire and Glenn.

Pierre is going to talk about our pipeline in terms of how we select our pipeline and really, how do we see the launch value coming from both those biosimilars and the generics pipeline.

Pierre has -- he's my Chief Commercial Officer. He's had numerous roles in both Novartis, Alcon and Sandoz. Last role he's had is really leading the biologics organization. So a lot of the portfolio expansion that you see today really is down to his and his team's hard work.

Following Pierre, you're going to hear from Claire. Claire has had a distinguished career in originator pharma, GSK and a number of other companies, as well as Teva in terms of development, and she's our Chief Scientific Officer. And she'll talk you through our development capabilities from an end-to-end point of view, our legal, regulatory and IP framework and our in-house capabilities and our centers of excellence in sort of developing our pipeline.

And then lastly, you're going to hear from Glenn. Glenn is our Chief Supply Officer. Glenn has, again, significant experience both in originator pharma all over the world and also generic pharma, particularly with Teva in terms of understanding the network design, how we intend to expand our margin, particularly around simplifying our network and delivering operational excellence and procurement excellence. So with that, I'll hand over to Pierre.

Pierre Bourdage Executive

Thank you, Richard. Now I've been given advice to bring a lot of energy to this presentation. It's a warm room, we're metabolizing sugar. We're looking forward to caffeine 1.5 hours from now. So I'm going to bring a little bit of zest and energy to the presentation.

How does that sound? Yes. Okay. So Richard talked to you this morning about the really unique position that Sandoz is in. And he highlighted the fact that here we are, as a company, uniquely positioned with scale and leadership across both off-patent categories of generics and biosimilars.

And building off that, you heard about our commercial platform across the regions and the strength that we have in being able to have market proximities, really understanding what customers need and why in each market, being able to have portfolio scale, the right portfolio and the right country framework.

And then last but not least, very important, being able to launch at exclusivity, or what we call LOE, loss of exclusivity. And together, those things really drive a lot of value.

So I'm going to build off that now. And I'm going to have just 5 slides to walk you through on our pipeline. And I'd like to tackle 3 things: First and foremost, our strategic pipeline framework and operating process. In a nondifferentiated world, how do we actually manage our pipeline, what choices do we make? And how do we execute on it so that we can deliver high value in market?

The second aspect I'll give you are highlights of our generic and biosimilar pipelines, including a bit of a deep dive on 4 upcoming global launches of biosimilars. And then last but not least, I'll give you an overview of the value delivery expected in the next 5 years, based on the pipeline potential.

So here we go. Now -- Okay, got it right. Okay. So starting with the strategic framework. This is really important, and you're going to see this flow through in almost every comment that I'm

making in the slides ahead.

And I don't want to read the slide didactically, I want to point out some key elements that are really important for us to understand. Selection frame. Here's what Sandoz will not do. Sandoz will not select development programs on late-to-market assets that are entering the market that is already fully genericized and facing a lot of options already.

What we will do and as was highlighted to you is the majority of the pipeline that I'm going to present to you our programs and assets that are scheduled to launch at loss of exclusivity so that Sandoz can be there day 1 of market formation and be able to drive value and uptake.

The second important aspect is the commercial lens. We're in a marketplace where ultimately, we can get a lot of insight and leverage that insight from commercial regions in all our pipeline and portfolio operations. So everything you're going to see today has had deep commercial input and market input to ensure that what we're choosing, whether we're developing in-house or licensing, is an asset that ultimately can succeed at launch.

The next area of scenario evaluation, you're going to learn that our pipeline, 70% or more of the programs are targeting complex generics and biosimilars. That means we are starting 7 to 10 years before loss of exclusivity. So we do a lot of scenario mapping to understand intellectual property scenarios and to understand what product do we need to develop internally.

So that 7 to 10 years from now, when that development program has been finalized and gotten regulatory approval, we win in the market that will be at that time. What are the product features and potentially differentiating properties that we can bring? I'll try and bring that flavor to you as well when I show you our biosimilar near-term launches.

And then clearly, because we are mix shifting into more complex assets, the technical lens is incredibly important. My presentation will be followed by Claire, and thereafter Glenn, as heads of development and manufacturing who are going to share with you the technical expertise behind what we do. And from a pipeline strategy perspective, their expertise, their voices, their teams are fully integrated in our operating cycle to ensure that we have real end-to-end visibility on what we're building.

And then last but not least, very importantly, the operating rhythm. You see that on the upper left here. The operating review includes all members of the executive team that have presented to you today are part of that monthly operating review so that we keep high diligence and very high visibility of the pipeline and near-term launches to ensure that ultimately, we're executing and executing for value. So overall, this is the strategic framework, and we're proud of this because it allows us to ensure that the slides I'm going to show you now, I show with a very high level of confidence and enthusiasm.

Okay. Starting with the big picture, Richard had pointed out to you that we have a very broad and deep pipeline, more than 400 generic programs, 24 biosimilars in the pipeline. And as I shared, a very important mix shift occurring, with 70% of the total value covered now being through complex generics and biosimilars. That's important from a strategy perspective, and you're also going to see it flow through when Colin presents at the end of the day on our financial outlook because mix shift is not only supporting our growth agenda, but our margin

agenda over time.

So let me start with a view of the big picture of our generic pipeline. Here, we have more than 400 projects covering $145 billion in LOE. And clearly, you have the mix shift element here of covering $44 billion in complex generics over that planning period. Now on standard generics, we have 2/3 of the projects that are in this category.

And let me make a few remarks and bring to you one very clear example to understand how focused we are on creating value here. We're looking for assets that have high value. Assets where we launched at loss of exclusivity and assets where we can, we scale. And I want to highlight to you the example of Farxiga. Farxiga is an originator brand in diabetes with more than $4 billion in annual revenue.

Three weeks ago, we launched on day 1 of market formation in the Canadian market, our internally developed and manufactured generic to Farxiga. Now launching in Canada on day 1 gives us the opportunity to create value. But from there, we're going to scale the program. We're going to launch in Europe. We're going to launch in the U.S..

We're going to launch internationally over the next 2- to 3-year cycle as intellectual property market formation unfolds. Why is that important? It's a high-value asset. We launched at LOE, and we scale our infrastructure to ensure that we drive efficiency and competitiveness and ultimately, value for the company.

On the complex generic side, clearly, this is a different segment with much higher barriers to entry, higher technical difficulty and technical thresholds to overcome. And we're really excited about our pipeline here. You've got a variety of different technologies in this category. You have complex high-dose injectables and IV medicines. You have complex peptides, you have drug device combinations, and you also have oligonucleotides, which are an emerging segment that will see LOE formation 2030 and beyond.

And so Claire, in her presentation, is actually going to give you many actual examples of complex generics that we've launched in markets across different technology segments. This is a very important strategic capability and important pipeline component for us moving forward.

So now moving to biosimilars. Now Richard pointed out to you in his presentation that we have 8 biosimilars. And today, they're generating approximately $2 billion in growing revenue. Imagine the opportunity now and why we're so excited to have 24 additional biosimilars in our pipeline and the long-term value that, that can generate. So clearly, we're very excited, and we're also utilizing the strategic framework.

These are assets that typically, over the long term, are chosen 7 to 10 years before LOE. And so we do a lot of deep diving, as I shared with you on the original side on how do we make sure we win? Because you have a concentrated investment over a longer duration of time. And you will be in a competitive environment.

How is it that Sandoz can ensure that there's value delivery and leadership as you've seen already with our launches executed in Europe and across the world? So now I'm going to spend time going through exactly that. And I'm going to walk you through our 4 near-term

global launches that are coming and highlight to you why we're excited about the programs, what could be some differentiating features that we bring to market and why we're confident that we'll bring value.

Let me start with the most obvious candidate, adalimumab, where we have a biosimilar to the originator HUMIRA. Clearly, this is a very large value pool, $21 billion in global revenue. Now the LOE has already occurred in Europe, but there are still -- there's still a lot of value in Europe, with the originator still holding a sizable portion of the European opportunity. So here, we have a high-concentration formula approved. Now why is that important?

Because the originator has both a low- and a high-concentration formula, and they have shifted 85% of their business to the high-concentration formula.

Sandoz, in the United States, is 1 of only 3 FDA-approved high-concentration formula biosimilars expected to launch just in the next couple of weeks ahead.

This is 1 example where 4 years ago, we identified the need to invest in this program, ensure that we did it early, and ensure that at least at the time of launch, we can have a level of potential differentiation compared to some of the entrants.

Now there are other unique elements that we bring to the table here. If you're engaging with a U.S. customer, you have 5 years of data on your supply reliability globally, in Europe, in Canada, in the U.S.. And so you have a track record of success that you can demonstrate to them, which is critically important, because as Keren pointed out, it's not only about price, it's about supply reliability and partnership.

Now on the price side, clearly, being #1 ex-U.S. gives us scale and allows us to be able to compete in what will be a very competitive market. And we have 2 other features here that I want to highlight to you. The first being our device. We have what we believe to be a unique and very compelling device that has different features than many of the competitors, including the originator.

It's got a triangular shape, which is ultimately designed to be very ergonomic so that patients with rheumatoid arthritis who have dexterity issues can actually have an easier time handling the pen. And in real-world evidence in the last 5 years, we've been able to show fantastic results, including satisfaction not only from patients, but from the pharmacist, the doctors and the staff that are training them as they transition from the originator to the biosimilar.

We also have invested in a starter kit. Now again, this was several years ago, thinking, if the U.S. market forms and takes 6, 12, 18 months, what could we bring to the table that could be unique? And we now have a starter kit that will be there at day 1 of launch, and we believe could put us in a unique position, being 1 of very few companies that can make this offering. So here you have the picture of adalimumab, and let me end with the last view ex-U.S..

Because we're #1 in Europe and we're #1 in many other geographies, including Canada and Australia, now bringing the high concentration formula allows us to solidify that position not only for the short term, but for years to come. Adalimumab is a segment and a class that is growing high single digit annually. And so it's already a very sizable contributor for Sandoz, and we see a runway of opportunity and growth behind it.

Now moving to natalizumab. Now this is a very unique and different launch. Keren pointed out to you that we expect to be potentially alone as a biosimilar launching against the originator, Tysabri, in multiple sclerosis. Why do we believe that? Because we see no competitor establishing or initiating a clinical trial on the horizon, which typically gives you a 2- to 3-year minimum window of time to be exclusive on the market.

Now what's really important for you to know here is that the originator has been on the market for more than 15 years and continues to have a very stable position in the MS market. And for those of you who follow the MS market, you know it has seen many new innovations launched in the last decade. Many new medicines have come to disrupt the MS market. Interestingly, Tysabri has held a relatively stable share in a very dynamic and growing MS market.

And so this is a medicine that we believe will have a lot of durability. Because ultimately, it's positioned as a high-efficacy treatment, as a second or third line option for patients with highly active relapsing, remitting MS.

So we're very excited about this opportunity. We partnered with Polpharma Biologics, which Richard noted as 1 of our key partners, and we look forward to bringing this medicine to market in the short term. It's already submitted across Europe and the U.S..

The last 2 medicines definitely are not last but -- and least. They're just as exciting. They're a little bit further on the time horizon but very exciting. And let me tackle denosumab first. Denosumab, the originators are known as Prolia and XGEVA.

These medicines are used in osteoporosis and in oncology. And when you look at the LOE value, about 2/3 of the $7 billion is in the osteoporosis indication, which has seen very continued and healthy growth over a long period of time.

Now why is this exciting? We have to look back at 2 aspects. Number one, we are the most advanced industry program. So part of our strategic framework is ensuring that we launch an LOE and lead in the markets. This program is a great example.

The other aspect here is -- Richard explained to you this morning that in biosimilars, you don't just convert the originator, you can expand markets. So in osteoporosis, denosumab is given as a twice yearly injection. Great efficacy and great safety track record.

But interestingly, ex-U.S. and public markets where, as you know, in osteoporosis, it's typically going to be on public formulary in post-menopausal women over the age of 65, public formularies have been pretty stringent in the management of denosumab, and only 15% of patients have gotten access to denosumab in the EU5, for example. So imagine the ability to bring a much more affordable biosimilar version, commercialize that, convert the originator, but drive expansion of markets up to several multiples. The possibilities are significant.

Last but not least, we have a biosimilar to the originator, EYLEA. This is used in ophthalmic indications, a very large market. And here, again, we have a differentiating feature that we believe could be potentially advantageous for Sandoz. We will be launching with a prefilled syringe. A prefilled syringe is very important.

More than 80% of the market for EYLEA is in the prefilled syringe format. They also offer a vial.

But a prefilled syringe is preferred by health care clinics for health care clinic efficiency, ease of use and safety in the handling and administration of the medicine. Here, the originator, EYLEA, actually faced a CRL, a complete response letter from the FDA and its initial attempts to bring a prefilled syringe to market just a few years ago, pre-pandemic.

They were able to resolve it on their second attempt. But it gives you an idea that it's a very difficult area to bring prefilled syringe technology at scale. We're leveraging an internally approved prefilled syringe that also have leveraging a manufacturing site that is FDA-approved for this technology setting.

We feel really excited about this opportunity, clearly a large and growing market. And if I zoom out of all 4 of these, what I'm hoping that you see, as I talked to you about our strategic framework, launching at LOE, high-value assets, differentiation within the biosimilar scope where we can execute it. I think these are all 4 great examples of value generation coming.

Okay. Let me land on my last slide and hopefully, you might feel as warm as I do. I'm not sure. For those of you on the web, we're on Slide 80, this is an important slide. In the last 5 years, Sandoz launched $1.6 billion worth of medicines.

Clearly, a high-scale, high-volume operation with many launches. Biosimilars accounted for 31% of that contribution. Why are we so excited about the next 5 years? You see it on the slide in front of you. The potential of the pipeline is nearly double, looking forward, than it has been on actual over the last 5 years.

And not only that, what we strategically outlined to you as our mix shift, biosimilars are now approximately 50% of that shift. And that mixed delivery in the value and complex generics are also a more important part of the value. So that's really exciting for us. And as you know, we have a strong discipline and monthly operating reviews of this pipeline and near-term launches, and we're looking forward as a team to commercializing this in the years ahead. So with that, I welcome you to take a deep, energizing breath and welcome my colleague, Claire.

Thank you.

Claire D'Abreu-Hayling Executive

Thank you, Pierre, and thanks, Richard, for the introduction. I'm Claire. I'm the Chief Scientific Officer for the company, and I'm immensely proud to lead the development organization. You've heard from our colleagues, Rebecca, Keren and Paco about the commercial engine that we have in the respective regions, and you've also heard from Pierre about our selection strategy. And I think it's true to say that without a supply of new products, you don't have a business.

And I think that's really the criticality of the role of the development organization.

And with generic erosion being such an important part of the industry as well, continuing to provide a constant supply of new products remains a critical need for us to be able to support the growth strategy of Sandoz. So I can say, truly, that the development organization

is the engine and the very heart of Sandoz. And I'm proud to be leading that, and I'm really proud to have a very experienced, highly skilled and capable team passionate about science and passionate about our purpose of getting products into patients' hands.

Sorry. I've got the wrong -- okay. Great. From a personal point of view, my background, as Richard said, I started innovative pharma and then I moved to generic pharma. And I think one of the things I'm particularly excited about is the separation from Novartis.

And I think certainly from a generic point of view, doing development in an innovative company is very different from generic development. And I think some of the opportunities we have in terms of opening the market with lots of exclusivity, leaning into a more assertive IP strategy, really looking at how do we build agility, and that was the market approach to get products to the market is something that I'm particularly passionate about.

So as I said earlier, we have 1,700 people working across the development and regulatory organization. And it's not just development scientists and regulators. We also have patient safety because the criticality of products, the patients, and understanding how do we bring it in a safe way is an important part of our business. Our team is situated in the 6 development centers, and I will speak to you about that in a very cost-efficient footprint which optimizes the balance between access to talent and cost-efficient locations.

And more significantly, we have a really strong development track record, particularly in the biosimilar space, where we have had 100% success in going through our clinical programs and bringing products, particularly to Europe. But right across, as you heard from my regional colleagues, the presence that we have in the market of over 900 molecules in Europe means that we have succeeded in every product that we've started to develop. What I particularly like is the fact that we have synergistic capabilities across the biosimilars and small molecules. And I would call generic small molecules.

If you look at the size of the molecules at generics, anything, particularly in the peptide space, less than 40 amino acids. So small molecules and biosimilars. There is a very common technology platform, particularly in the injectable space and around the devices that means that we can really lean into the synergies, and there's a lot of power in having 2 combined under 1 umbrella.

Another key aspect is you've heard, I mean if I were to add up the number of markets, 40 in Europe, 26 main ones and 26 other channels in international and 2 with U.S. and Canada. We serve nearly 100 markets, so we have to understand the regulatory requirement for nearly 100 markets to be able to succeed in bringing products to market. And we do all of that between a combination of our own internal R&D capabilities and working with high-quality external partners because, again, because of our scale, reputation, technical capabilities and regulatory understanding, we're a partner of choice.

To Sandoz's development, regulatory organization, as I said already, has a proven track record in generics. You've heard already that our focus is really to come to the market in the first wave. We want to be first to market, because I think when you're first to market, you maximize the value you can actually bring. I've already spoken about the complexity of the different regulatory requirements across the different regions. And I think this is where we have built

and excel in that capability.

My organization truly understands how to manage complexity.

You've heard the word leverage mentioned on several locations. Leverage means that we get an asset identified by Pierre and his organization. We look at the regulatory landscape and which markets we want to play in. We work with Ingrid and her team and look at the IP landscape for each of those markets, and we understand how do we develop 1 product, 1 formulation that we can put into all the different markets, add the respective loss of exclusitive windows to ensure that we can cost optimize and [confers] the market with every opportunity.

And we've been very successful with that model in having over 280 launches in Europe in 2022. More than 80% of our launches are first to market in Europe. Similarly with Keren and her organization, we've worked to stabilize the U.S. and rebuild our pipeline, really leaning in on our first-to-file opportunities. And again, running that race that says, how do we optimize our development approach as we get to the window where we are in the first wave, either exclusive first to file or shared first to file?

And because of that, we can say that 1/3 of our launches are going to be first to market as we move forward.

And similarly, international, we've understood what the key markets are and how we've been able to successfully move from 10% first to market to more than 25% first to market in day 1, really building strong credibility, regulatory-wise in all of these markets.

I want to take a little bit of time and talk you through some of the leading capabilities and successes in complex generics. And maybe again, talk about my own experience, what really attracted me to Sandoz, and I unassumed in saying that was my curiosity, my scientific curiosity. I knew that Ferumoxytol was first to file from Sandoz, and I sat then I said there's a level of capability. And in this organization that I would love to understand how they manage to get this product as a first-to-file opportunity because it's a highly complex product.

It's an iron-containing molecule, complex API, active pharmaceutical ingredients, complex final dosage form characterization, significant barrier with respect to the FDA requirements for clinical studies. And to be able to develop it in-house and manufactured in-house, comforts to file and successfully launch meant that there was something in Sandoz that I wanted to find out about. And I'm pleased that I joined Sandoz because I was able to come in and really understand their capabilities in complex generics.

Another one that -- is only as a fulvestrant -- and I will compare that with the albuterol. We also have developed, quite extensively, our drug device combination capability. You can see 2 different types of products there. The fulvestrant is a prefilled syringe PS booked earlier by the prefilled syringe that we need for the EYLEA prefilled syringe capability. And again, the regulatory requirements about getting that approval is quite a critical skill.

And similarly, albuterol, a very different product, which is inhalable.

It's actually a meter dose inhaler. Those types of capabilities, again, is something that we've

optimized within Sandoz. And lastly, the other one, there is a transdermal, which again is a complex product that's been successfully launched in Europe. So the ability to bring high-barrier, high-technology, challenging products that have a high regulatory challenge is a success that we've mastered in Sandoz, a platform that we will continue to lean on and into as we continue to bring new technologies in the future.

Moving off our small molecule generics, I also want to talk about the biosimilars. Because that same spirit of entrepreneurial, the same spirit of innovation, the ability to bring new technologies is very much a characteristic of the development organization. Sandoz was the first to open the market, Europe, Canada, Japan, U.S. with biosimilars. We've been very successful at all the execution of the clinical programs we've done so far.

You heard Pierre talk about our 24-plus biosimilars, where we already have 8 that are in regulatory and clinical review and 16 that are in early development.

And I'm very excited about the 4 products that we're going to be launching within the next 2 years. Building on that, we're evaluating new technologies in the biosimilar space and leaning into really understanding how do we continue to optimize the biosimilar opportunities that we have, to launch them all and succeed with the development globally.

So maybe just to put the generics and the biosimilars into frame. I want to spend a little bit of time talking about our leading capabilities that allow us to deliver that 400-plus small molecules and 24 biosimilar assets that we have. And let me start by saying we work across 4 key technology platforms. Yes, we have the capability to work in every space. So we do nasal sprays.

We do ophthalmics. But primarily, our focus is biosimilars, oral solids, injectables and respiratory. And particularly, across the generics or so is injectables and respiratory, we are specializing in complex technologies.

The concept of end-to-end development, we really started looking at where do we start, identification of the asset, identification of understanding, how do we form small molecules, find the right active ingredient and for biosimilars have the right cell bank, all the way through formulation development, then the design of our clinical programs because for many of these products, particularly the complex ones, we have high barrier clinical requirements. Regulatory strategy and IP understanding, how do we find the sweet spot between regulatory and IP that allows us to leverage and get into all the markets. And lastly, working with Glenn to ensure we have the right manufacturing infrastructure, either internally or externally to be with the launch first-market and continue to supply the market because we're operating at the right batch size and scale.

Again, focus and strategy is an important part of the way we operate. Looking strategically on where we play and where we don't play. So from a vertical integration point of view, with APIs, active pharmaceutical ingredients, we are vertically integrated for our antibiotics as well as our biosimilars. So we want to have our own cell bank and our own anti-infective API internally. For our small molecule portfolio of generics, we partner externally, primarily because I think it gives us access to APIs at a very early stage that again allows us to continue to be first to file and laterally first to market with these opportunities.

Understanding the regulatory requirement and understanding how we shape policy is an important part of the way that we operate from capabilities point of view. Now these capabilities and my people are absolutely located in 6 development centers. And then I spoke earlier about the cost-efficient network. We've done a lot of work in Sandoz to really optimize the footprint, to ensure we have enough managerial bandwidth, to ensure we have strategic location of which technology sit in which center. And you can see that on the slide here that we have the 6 centers, and I'm particularly proud of the location in Cambridge in the U.K.

where we have a team of device engineers who specialize in building, designing, and developing injectable devices and respiratory devices, and I'm particularly proud of that because it's an area of synergy. We were able to use that capability across both the biosimilar portfolio and the small molecule portfolio. We already had -- prefilled syringes are in Ferumoxytol and Fulvestrant and we also have it in the Eylea. We have our oral solids located in 3 sites. We have complex injectables concentrated in Ljubljana, but more significantly, as we move forward, and increase and focus our biosimilars, we're building our own internal biosimilar capability.

And we've taken a strategic decision to build up on the back of our complex technology knowledge in Ljubljana, the analytical capability we already have in Holzkirchen and we will also be building our cell bank capabilities with Glenn in our Lendava site, which he will speak to later. Complementing the Sandoz development centers, we've also developed centers of excellence because we don't want to operate in silos. There was a question earlier about silos, whether [indiscernible] in silos. But from a development point of view, we don't want to operate in silos. So we've created centers of excellence where we put particular capabilities like polymorphism and other types of scientific capabilities that are of great significance to the regulatory agencies to ensure that we're doing it in a smart optimized way and again leaning into the synergies we have across those business areas.

Complementing the development team, as I said, I lead [indiscernible], an organization, which is development and regulatory. It's really understanding how we lean in and work with our regional colleagues to shape the regulatory landscape through advocacy and scientific discussion. We have a large, capable global team of over 700 people running regulatory. And one of the changes I've made recently is to integrate the regulatory organization. So we now have small molecules and biosimilars combined, and we are leaning into how can we find efficiencies in terms of operation activities, having the right sort of databases and tools that we would use from a regulatory point of view.

But more significantly, many of our subject matter experts are working closely with the regulatory agencies shaping, influencing guidance, developing and shaping the way that we do our clinical studies, so that we're making best use of clinical tools and designing studies in such a way that we're faster, we're more cost efficient, and we're building that agility that's needed to really ensure that we can [compress the file] and [compress the market] all of our portfolio.

So I've just taken some time and spoken you through the internal capabilities. I want to spend a little bit of time talking about our high-quality external partners as well. Because as you can see, I spoke about a breadth of technologies. It's not practical that we do every single

technology internally, both in terms of access to technology, capacity and risk and reward sharing and because Sandoz of its size, its capability, its market access, we are a partner of choice. And one of the things I'm particularly proud of is that we've just recently signed an agreement with Just-Evotec, which to me is really a disruptive signing.

It's a disruptive technology that we've secured access to where they use artificial intelligence to accelerate the development of their cell bank API capability for biosimilars. In parallel with that, they've also been working with the FDA quite closely to ensure that all the aspects are on continuously manufacturing, are understood and approved, to clear the path to ensure that we have access to high-quality delivery of biosimilars for our future portfolio at attractive costs. And we also have the opportunity to license some of that technology internally as we build our own development and manufacturing capability. Similarly, we'll continue to have a relationship with Novartis, where they will continue to execute some of the internal technical laboratory studies, while the predominant concentration of biosimilar capability already sits fully within our Sandoz network.

So in summary -- and I'm conscious that I want to keep the energy up. So I'm going to ask questions, who remembers what I've just said in the last 15 minutes. In summary, I think we have a really strong basis to continue delivering the pipeline. What tempted me to Sandoz is what's kept me here, that knowing that we have a best-in-class development organization, of highly capable and passionate scientists that really are doing their best to get products to the market. I always say that I'm a patient every morning, I use an eye drop with Sandoz on the box.

I have glaucoma and every morning I open my bathroom cabinet and I'm reminded why I'm in this job. We have the breadth of capabilities to cover all technologies. We decide whether we do it inside or outside, but we can do all of them. We have a really strong track record. I think some of the strengths of the organization is being able to work collaboratively with Pierre and his organization to go after the right asset and build the right target product profile to meet patient needs, to work with Glenn to make sure we can get it out to the patient because getting a file into the regulatory and getting it approved, that's half the job.

The job is getting it in the patient's sense.

And lastly, feeding, continuing to feed our commercial pipe with new products, in full, on time, at loss of exclusivity that gives us that competitive advantage to be a leading and most valued generic organization. And because of that reputation and excellence that we have, knowing that we have access to flexible network, whether it's inside or outside to pioneer new technologies like the oligonucleotides that Pierre spoke about and some of the other biosimilar new technologies that are currently under evaluation and which I will tease you with because we'll be revealing to some of those to you in the future. So I'll hand over to Glenn.

Glenn Gerecke Executive

Well, good afternoon, everyone. My name is Glenn Gerecke, and I'm responsible for manufacturing and supply here at Sandoz, which means that I am responsible for delivering that tremendous in-line portfolio that was described to you by our commercial leaders a little bit earlier today, and also the development portfolio that was just described to you by Pierre

and Claire. I am also responsible for delivering those 350 basis points of core EBITDA improvement that was referenced by Richard this morning and will be discussed by Colin this afternoon. So let me say that I am privileged to be leading the manufacturing and supply organization here at Sandoz.

We deliver products, pharmaceuticals to hundreds of millions of patients every single year, and we do it in a very high quality and reliable way. So let me take you through some of the key facts, if you will, about our network and about the way we run it that I think are really, really differentiating. And I know a number of you know the industry quite well, and I think, you will agree with me, are differentiating. So let me start with quality, first of all. So there are many ways to measure quality, and we do measure it in a number of different ways internally.

But our external measurement really is from the health authorities, from the regulators who come and inspect our plants and look at our products. And this number that I have here, I think, is quite significant. There's 160 regulatory inspections of Sandoz facilities over the last 4 years, without a single major or critical observation. It's really incredible. I'm very proud of this, and I'm very proud of what the organization has achieved.

That leads to the ability to highly, reliably provide these products, provide these important medicines to patients. And we provide these medicines 90% on time, in full during the year 2022. So what does on time, in full actually mean? When we receive an order from a customer, it may have many, many lines on it. They want a particular quantity and they want it on the date they want it.

So you can imagine, 1.7 billion packs being delivered 90% on time, in full with a product portfolio of, say, 27,000 or 28,000 SKUs. It's really quite amazing and speaks to the strength of this organization. The last thing that I would leave you with in terms of our network in general is we are quite asset light. So we have maintained the maximum amount of flexibility with the minimum amount of fixed cost. We have 18 internal manufacturing sites.

We have 700 external supply sites. And I'll take you through this, and I believe it's really, really differentiating. So the 350 basis points of core EBITDA improvement come from 4 different areas, and I will take you through each one of them. The first is internal and external network design. The second is vertical integration where we believe it makes sense and we choose to be vertically integrated.

The third is operational excellence, and I define this really as continuing to get more value out of a given set of resources. And the fourth is external spend or procurement optimization. So let me start out with the internal manufacturing network. I would characterize this network is 18 sites, very well-maintained facilities, very modern equipment, highly engaged associates and where we have the ability to get more value on a continuous basis through modest and targeted capital investment. So we can continue to get value out of this network.

It is a very strong basis for internal manufacturing. The network is largely oral solid dosage. However, we do have the capabilities to deliver on all of the complex generics and biosimilar dosage forms that have been discussed earlier. So in addition to being quite lean, it is also quite comprehensive.

On the left-hand part of this slide, you see that we've actually reduced the size of this network

by 7 sites over the last 5 or so years. And this is in the context of also increasing volume. So what has happened here is we've reduced our fixed cost and we've reduced our ongoing exposure to capital maintenance and CapEx. And I think this is really, really important in terms of the competitiveness story and also the flexibility story in delivering the product portfolio. So let's talk about what we will do in the near future.

So those 18 manufacturing sites that are internal today, we will close 3 of those sites in the next couple of years. And again, keeping with the theme of increasing asset efficiency and reducing exposure to ongoing CapEx needs. We decide what we want to manufacture internally based on where we believe that we bring a competitive advantage. Where we believe others bring that competitive advantage, we will choose to externally manufacture. And we are constantly evaluating based on the platforms that Claire and Pierre discussed with you the technology platforms and the individual products, business case by business case, which way we will go.

We're quite flexible. Shifting a bit to the external manufacturing network for a second, we today have 700 external supply sites. It's a big number. So let me break the number down for you a little bit. A bit over 200 of those are small molecule active pharmaceutical ingredient supply sites.

And as Claire just told you a little bit earlier, we choose the manufacturer for API that will allow us to be first to market, first to launch at time of LOE. And then as we do ongoing life cycle management, we choose other suppliers quite often who can give us a better industrialization of the product with lower cost, higher volumes, and so we are very happy to have these 200-plus supply points for small molecule API. It allows us to leverage the right supplier for the right product at the right time. And it gives us the ability to spend our money on small molecule API in the most efficient and productive fashion. That means there are about 400-plus finished dosage manufacturing sites in our external network.

And here's an area that I believe we have a tremendous opportunity to improve. So what we will do over the next several years is we will move those products either internally to our network, should we decide that we want to invest in a particular platform of technology or we will consolidate those products in many fewer external supply points. So that we can build strategic win-win relationships with fewer suppliers and where we can really build out our supply chain in a much more effective fashion. So plenty of opportunity to improve on our external network, and this is where a substantial amount of our operational productivity will come from. So then I thought I should make a few comments on Novartis as an external supplier to Sandoz once we do the spin out of Sandoz from Novartis.

We will put into place manufacturing supply agreements with Novartis that will carry us through the entire planning period that we're talking about this afternoon. Novartis will have the capacity to supply all of the biosimilars that are in our plan, both the in-line commercial biosimilars, but also the launch products that have been talked about this afternoon by Pierre and the commercial region heads. So that supply is locked in for us by these MSAs, and it is locked in at a price point, which is advantageous to where we would be able to source these products in the commercial CMO market. So we're quite happy with this relationship. Novartis is a supplier of extremely good quality, extremely good reliability, and we will have reliability of

supply.

Now of course, we will be looking to diversify away from Novartis as a single source of biosimilars. We've already mentioned Just-Evotec, Claire brought that up in a development framework, but manufacturing often follows development and the Just-Evotec deal gives us the ability to also option their manufacturing technology and scale these products up as well. And there are other options for us as well, which we'll describe to you in the future. So staying with biosimilars a little bit, I'll now switch to focused vertical integration. And so biosimilars is a product line, a group of products where we do want to have some vertical integration.

We do want to make the drug substance as well as the drug product. So you've seen our press release, and Richard has already mentioned this morning, we are making a significant investment in a site that we already own in Slovenia for a biosimilar drug substance manufacturing facility. It's a fully integrated end-to-end facility starting with cell bank management through manufacturing, quality control, storage and distribution. We will start construction this year, and we will be ready for technical transfer in late 2026. An important point for you that is not on the slide is this gives us another step change in productivity for the products that will go into this facility, which is all of the in-line products plus the ones that are in near-term development.

So quite a good story there, part of our strategy for focused vertical integration.

Another place where we will -- we are today, and we will continue to be vertically integrated is in antibiotics. So Gilbert mentioned this morning that in the early '50s, Sandoz actually developed and marketed the first oral penicillin. Since that time, the oral penicillin and the antibiotics portfolio has really been a key for Sandoz. We're quite proud to have such a wide array of these products available for patients. But it's also been a cornerstone of modern medicine throughout that entire period of time.

The world is dependent on antibiotics. We are a vertically integrated European supplier.

We've continued to invest in this business. We are #1 today in both value and in volume for antibiotics. We've modernized our network. Recently, we have invested EUR 250 million into our network to make sure that it remains state of the art, highly competitive, truly advanced in antibiotics manufacturing. And again, I should point out this investment of $250 million has largely been made already.

We will see the fruits of this, this year and in the next several years, and they will represent another step change in productivity for a significant portion of our cost base. So I'm going to move now from vertical integration and talk a bit about operational excellence. So much of what I have described to you this afternoon has been the result of an ongoing operational excellence program that Sandoz has had for a number of years. This is what allows us to really keep our fixed cost as low as possible, keep our flexibility as high as possible and give us the leverage between internal and external manufacturing. It's all about asset utilization.

It's all about bringing more value from a given set of assets. So we are constantly looking at removing bottlenecks. We are constantly looking at simplification in the portfolio. We are also looking at ways to drive process improvement, things like yield, things like how we set up the plants, how we organize the production schedules. And this has been something that we have

benchmarked both internally and externally.

We know we're good, but we know we have a long way to go on this. And so we've built this into our plan over the planning period and we understand the amount of productivity that we can deliver coming off of a very strong foundation, as I mentioned earlier. The last element is external spend. So I show you on the left-hand part of the slide where we are, call it, the end of 2022. $4 billion of external spend spread out over 13,600 suppliers.

It's a very diversified spend base with suboptimal to say the least leverage. And it is executed -- in '22, in the current day, it is executed by different parts of the Novartis procurement organization, not focused on generics. So a huge amount of improvement and a huge amount of opportunity exists with our external spend. Of the 350 basis points that I'm describing to you this afternoon, roughly 60% of those will come from external spend improvement. So the first thing we need to do is leverage our scale.

We have many projects queued up today both in the direct material space and in the indirect services space that are ready to go day 1. We will implement a very different way of, let's say, implementing these projects, and we will be able, as a generics company, to go much faster and much more deliberately. We will reduce complexity. So we will harmonize our product portfolio, making it much more efficient to produce, but also this will allow us to do a consolidation of spend on many of the commodities that we use in production. We will reduce our internal demand management as a generics and biosimilar company.

Demand for services should be appropriate for our business. We should have a set of services and business processes that are appropriate for us. We've started to map those out. We will have an execution plan ready for day 1. And finally, we've put together a procurement organization, starting with a brand-new CPO that has experience in both fast-moving consumer goods and in pharmaceuticals.

She has built a tremendous team, and they will be quite focused on what is needed for a stand-alone generics and biosimilar company.

So to sum up, we're starting in a really good place. We do have a high-quality and reliable supply network capable both internally and externally of supplying today's products and our future products. There are multiple levers, and I've named 4 of them for you, but they're broad categories. There are many, many, many subcategories to drive optimization over the near term and in the midterm. And we have an organization, which has all of the capabilities to deliver both short-term and long-term ambitions.

So thank you very much for listening. I appreciate it, and I'm going to hand it over to Richard.

Richard Saynor Executive

Happy to take your questions.

Anja Pomrehn Analyst

Yes, Anja Pomrehn, Mirabaud Securities. Two questions for Glenn, please. Glenn, you mentioned the cooperation you have with Novartis for this capacity for biosimilars. You say it's a long-term contract. Could you give us a little bit more color sort of what do you define as

long term?

Are we talking 3 years, 5 years, 10 years?

Glenn Gerecke Executive

So it covers the planning period we're talking about this afternoon, Anja, and beyond that. And we're not disclosing any real -- any more information than that right now, but it certainly covers the planning period we're talking about here. And as I said earlier, we're diversifying also away from Novartis in due time.

Anja Pomrehn Analyst

The second question would be regarding, again, the supply chain. I mean you indicated on Slide 94 the manufacturing sites. You said you're going to reduce them further. Most of the raw materials are coming from China. We came from a period now of supply chain disruption.

We might potentially face some more supply chain disruption from a geopolitical situation. How do you mitigate the risk that you will not enter into any kind of supply chain disruptions from this point?

Glenn Gerecke Executive

Right, Anja. Thanks for the question. And you're absolutely right. I think that geopolitical risk is probably the big one that is out there now. And the -- relative to China, from an API perspective, the raw materials for the API, whether you'd be in the innovative industry or whether you'd be in the generic industry, probably 80% or 90% of the raw materials that make the API do come from China.

So how do we mitigate against this? I think the first thing is strategic partnerships with our suppliers, right, which we will talk about. We talk about in terms of starting the life cycle in development, making sure that we have high-quality suppliers at that point in time, making sure they're selected carefully and then if we do transition that supply, we transition to another supplier that we know well, that we work with, that we have a significant amount of our portfolio with and that we constantly monitor and that we stay close to, et cetera, et cetera. So strategic supply relationships are important. The second thing that we can do, of course, is inventory.

And we did a fair amount of this in terms of coming out of the pandemic, I think all companies do put extra inventory where they believe that there is extra supply risk. And we're very, very close with our suppliers, our procurement organization. That's one of their major roles is to make sure that we identify those kinds of risks. And then thirdly, because of the way we do business, we actually have a lot of our key products dual sourced from an API perspective, again, starting in one place, transitioning to a second place with life cycle management. This -- so those 3 things really put together, I think are the mitigations that we do today use, and we will continue to use as we maintain our reliable supply and 90% on time, in full coming out of a pandemic year, I think, is a good proof point that the supply chain works as well as it really can.

Richard Saynor Executive

I would like to just add a couple of things. Clearly, it's not our intent to become vertically integrated into a molecule API. Okay. We do become vertically integrated in complex biologics and already are vertically integrated in anti-infectives. It's also worth noting -- I take your point on this drive, but actually the disruption on supply isn't due to API.

It's due to site closures, very thin margins at a manufacturer level.

And also, we [indiscernible] forced to use Indian or Chinese API because of the patent framework to find a non-infringing API in Europe is impossible because of the [indiscernible] framework. So, yes, there's a number of regulatory reasons why we have to do it. Certainly, we've had no major issues in terms of [indiscernible] even through COVID. But as a company, clearly, we're investing in our own API, but around biologics are complex, just...

Florent Cespedes Analyst

Florent Cespedes from Societe Generale, a quick question on complex generics. Could you elaborate a bit on, let's say, your plans, notably on oligonucleotides or eventually in peptide, would you consider to enter the GLP-1 market? And would you be prepared to build your own manufacturing capabilities? Or what could be your strategy on this already pretty big market and potentially even bigger in the coming years with development in obesity?

Pierre Bourdage Executive

Yes, sure. So as you know, as a matter of policy, we'll never comment on individual products. But let me take the opportunity to confirm that given complex injectables, complex peptides are part of our pipeline. Clearly, the GLP-1 space is a category where it strategically fits within our pipeline. From a capability perspective, I think I'll pass to Claire to talk about that from a manufacturing perspective.

From a horizon planning perspective, I would say we probably have enough time to discuss and really explore strategically what we want to do. It will depend on each unique asset. Not every GLP-1 is the same. Some are much lower volume, some are much higher volume and also depends on the indications and when they go off patent. And then oligonucleotide.

So I'll just capture by saying this is an emerging class. It's going to be a multibillion-dollar segment. The technology is early. But the early technology that we're seeing includes some technology, for example, that you'll know well from spinal muscular atrophy where Biogen has successfully commercialized Spinraza, which is categorized as an oligonucleotide. So that is just an example of the class and the specialty of medicine that will come and that -- this is a complex technology that I can't go into, but kind of short single-strand RNA or DNA.

Claire?

Claire D'Abreu-Hayling Executive

And maybe to pick it up from a capability point of view, I think looking at the GLP peptides and the oligonucleotide, a lot of it really sits around our analytical capabilities, the formulation capabilities, on your final dosage form. We have the right final dosage form platforms already

in-house and with some of our CMOs. And certainly, in terms of your complex characterization, that's capability we already have. So it provides a strong platform and foundation for us to internalize a lot of these and other new imaging technologies as well because we have those skills that are transferable and we will work with the regulatory agencies to ensure that we help influence and shape the right regulatory guidance, is to accelerate review and acceptance of the files once we move forward into -- in early to development stages.

Holger Blum Analyst

Holger Blum, Patinex. A question on Eylea and your perspective on high dose Eylea, whether that's making the party less fun for you or whether you plan to have such a formulation as well? And also sticking in the ophthalmic space, I mean, there's a more vital use compound with bimekizumab, Avastin brand and would you be interested there over to have an ophthalmic formulation on the market? Last question to finish it up, just maybe you highlighted. I appreciate the color on the 2024 launches.

Could you preview the class of 2025, what will be the biggest launches there?

Pierre Bourdage Executive

Yes. So on Eylea, I think, let me frame it up by saying aflibercept is given as an intravitreal injection on an 8-week basis, typically. And now there is high-dose Eylea that gives the option for patients to either move from 8 weeks to 12 weeks or up to 16 weeks depending on patient response and the decision of the ophthalmologist. Clearly, that's innovation coming into market that we'll face. There's also equally innovation coming from Vabysmo from Roche as a bispecific antibody.

Very good competitor, doing very well on uptake and also seeing the 16-week injection cycle.

So there are a few ways to think about it. Number one, we're used to facing new innovation. Adalimumab faces lots of innovation from many different classes in the immunology space and yet continues to grow. The second aspect is, for us, thinking about the market and looking at the fact that in U.S. and Europe, 45% to 55% of the total market is split between off-label Avastin and Lucentis, which are given on an 8-week cycle.

And so we believe with an $11 billion LOE, we will face some competitive pressure from the new formulation of aflibercept in high dose and from Vabysmo, but we think the market is very large and will still remain a very compelling opportunity. So that's the first one. The second one I'll make very short. On bevacizumab, we do have an in-licensed program by an external partnership. What I would say, though, is that we would never in-license and commercialize an asset off label.

And so we follow the label in terms of commercialization and off-label would not be a consideration for us in terms of bevacizumab. And then, for 2025 launch, I can likely clarify denosumab and aflibercept are in that time horizon, particularly as you look at Europe. Europe, we're looking at second half of 2025 base patent expiry market formation we're very confident on.

Graham Parry Analyst

It's Graham Glyn Parry from Bank of America. Just going back seeing in-house technologies in the oligonucleotide technology. Is that something that came from your parent from Novartis and what other technologies do you think you need to bring in-house over time, so you're interested there in cell therapies or radioligand therapy, for example?

And then secondly, when you're transferring your marketed or your late-stage biologics in-house from Novartis manufacturing, can you just talk us through the regulatory and technical hurdles that you have to overcome as you have to file sBPLAs? Do you need bioequivalence data for those as well? And then lastly, over the next 5 years, your launches with [3 billion peak] that you talked to, could you help break down that the biosimilars and generics across geographies? And is the majority of that coming from the U.S. or is that split more evenly across U.S.

and Europe?

Richard Saynor Executive

I guess that's Claire, Glenn, Pierre.

Claire D'Abreu-Hayling Executive

So I'll take the question on oligonucleotide and some of the other technologies. I think it's clear to say that the development organization for the oligonucleotide is small molecule organization, which sits completely within Sandoz. And there's been no interaction between Novartis and Sandoz on the development or evaluation of oligonucleotide as a technology. And we will not rely on Novartis to support any activities moving forward. It's a completely Sandoz internal capability based on the excellent foundation in analytical and formulation and regulatory that we already have.

And for some of the other emerging technologies, they are an interesting part of the portfolio as we move forward. We work very closely with Pierre's organization and look at what technologies and what molecules are coming off patent. And we start doing an evaluation on do we want to internalize that capability or partner on that capability or not. And at this stage, because of competitive purposes, other than the oligonucleotide, we won't be sharing any other technologies at this stage.

Richard Saynor Executive

Glenn?

Glenn Gerecke Executive

In terms of manufacturing and technical transfer, there's a portion of that, that has to do with the physical transfer of the products into the new manufacturing facility. And there's a portion of that, I think, in your question that had to do with the regulatory aspects of that. I'll take the first part, Claire will take the second part.

So in general, the entire process is about a 30-month process. There is a matter of bringing the existing molecule into the new manufacturing facility. And since ours in Slovenia, for

instance, will be brand new, we need to demonstrate that we can manufacture that product, that it can meet all of the quality attributes, and we need to do that in multiple times for what we would call a process validation. That data will become part of a regulatory file, which Claire's organization will submit to the various agencies. And so Claire, you can maybe talk about what that involves.

Claire D'Abreu-Hayling Executive

Yes. And I think certainly, that involves generating the data once we've executed the manufacturing aspects and manufacture the batches and really working very closely with the regulatory agencies to add the new site on as an additional site of manufacturer and going through the typical regulatory process. And again, from a cost and time line point, it would then vary on which market you're addressing.

Unknown Analyst Analyst

Is there clinical data needed for that?

Claire D'Abreu-Hayling Executive

I think, again, that's dependent on the market. We -- our preferred approach is that we would do it based on analytical characterization, the strength of that, and also compare it against our own internal product rather than comparing it to the brand product. But again, that's something that, as part of the tech transfer approach, we would have to have dialogue with the agencies to understand what they want to be able to demonstrate that we can do the tech transfer appropriately.

Richard Saynor Executive

Pierre?

Pierre Bourdage Executive

And then, yes, the last part of the question, I think, was bio -- or the $3 billion how much is bio contributing in geographic highlight. So biosimilars are expected to contribute approximately 50% of the $3 billion value potential. And I think the question was more ex U.S. To give you a little bit more flavor, let me use Europe as a really good example. So adalimumab high concentration in Europe is still going to face an originator with a sizable value.

And so, yes, we launched several years ago and we have a #1 position in Europe. As Rebecca outlined, we're growing double digit in our current net position in Europe.

We think high concentration is going to allow us to continue that growth. But the other assets have a lot of potential in Europe, natalizumab LOE in Europe is $750 million. The denosumab LOE in Europe is projected to be $1 billion or more. And as I alluded to, that $1 billion is from only 15% patient access today. And so the way I would think about this is denosumab is a very significant opportunity in Europe, perhaps larger than the LOE value.

And then aflibercept is a $2.5 billion LOE in Europe. And so I guess the general answer is that there's a good balance in the biosimilar launch pipeline, both on U.S. and ex U.S. scope.

Richard Saynor Executive

And it also is associated value. This is just the value we'd expect to extract within the next 5 years. Our human growth hormone is 15 years old. I still don't think it's reached peak value. So I think the opportunity for these products to continue to expand and grow beyond that 5-year horizon is also worth considering.

So I don't really think of it as a peak value, just as this is the value we would expect to create in the next 5 years, really in line with our guidance.

Simon Baker Analyst

Simon Baker from Redburn. A couple of questions for Glenn first. You hopefully gave us the contribution to the 350 basis points of operational optimization from procurement. I wonder if you care to give us the absolute or relative contribution of the other 3 buckets. And related to the issue of costs and refining the manufacturing footprint, to what extent is the ongoing pressure/chatter from the European Commission on reshoring pharmaceutical manufacturing in Europe?

And then a final question, picking up on something that Claire said about, I think you described the more assertive IP policy as an independent company. We've known for years that you've had to play nicely, owned by Novartis, which is why we [indiscernible] for instance, when there wasn't a paragraph IV challenge to Kisqali March '21. So on day 1 of the split, are there any restrictions on your freedom to operate from Novartis?

Richard Saynor Executive

I'll take the last question first and then pass to Glenn. No. I mean, clearly, what we haven't done is develop assets in competition to Novartis whilst we've been part of Novartis, It would be -- incrementally, it's crazy to spend money developing competitors to Novartis. Post separation, we would be free because, obviously, we're creating 2 completely separate entities. There'll be a period where we clearly can't -- where we'll be very cautious about any knowledge gained whilst being part of the Novartis Group.

But ultimately, these will be 2 separate companies. And clearly, we would look -- and no other pipeline in the medium, long -- in the short to medium term is included in terms of the Novartis portfolio. So we don't -- yes, it's not a major opportunity for us in the short term, but in the medium and long term, clearly, we would be a competitor.

And you're right, clearly, we would take a more assertive position around IP, policymaking and positioning with authorities, but that's a natural. To be fair to Novartis, they've given us a pretty reasonable framework up until now. So I would not -- Glenn?

Glenn Gerecke Executive

Sure. So yes, the external spend optimization is about 60% of the 350 basis points. I can go into a little bit of semi-qualitative detail on the other ones. So the vertical integration, for instance, in antibiotics enables us to close 2 of the 3 sites that I mentioned that we'll be closing in the next few years. So that kind of works together, where we make that investment and then we're able to take some assets off-line, some fixed cost and some ongoing CapEx

obligations off-line by developing a much better process, making the other -- the processes run at the other 2 sites really obsolete.

And then if we think about operational excellence, it enables us to really internalize more of our supply and enables us to reconfigure the network, right? So the operational excellence really is an ongoing program. So I really -- although we have built up a bottoms-up plan, for you, I would really think about the other 3 elements besides procurement to be contributing the other 150 basis points, really working together and giving us the flexibility to optimize.

Richard Saynor Executive

I think we're pretty much of time, Rebecca you can make a couple of comments about the European move in terms of localization. Because I know in your current position as Vice President of Medicine for Europe.

Rebecca Guntern Executive

I think I'm loud enough.

Richard Saynor Executive

We can use -- or use that.

Rebecca Guntern Executive

No, listen, there is a lot of discussion ongoing for reshoring. And I think there's a huge interest to bring back manufacturing footprint. What we're saying always in Brussels in terms of medicines for Europe, let's make sure that we keep what we currently have in Europe. That's first and foremost, the most important priority. And let's create a framework where products being produced in Europe will be consumed by patients in Europe.

And then, of course, it's going to take time. It took 10 years for offshoring. It's going to at least take the same time. And I think we need to think in a global supply chain. It's not going to be European or U.S.

or an Asian supply chain, It's going to stay global because for many reasons, right? It's not going to be that we bring API back to Europe.

Richard Saynor Executive

Perfect. Thank you. Okay. I think we're at time now. So I'll now move on to the finance section.

So I'd like to invite Colin to the stage. Colin, I've worked with Colin on Sandoz just over a year ago. He has deep capital markets experience, particularly in Switzerland. He was CFO for Vifor and also Evotec SE. He's a Board member of Siegfried, and he's brought [core] strength and support over the last year as we take the company public.

So Colin, I'd like to introduce you.

Colin Bond Executive

Thank you, Richard. I'm British, but also became Swiss. I arrived in Switzerland in 1995, just as

Ciba and Sandoz were being put together to create Novartis. And for me, it's unimaginable to be here in London as part of Sandoz, promoting the company ahead of a spin. The sponsoring banks and the media experts banned me from using a certain word, but I'm going to use it once to describe how I feel.

I think it's cool. It's really very cool. So you've heard from my colleagues during the course of the day about the uniqueness of the Sandoz business and the exciting potential, and it's my job now to summarize what that means from a financial perspective. And the best way to do that is to look at 3 distinct time periods: the period '21, '22, the past, where there were clear known macroeconomic challenges; then the present '23, which for us is a year like no other separating the businesses; and then most excitingly, the period from '24 to '28 when we will accelerate profitable growth as an independent stand-alone generics company. So to the first of those periods, '21 to '22, the macroeconomic challenges are well known: the pandemic, the war in Ukraine and resulting supply side inflation.

What was really impressive is that we continue to invest in commercial initiatives and the pipeline during that period. So I will start with a summary of the key financial highlights, starting with net sales. Net sales grew in constant currency in 2022 by 4%. Core EBITDA reduced by 0.9%. This was due to inflation primarily that accelerated in the second half of the year.

And then free cash flow declined from 10.7% to 9.2% of net sales, but this was for a positive reason, that we needed to increase inventory in support of the strong top line growth. What I would like to highlight is how robust the business was during COVID and how strongly it recovered post-COVID. And of course, we will be publishing our prospectus with full carve-out financials in due course. Looking at the net sales growth between '21 and '22. We will report in U.S.

dollars as Novartis does, and about 40% of our revenues are in euro. After adjusting the '21 sales for the depreciation of the euro against the dollar in '22, we reported 4% constant currency growth. We had approximately 10% volume growth or [$0.9 billion], and that was offset by approximately $600 million or 6% price erosion. Price erosion is fundamental part of our operating business, of the generics business, and that 6% is absolutely in line with what we've experienced in previous years.

Richard presented the split of net sales between the 2 businesses this morning, but it's a significant slide so I'll present again. Generics account for 79%. From a financial perspective, generics represent a diversified, stable cash-generating platform. Biosimilar, as you've heard from my colleagues this morning, we have 4 biosimilar launches. Biosimilars are growing strongly at 9% ahead of those launches.

The next slide, looking at the regional distribution of the sales in 2022, was again presented by Richard this morning, but it highlights the size and scale of our European champion region, 50% of the total sales. It highlights the strong growth in International, plus 7% despite the challenges in Ukraine and Russia. And as Karen described after many years of decline in the U.S., the U.S. business was in the process of stabilizing ahead of the 4 key biosimilar launches. Looking at the EBITDA bridge as a percentage of net sales between '21 and '22.

There's 3 bridging items I'd quickly like to call out. Firstly, operational improvements added positively 80 basis points, and that was a combination of procurement savings and conversion cost reductions. Why I want to highlight this, it's a great proof point for the margin expansion that Glenn just spoke about. Secondly, investments were minus 80 basis points. That was due to positive business reasons.

firstly, we invested in commercial initiatives in support of the strong top line; and secondly, we had integration costs to bring onboard the 2 acquisitions that [Paco] spoke about, the GSK cephalosporin business and the Japan Aspen business. And finally, inflation, as I said, accelerated in the second half of the year and had a negative impact of 120 basis points. Looking to the second time period, the present. What's really exciting about this year is the 2 biosimilar launches timed for the second half of the year. Supply chain inflation is clearly there and it's -- but it's an industry-wide issue, and I'll come to the details in a moment.

And what's impressive is that we're continuing to invest in capability, capacity and pipeline, as you've heard from my colleagues during this year. And of course, we have stand-alone costs to set ourselves up as an independent generics company. Looking at the net sales momentum into 2023. We recorded 8% growth in net sales in Q1. What was particularly encouraging about this number is that Europe had a growth of plus 16%, that's our champion region.

And secondly, biosimilars grew at 17%, which is critical given the importance of biosimilars to our strategy. Looking at the EBITDA bridge from 2022 to '23. The key items to call out are 2 stand-alone costs that will affect the margin by about 100 basis points. These are the costs to operate as a standalone generics company. And secondly, inflation, what we see is input costs increasing by up to 10% this year.

But I think what's really encouraging in the first half is that we see significant signs of inflation decreases, particularly in areas like utilities, which give us confidence for the future. Then looking most excitingly to the future. And what we've tried to do in the next slide is give you enough information that you can develop your models in advance of Sandoz becoming a stand-alone company. So we're committing, as you heard from Richard, to mid-single-digit top line growth over the period, That will be driven by the 400 generics in the pipeline that you heard from Pierre and the 4 commercial biosimilar launches. We will expand the EBITDA margin, as you heard from Richard and the details from Glenn, from 18% to 19% to 24% to 26%.

And we will improve free cash flow conversion as a percentage of EBITDA to 70% over the midterm. Now cash is fundamental, and this is a conceptual slide, I know, but it's important. It starts with the top line. We're committing to mid-single-digit top line growth, You've heard we're in a highly attractive market. We have scale in a leadership position, and we have multiple top line drivers of growth.

Secondly, margin expansion. You've heard from Pierre the mix effect from the bio, from Glenn, the operational improvements. And in addition, we will have organizational efficiencies that I'll come to in a moment. And both of those things together will drive strong free cash flow conversion. And in addition, as a stand-alone company, we will have the opportunity to use assets more efficiently, particularly working capital.

Looking at the net sales growth over the period from '24 to '28, split between the 2 businesses. It's balanced growth behind the mid-single-digit growth: generics, because of the size of the denominator, and biosimilars because of the strength of the top line growth. And as Pierre said, we expect the proportion of bio to change from 20% in 2023 to 30% by 2028, and that will have an impact on the mix that I'll come to shortly. Then looking at this mid-single-digit sales growth by region. Approximately 50% will come from the U.S.

That should be no surprise because it's driven by the 4 biosimilar launches. And the other 50% will be split approximately evenly between international and Europe.

Now the EBITDA margin as a percentage of sales for the period '23 to '28, and I will spend a little bit of time on this because it's key, and I understand that. So we started at 18% to 19%. And the first impact that we have is volume. Let's say that we grow at 5% a year over the period, cumulatively, that's approximately 30%. We can leverage that 30% more volume through our infrastructure and get a volume impact on the bottom line.

Secondly, the product mix. I spoke about the proportion of bio increasing from 20% to 30%. Historically, bio has had a margin that's 20 percentage in absolute terms higher than generics. Now taking that 20% to 30% top line increase and applying a 20 percentage margin improvement gives you approximately 100 basis points improvement over the whole business. Glenn spoke about operational improvements contributing 350 million basis points.

Approximately 60%, we believe, will come from procurement and then 40% from vertical integration, network design and operational excellence.

Finally, organizational efficiency will contribute 150 basis points. We have a fantastic opportunity now to redesign the organization to standardize, to automate, and this will improve the performance from an organizational efficiency perspective. You will clearly ask how is that phased over the time period? And perhaps I'll give a little bit of color on each of these components, firstly, volume. We expect that to be evenly phased over the time period.

Likewise product mix, we think that, that will be spread in a balanced way across the midterm, that increase. Operational improvements, the procurement piece, 60%, again evenly spread. But the other 40% related to vertical integration and operational excellence and network design, that's more skewed towards the back end of the period. Organizational efficiency, we see that being skewed towards the front end of the time period. Then looking at the CapEx over the period from 2023 to '28.

Historically, we have spent 2% of net sales per year on CapEx, replacement CapEx, and we expect that level to continue. So that's the right-hand half of the pie chart, the $1.1 billion. That's 2% of sales for 5 years. Then looking on the left-hand side, Glenn talked about the biosimilar investments that we're going to make, particularly in capacity in Lendava, and that's going to be $0.6 billion. And then the bottom left-hand segment, $0.6 billion of CapEx to support the 30% growth in the generics business over the time period.

Richard spoke this morning about cash generation, and this one is key. We expect to go from $0.8 billion in 2022 to 2.5x increase by 2028. That's driven by the top line, which I've described, the mid-single-digit growth, it's driven by the margin expansion, and it's also driven by the opportunity to use our assets more efficiently.

Richard also spoke about our balance sheet this morning, and we will be uniquely differentiated versus our competitors. We're going to be spun with a really strong balance sheet, that we will be financed through bank loans. We will access the capital markets in the months following the spin to refinance with mixed durations. And we expect at the separation to have a net debt to core EBITDA ratio, as Richard described this morning, of 2 to 2.5x. And we're in the process of getting 2 investment-grade ratings ahead of the separation.

Richard also spoke about capital allocation this morning, but its key. Capacity expansion, that's the $0.6 billion in the bio capacity and capability in the $0.6 billion in the generics expansion, together with the stand-alone capabilities. On D&R, we currently spend about 9% of our net sales on D&R. We expect that level to continue because that's creating the pipeline, but we will shift the proportion increasingly into bio. Returning capital to shareholders.

We have a progressive dividend policy. That means as the profitability increases, the dividend will increase and we will increase the portion of the dividend as a percentage of net income, and I'll come to the details in a moment. Finally, we will look to exploit external opportunities with our strong balance sheet. We think we're uniquely positioned to compete in actually accessing M&A and BD&L opportunities.

This is my final slide. Again, Richard presented it this morning. It's a summary of the guidance. Mid-single digit for 2023, mid-single digit through to 2028. Core EBITDA margin, 18% to 19% this year for reasons that I've clearly explained, increasing to 24% to 26% for the developments that we've covered.

Then the dividend policy, as Richard said, the '23 dividend will be 20% to 30% of core net income in '23. And we will pay a full year dividend. And then we will increase that proportion to 30% to 40% by 2028. With that, I'd like to hand back to Richard.

Richard Saynor Executive

You've stolen my pen. I can't leave anything down. Right. Okay. Thank you so much, Colin.

I'd now like to talk about our sustainability story. We started to talk about that at the beginning of the day. And clearly, as we separate from Sandoz, we have an incredibly foundation in terms of corporate governance. I'm clearly led by Gilbert and have an incredibly strong Board. Access is very much core to our business.

Driving patient access, particularly about biologics, democratizing these products around the world is core to our very purpose and core to our varied business. As we separate from Novartis, clearly, we inherit a strong framework in terms of environmental footprint, and I'll take you some through the details there. And we'll give clear guidance early part of next year when we publish our annual report in terms of our future targets and expectations.

And as an organization, we champion diversity, equity and inclusion. Actually, of all the slides I presented today, this is the one that probably I'm the most proud of. It really comes to the reach and the impact that Sandoz as an organization have and it's significant. Directly, we save about nearly $17 billion to $20 billion directly from U.S. and European health care systems.

As we've said before, we reach over 500 million patients a year and have a social impact of nearly $200 billion. We've launched biologics now in nearly 90 countries. Some of those I've said before, the originator hadn't even launched those assets. 8 marketed today and 24 in our pipeline, a significant opportunity to transform patient lives as we go forward.

Also in terms of antibiotics, we're one of the few, if not only remaining antibiotic manufacturers left in the Western world. We're, however, 50 antibiotics in our portfolio. We invest heavily in terms of connecting and educating physicians around the right use of antibiotics and are continuing to invest in world-class technologies to ensure that these products stay sustainable for generations to come. So incredibly proud of the social impact that Sandoz has at its very core. Clearly because of that, we're very actively engaging with key stakeholders.

So I'm Chairman of the IGBA CEO Advisory Board, Rebecca is our Vice President of Medicines for Europe, and Karen is Vice President for AAM, the Association of Affordable Medicines. We started a program called Act4 Biosimilars. This is a way of connecting and engaging payers, patients and physicians in terms of driving the access and the uptake of biosimilars across the top 30 markets in the world. And we're also actively engaged with key opinion leaders and key active actors, so the FDA, the EMEA in terms of the European Commission. We're investing in technology platforms to support antimicrobial resistance.

And we're also part of the AMR networking group, really thinking about clean manufacturing, sustainable manufacturing in these critical products.

In terms of our environmental credentials, over the last 5 years, we've decreased greenhouse gases by nearly 50%, water consumption by nearly 42% and total waste by nearly 60%. And clearly, going forward, we'll continue to focus on decarbonization, water and waste management, and ultimately, sustainability across our supply chains. And again, we'll give you details of those early part of next year.

As an organization of over 22,000 associates in nearly 100 markets, this is what makes Sandoz today. We have a diverse workforce with nearly 50% leadership positions represented by women. We've engaged enhancing inclusion and organizational belonging. And you see this in our engagement scores and the external Glassdoor scores, which are industry-leading. And we're committed going forward to 100% pay transparency of all our associates by 2025, maintaining a strong gender balance as an organization and continues to build an environment of inclusion and inclusivity across our leadership and our organizations.

Also founded on a very strong corporate governance. As I say, Gilbert was announced as Chairman-Designate, 10 fully independent and very strong Board members with strong female representation. A very strong cultural foundation is embedded in our business with a robust code of ethics we take away from our parent company and an integrated risk management program. We commit to best [rule beholding] practices through GRI and TCFD going forward. And again, we will publish those in the early part of next year.

We've covered a lot of ground today. And really, the next few months are going to be critical. This is a 100% spinoff as we separate from Novartis. We intend to list on the Swiss Stock Exchange and headquartered in Basel in Switzerland. As Colin has discussed, we intend to

maintain an investment credit grade rating, which is a key differentiator versus our peers.

We will publish our half year results with Novartis on the 18th of July, and we expect this transaction to close in the second half of 2023. We covered a lot of the ground, as I said today. The attractive market fundamentals, our leadership and scale, multiple growth drivers, our margin expansion plans, our strong cash flow, and our sustainability. But really I want to reflect about what we've covered, really, there's 4 things that I'd like you to take away. Firstly, our growth agenda.

We have a strong and dynamic business coming from numerous growth drivers. We have been champion in Europe and a strong and dynamic international. We stabilized the U.S., and we're now positioned for strong growth. At our core, we're a biologics company. Today, we're already represented as #2.

We have one of the strongest portfolios in market. We're a leader in Europe and many other geographies and an unparalleled pipeline of which significant numbers of assets will launch over the next few years. And lastly, we can deliver strong margin expansion as we separate from our parent we have clear routes to expand our margin, improving on our EBITDA and returning cash back to our shareholders. I thank you for your conversation today. I thank you for your questions.

Ladies and gentlemen, I give you Sandoz.

Richard Saynor Executive

So we'll have 30 minutes of Q&A.

James Vane-Tempest Analyst

James Vane-Tempest from Jefferies. Just 2 on cash flow, if I may. Firstly, the development and regulatory spend, how much of, I guess, development expense versus capitalized? And how should we think about that, the impact to the P&L and the cash flow statement over time as you continue to invest? My second question is on CapEx.

You've highlighted investments in potentially software reducing systems and other costs. So when we think about the evolution of the cash flow bridge, is that expected to be more back-end loaded towards the investment time horizon?

Richard Saynor Executive

Colin, both for you.

Colin Bond Executive

Yes. So on the first of your questions, we don't capitalize the D&R spend. We put it through the P&L, which is different for some of the competitors out there. Secondly, I was galloping through the slides because of the energy levels. And I forgot to highlight that there's $0.7 billion of separation costs, including of which $0.5 billion -- actually, $0.2 billion is CapEx, but there's $0.7 billion of separation costs that are in the cash flow, which will occur in the period '23, '24 and '25.

Unknown Analyst Analyst

[Bettina] from UBS. This is, I think, a question more for Richard. In terms of the medium-term growth expectations. What do you think is the disconnect in terms of consensus current forecast of 3%? What is the market not seeing at the moment?

Richard Saynor Executive

I would say probably the strength of our pipeline and our ability to expand and grow, particularly in biologics, I think, myself, I didn't really appreciate this expansion of the biologics business, the fact that we have a business in Europe that's still growing 3 years after we last launched a biosimilar at nearly strong double digits. I think that -- more than that and the strength of our pipeline. I think we have 24 assets, 4 assets in the short to medium term, some of which actually will have very low levels of competition, presents a significant opportunity coupled with the small molecule expansion. And I think Pierre summarized it very well. The fact that we've got really double the value creation opportunity, we put the portfolio over the next 5 years versus the previous 5 years is really key to that growth driver.

Marietta Miemietz Analyst

Marietta Miemietz, Primeavenue. Just a couple of questions on the margin, please. Do you see any scope for further margin improvement beyond 2028? Because I assume that you're still going to have -- you still have a long of -- lot of runway for your biosimilars business beyond your planning horizon. So you could still get very good mix effects post-2028 and maybe some of the operational excellence initiatives will sort of carry beyond 2028.

Or do you think that, that is going to be a high watermark in '28 and you're going to start reinvesting? And also, just to quickly clarify, on the margin target for '28, would you still stand by that if we were to have double-digit inflation throughout your planning horizon? Because I do hear you that energy costs are coming down, but some of the structural factors that led to the high inflation in the last couple of years are not going to be going away. So I'm just wondering have you played devil's advocate and kind of like simulated what your business would look like if this high inflation were to persist?

Colin Bond Executive

Yes. So on the first of your questions, we're at the start of a journey here. We are becoming a stand-alone focused generics company, and what we're committing to is the 2023 guidance and then the 2028 guidance. But again, '28 is just partway through the journey. And you've heard from Pierre and Richard, the 24 biosimilars that are in the pipeline, 4 of which are being launched during the period to '28.

So clearly, there's the opportunity to further improve beyond '28. In terms of inflation, I think it's important just to spend 2 or 3 sentences explaining that we actually have a very balanced assumption in our midterm projection. So historically, price erosion has been 5% to 6%, and as you heard from Richard this morning. And we've had over the last 3 to 4 years low single-digit input cost inflation. Now what we have this year is up to 10% inflation on the input costs.

What we're expecting next year based on what we now see is that there could be some

declines in 2024. But those will be offset by the fact that we capitalized higher inventory costs, and there's a 6-month delay before they hit the P&L. So our assumption is zero inflation in 2024 and then we revert to what we experienced prior to this disruption, which is minus 6% -- 5%, 6% on the top line and low single-digit inflation on the input cost. Of course, since we got hit with those input cost inflation, we're working with the payers and the health care authorities to try and get fair and sustainable pricing for our products, but there's a lag in that. And if those assumptions that we have on inflation turn out to be different, then we will have to work to then leverage with the payers and the health authorities to get the appropriate pricing for our products.

Richard Saynor Executive

And also it's an industry-wide effect. It's not a Sandoz-specific effect. Okay. If we have no more questions, I suggest we close here.

And thank you so much for your engagement today. Thank you for your questions. Thank you to my colleagues. Thank you very much, ladies and gentlemen.