Novartis AG

Analyst/Investor Day - Novartis AG

Thursday, June 8, 2023 9:00 AM

Event Participants

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Samir Shah Executive

Good morning, everybody. Welcome to the Sandoz Capital Markets Day. And what I wanted to say is a big, big thank you to all of those people who've actually managed to get here. We've had a number of people who've actually had to cancel because of their flights and things like that because of the New York related issues with the weather and the smoke. So for all of those of you who've made it here, congratulations getting to the place.

So it's wonderful to see you all. If we just go through, we've got a packed agenda, and it's on Slide 4 for the people who are on the webcast. We've divided the day into 4 main areas. Initially, we're going to go through the Sandoz business, the strategy, investment proposition, which is going to be led by Gilbert, the Chairman-Designate as well as Richard, the CEO of Sandoz. We then go through into the commercial section, which is our session 2, and you'll hear from the heads of the commercial parts of the business across the 3 regions for Sandoz.

Following that in the afternoon, we're going to go into the operations part of the presentation. And finally, we'll finish off with the financial outlook and the overall wrap-up of the day and with the key messages, et cetera. One thing to emphasize is there's going to be plenty of time for Q&As at the end of each session. Today's objectives for the Capital Markets Day is, obviously, people are here from Sandoz management, so you have an opportunity to actually meet them. We're going to introduce you to the Sandoz, the company, its strategy, the growth drivers.

[We're going to] explain the benefits of Sandoz as a stand-alone company as opposed to being a part of Novartis. We're going to go through the financial framework as well as the guidance to midterm. And of course, I would like to answer any of your questions. Now a couple of things just to bear in mind. The first one is the Sandoz [indiscernible] is still subject

to the Novartis Board of Directors' approval.

And subsequent to that, it's got to go through the shareholder vote, and we're planning to do that at the Extraordinary General Meeting. And besides that, and before I hand across to Gilbert, who will introduce some of the management, I just wanted to read the safe harbor statement. So the information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. For a description of some of these factors, please refer to the company's Form 20-F and its most recent quarterly results on Form 6-K that respectively were filed with and furnished to the U.S.

Securities and Exchange Commission. And these are the presenters, and I think Richard is going to spend a bit more time actually going through. It's my great pleasure to now introduce Gilbert Ghostine, the Chairman-Designate. Gilbert?

Gilbert Ghostine Executive

Good morning, everyone. [indiscernible] introduction. We are all extremely excited to be here today. This morning, this is our first Capital Market Day for Sandoz. It's a very important day, a very memorable event.

And at the same time, Richard and I and the Executive Committee are extremely excited to share with you our passion for this business. And although, as Samir said, there is fog outside, we will give you very good clarity into why we're excited about this business and what will be the key milestones that we will deliver against between now and 2028. My name is Gilbert Ghostine, and I'm extremely excited to be -- to have been and honored to have been appointed by Novartis as the Chairman-Designate for Sandoz during this very important transition for this business. We will share with you some deep insights into what makes Sandoz a really European champion and at the same time, a global leader in the worlds of generics and biosimilars. We are extremely proud of our past, but at the same time, we are extremely excited about the future because we will share with you later on why we're excited and what are the opportunities and milestones that we have ahead of us.

I joined Sandoz in February of this year and immediately have been extremely impressed by the quality of our team, the entrepreneurial culture and at the same time, how proud and excited are our people to be able to shaping health care and to make a difference to society. And the reason I was extremely excited to join this company is this mission. When we are thinking about bringing affordable medicine to underserved population, and at the same time, all of this coupled with the exciting value creation opportunity for our shareholders and key stakeholders. Now turning to Sandoz. The uniqueness of this brand starts with its name and its roots.

Sandoz is not only recognized in its home market that is Switzerland, but all around the world and the recognition and the credibility that the brand has is mainly driven by its commercial strength and at the same time, by the credibility that it has built over time in the market with customers, with consumers, making a difference to society. And at the same time, making a difference and taking a leadership in everything related to off-patent medicine. And this is a

result of not only a long-standing Swiss heritage, but at the same time of a consistent commitment to its purpose of pioneering access for patients on a global scale. And this, combined with a long and strong track record of high-quality delivery and reliability as well as the ability to select first-to-market opportunities through constant innovation will continue to make Sandoz a credible global brand that will stand out in this industry over time. Now Sandoz has come a long way since its creation in Basel back in the late 19th century.

With innovation in its core, the company has a strong heritage in bringing life-saving medicines to patients. Sandoz was not only the first company to introduce oral penicillin in the early 50s, but most importantly, the first biosimilar in 2006. In 2005, Sandoz established its leadership position in the generics industry with the strategic acquisition of Hexal in Germany. It later became the first company to achieve blockbuster status or more than USD 1 billion in sales with a generic enoxaparin. In the last decade, Sandoz continued to strengthen its leadership in generics and biosimilars with targeted investments in biosimilar capabilities, combined with value-accretive M&A and strategic partnerships.

This contributed to the creation of the current strong and rich pipeline of more than 400 generics and 24 biosimilars and one of the broadest generics product portfolio and a leadership position in biosimilar in 6 out of 10 of our big global markets globally. Our heritage sets a strong basis for future success, deeply rooted in Basel, we announced our intention to keep our headquarters in this global life center and at the same time, that is ideally located for us to attract high-quality top talent. We will remain a key player in antibiotics and keep investing in the last vertically integrated antibiotics generics production in Europe to support increasing global demand. We will also continue to invest in capabilities that offers us the flexibility to develop new technologies and support our focus on first-to-market opportunities in complex generics and biosimilars and beyond. With its leadership position in generics and biosimilar, Sandoz is at a very different point along the biopharma value chain compared to the Innovative Medicines business of Novartis.

The limited synergies between the 2 businesses support the proposed spin-off, which offers numerous additional benefits. Enhanced focus with simplification and optimization of resources allocation to deliver on our ambitious objectives, greater agility and freedom to operate and adapt to evolving off-patent medicine market conditions that will require lean and fast decision-making, improved accountability with ambitious value-creation goals and clearer business objectives as a stand-alone company more aligned to the specificities of our industry, value creation with a clear path for more profitable growth and enhanced shareholder returns. Our business is poised to grow in the midterm with significant margin improvement and free cash flow generation as you saw this morning from our press release. And last, a generics culture fostering an entrepreneurial and agile mindset with a drive for executional excellence. A spin-off will allow Sandoz to pursue its vision to become the world's leading and most valued generics and biosimilar company and continue to create sustainable long-term value creation for our shareholders and a major impact for society.

Now my first task as a Chairman-Designate has been to set up the Board of Directors of stand-alone Sandoz. And I'm pleased with the group of leaders we have put together, a truly world-class Board at the level of Sandoz ambitions. The new Board brings a broad range of expertise and capabilities to help Sandoz fulfill its value creation aspiration. And as you could

see on the screen, its 10 members are or have been active in some of the largest companies in health care and across a wide range of other industries as Board members or as executives. And Sandoz Board composition stands out with 60% of its members being current or past CEOs or CFOs, 50% have deep health care expertise, 50% have strong experience and expertise in FMCGs, 40% are female, 100% are independent and no overboarding.

The Board of Directors will have 3 subcommittees: an Innovation, Development and Science Committee, a Human Capital and ESG Committee and an Audit Risk and Compliance Committee. We have started the preparatory work and will be effective following the planned spin-off of Sandoz in the second half of 2023, obviously, as Samir mentioned, subject to Novartis Board of Directors and shareholders' approval. So I'm looking forward to working with the new Board to help set up the strategic direction for Sandoz and support its future development. Now before handing it over to Richard, I would like to express my appreciation for our fruitful collaboration over the past several months. Richard is a seasoned and proven CEO with a wealth of experience in the generics and biosimilars industry.

Richard is someone that is truly passionate about this industry. He really cares, he wants to make a difference. He wants to make Sandoz a big success. And at the same time, he is really committed to shaping health care and giving access to clients and deal in a leadership position with off-patent medicine. Because of his in-depth expertise of this industry, he has been appointed as the Chair of the International Generic and Biosimilar Medicines Association CEO's Advisory Committee.

And Richard, since he was appointed as a CEO back in 2019, has proven his capacity to transform this business, put around him an outstanding leadership team that you will have the opportunity to get exposed to later on, drive performance and at the same time, create through his relationship, a pipeline of innovation that can transform this business into the future. This is why we are extremely confident that we will be able to deliver against our ambitions. And with this, I will hand it over to Richard. Richard, over to you.

Richard Saynor Executive

Good morning, everybody. It's a pleasure to be here, and thank you for coming. Perhaps just a few words about myself, and then I'll take you through the rest of the presentation. I'm British. I've been in the generics industry pretty much all my working life.

And this is actually the second time that I've been in Sandoz. I used to be here about 10 years ago. [At first,] I did Paco's job, and you'll hear from him a little bit later on, running the International market. I then had a [indiscernible] and then came back 4 years ago, really to think about how we could really focus Sandoz as the world's leading generics and biosimilar company. In many ways, Sandoz is truly a unique company, and that's very much what I'd like to take you through today.

But fundamentally, the most important thing to reflect is Sandoz is the only global generics and biosimilar company that actually wants to be a generics and biosimilar company. And that is core to our focus, core to our passion, core to our reason and key to our future. So I'd like to just perhaps take a little bit of time, take you through who we are as a company, the

journey that we've been on over the last 4 years or so. And then critically, why Sandoz is such an attractive investment proposition. Really, Sandoz has one single purpose, pioneering access for patients.

Our reach globally is just truly phenomenal. We serve over 500 million patients every year and the social impact in terms of savings to health care systems and payer frameworks is nearly $200 billion. So it's an incredibly proud moment to be able to stand here and to explain to you the impact this company has, not just in Europe or the U.S. but globally. There's a lot of numbers on this slide, but really what's key.

The market we operate is significantly large, about $200 billion. Our sales for 2022 were $9.1 billion. We have a European champion, strong in leadership in the majority of markets around Europe, and you'll hear from Rebecca a little later on about our incredible business there. We have a pipeline that I believe is unrivaled. Over 400 small molecules in development and 24 biosimilars, which is an industry-leading portfolio.

We serve over 100 markets and have an incredibly strong and diverse leadership team that is behind and supporting the growth of this business. If we look at our business for last year, sales, $9.1 billion, of which 79% were made up by generics, small molecule business, growing at about 3%. And we have a 9% -- 21% of the biosimilar business growing at about 9%. And it's worth noting that the biosimilar business consistently grows years after launch in a way that the small molecule business doesn't. It's also one of the broadest portfolios globally and we have launched 8 in-market biosimilars, again, a leading position.

And what's exciting is the increasing proportion of biosimilars of our business over time. 5 years ago, it was about 15%. And clearly, that proportion is accelerating with all the benefits in terms of growth and also in terms of margin expansion. And then when you flip it and look at it by region, clearly, Europe is the foundation of Sandoz. 50% of our sales growing at 6% is our European business, covering nearly 40 markets but again, strong position.

One market is up, and one market is down. We have a very strong, consistent business. And again, I'm delighted that Rebecca could take you through that. Paco has built a really focused, strong international business serving about 50 markets globally, consistently growing, delivering about $2.5 billion of sales and last year growing at 7%. And then Keren and the North America.

Probably the single biggest challenging element to the generics industry. Keren and her team have done a phenomenal job stabilizing the business and now positioning our business to be accretive in terms of growth and margin as we bring a strong pipeline to the market over the coming years. A little bit of thought about the journey that we've been on, getting Sandoz back into sustainable growth. I guess as any organization, we focused on our talent, thinking about how we've built a strong, capable leadership, either experts in their field or with deep experience in terms of this industry and the opportunities that it presents. We've aligned a long-term vision to become the most valued and valuable generics and biosimilar company in the world, focus ruthlessly on sales execution, and at the same time, expanded our pipeline and improving our launch performance, investing in capabilities and forming strong strategic partnerships, both in development, supply and commercial.

You'll hear from many of my colleagues today, but I have a team that has deep experience in the generics industry and are leaders in their field and capabilities. And as a team, we all share the same passion in terms of delivering access to our patients. Ultimately, as I said at the beginning, we are proud to be generic. And that's driven a mind shift culture in the organization, focusing on execution, entrepreneurial leadership, and that's allowing us to attract talent and retain a strong employer brand. We celebrate empowerment and promote agility and accountability across the organization, all consistent to our vision to become the world's leading generics and biosimilar company.

And we focus ruthlessly on sales execution. We've prioritized growth by expanding share and winning new products in new markets. We've invested in our pipeline on capabilities, particularly in the U.S., and again, we'll spend more time reflecting on that today. We've executed targeted accretive M&A and BD&L. And we stopped doing anything that was noncore.

And the results are followed. We're now in the position that we've had 6 continuous quarters of growth. We've expanded our European leadership, taking share against most of our competitors and accelerating our growth in international and stabilizing our U.S. business. There's a lot of numbers on this slide, but in many ways, this starts shaping where our future starts to come together.

We expect more than double the launch contribution sales from the pipeline that we intend to bring over the next 4 to 5 years. We have over 400 small molecules in our development pipeline. Since 20 -- in the last 4 years, we've nearly tripled the number of biosimilars in partnership in development. And now with a position, we have 24 assets as well as clearly the 8 assets that we've launched to date. And more than 50% of the launch contribution going forward will come from biosimilars, driving the mix and driving our growth.

And in the medium -- short to medium term in the next couple of years, we expect to launch at least 4 assets into the U.S. and European markets. And again, you'll hear more about that from Pierre and Claire later today. We've also started investing in our future. We recently announced a significant capital investment in Slovenia to build the state-of-the-art biologics manufacturing facility centered around the current manufacturing capacity that we already have.

And we're also investing in our development capabilities by expanding our resources in Munich. And we continue to leverage our strategic partnerships. We recently announced our partnership with Just - Evotec Biologics. This gives us a best-in-class technology-based platform to accelerate the speed of development and significantly reduce our cost. We really believe this will be a transformative deal and a transformative platform for Sandoz to expand our pipeline and to really drive best-in-class product.

And again, Claire will take you through that a little bit later on today. We have partnerships with Polpharma Biologics. And again, we'll talk about the natalizumab launch, which we're excited to be bringing to the market later this year. And clearly, we will continue to work with Novartis, both as a development partner and a supply partner in the short to medium term as existing partnerships go forward. But ultimately, what's exciting about Sandoz, it's truly unique versus any of our competitors.

We have technical development capability, medical regulatory, manufacturing technology capability and significant commercial capability. We are the partner of choice for many of the leading industry suppliers and organizations. And let's now look to our future. Really, there are 6 key drivers that drive the fundamentals of this business. First and foremost, we operate in a highly attractive growing market.

We have leadership and scale in the geographies where it really counts. We have a diverse set of multiple growth drivers across broad portfolios and broad geographies. As we step away from Novartis, we have clear plans to drive our margin expansion over the coming planning period. This will deliver strong cash flow, and then we can reinvest that back into the business and return capital back to our shareholders. And all of this supported by an extremely compelling sustainability story.

Let's talk about the market. So over the next 9 years, we expect the market size in terms of the addressable market to nearly double, growing at about 8%. And there's a few things that's driving that. Clearly, demographics, patients are getting older, governments are getting more challenged. There are significant LOEs coming up in the next few years.

And clearly, there's a technology shift to more complex and biologic platforms. And at the same time, clearly, small molecules will continue to make a significant component. So we see strong growth drivers in terms of accessing that opportunity. And clearly, the biosimilar element is going to be the fastest growing with relatively lower levels of competitive intensity and significant growth driver opportunities. And for me, in many ways, this is probably one of the most important slides because it explains why Sandoz is so unique.

If you generally look at our industry, the companies in the top right-hand corner tend to be the pure-play biologics companies, the Koreans or originators who thought to go into that space. What they don't have is the scale or presence in the market to leverage and drive value. Many of them struggle that will have to form strategic partnerships in order to extract value. And it's also worth noting in the top corner or the biologics space, 5 companies, including Sandoz, represent about 80% of the world market for biosimilars. So it's already significantly consolidated and we're a very strong player, currently ranked #2, but clearly with plans to regain our leadership.

On the bottom left are the more traditional generic players, the small molecule players, the local players, the regional players, but they just don't have the capital infrastructure or technical capability to make the investment leap to deliver biosimilars. We have both. We have the cash generation and the scale that small molecules bring, but the long-term cash and margin expansion opportunities that biologics have and there are strong synergies by having the 2, both in terms of development, clinical and regulatory, and Claire will explain that to you later, but also in terms of our commercial capabilities. And again, you'll hear from Keren, Rebecca and Paco about how that really drives and supports our business. And having the 2 means that we have a stable cash flow.

So if you think about it, a small molecule takes about 2 to 5 years to develop a normally $2.5 million to $3 million; a biologic, 10 years and $100 million to $200 million. So very different scales and very different kinds of return profiles. But by having both, we have the cash from the small molecules and the margin expansion and growth driver from the biologics portfolio.

And then when you look about scale, clearly, Europe, we are very, very strong, a champion of a business, a leader in the majority of the markets in which we operate. We have a strong and dynamic international business and a U.S.

business that now is stable, ranked #4, but positioned nicely to grow. And again, you'll hear from Keren about what those growth drivers do and how this business will develop over the coming years. When I talk about the biosimilars, Sandoz defined this market. We were the first company to launch a biosimilar in Europe, Japan and the U.S. 15 years ago.

And that biosimilar was human growth hormone, Omnitrope. And I'm absolutely delighted to say today, this is the single largest human growth hormone product in the world. We've consistently taken share, consistently served our patients and consistently grown and developed our business. So we're now ranked certainly in the top 5, if not #1, in the majority of the leading markets in terms of biosimilars. So we have the commercial presence, scale and relationship.

So bringing more assets to those markets drives significant value going forward. And it's also worth reflecting that there's very few small molecule generics that you can have a 15-year life cycle still be growing and still delivering very attractive margins and serving patients. So incredibly proud of what the team have achieved. There are numerous drivers to our mid-single-digit top line growth. So we're guiding that our sales will grow mid-single digits between now and 2028.

And there's a number of drivers of that, excluding any incremental or transformational M&A. We will assume a very low level of M&A in terms of BD&L, which was about $100 million a year. But other than that, this is all exclusive of M&A. Clearly, sales execution, winning share, winning against the competition, maximizing the significant portfolio opportunities that we have by the products we bring to market, driving and improving our product mix, leveraging the strong strategic partners that we have as a commercial and development partner, and again, you're starting to see that emerge and expanding the depth and breadth of our pipeline, investing in vertical integration where ads are the most technical and commercial benefits to the organization. And I then said additional M&A clearly dependent on cash and finding the right opportunities to potentially support the strategic objectives of the business.

On the margin side, clearly, as we step away from Novartis, there are significant setup costs. And again, Colin will take you through the bridge in terms of explaining how the investment has set up Sandoz to go forward. Our goal is to take our margin from high teens in 2023 to mid-20s by 2028 and really through a number of mixes. We think estimate about 200 basis points from the volume, price mix and the portfolios we intend to bring to the marketplace. Glenn will take you through a lot of the work that he's doing in terms of network design, our vertical integration, operational excellence and building a world-class procurement organization that should add at least 350 basis points in terms of margin expansion.

And lastly, stepping out of a large, complicated pharma organization, we see significant opportunities to simplify and execute our operational model. And we've attributed about 150 basis points to that. So this will expand our EBITDA from 18% to 19% in 2023 to 24% to 26% by 2028. As the margin expands, clearly, our cash flow -- our free cash flow will expand. So we expect to more than double that by 2028, sustained by core EBITDA margin expansion,

increasing our EBITDA to cash conversion.

And again, Colin will take you through that. And we have a number of programs now already working in terms of driving our working capital optimization. We will have very clear allocation priorities for our capital, number one, investing in our organic business, returning capital to shareholders and then deployment into value generating bolt-on M&A and BD&L in that order. This is actually very critical, maintaining optionality on our balance sheet. We -- at separation, we are targeting to have an investment-grade credit profile.

That's pretty unique in this industry. We estimate to have an EBITDA to core ratio of about 2 to 2.5x. And again, Colin will talk you through that, all driven with our prudent capital structure at spinoff, allowing it to invest in our business, drive our growth and support our growth ambitions. So this is our guidance on a page. As I said, sales guidance maintaining mid-single-digit top line growth in the midterm to 2028, driving our EBITDA margin expansion from high teens to mid-20s by 2028.

Supported by this will be a dividend policy. So we'll pay a percentage of core net income in 2023 between 20% and 30%. This will be on a full year basis, not just on the proportion of the year but a full year. And then we expect to expand that up to between 30% and 40% of percentage core net income by 2028. All of this is supported by an incredibly strong sustainability story.

Clearly, one of the benefits of stepping out of a company like Novartis and with the leadership of Gilbert and the incredible Board that he's built is a strong governance framework. So incredibly proud of our capabilities in that space. In terms of access, in a way, that is our business, driving access, driving biologics, being the only remaining antibiotics manufacturer left in the Western world is key to our whole reason for being. As we step away from Novartis, we have very strong environmental credentials, and we'll give guidance on those commitments at the -- when we publish our annual report in early 2024. And as an organization, we will continue to champion diversity, equity and inclusion.

Sandoz is extremely well positioned, as I said, to deliver sustainable growth over the longer term. Clearly, attractive market fundamentals, our leadership and scale, significant number of growth drivers, a clear plan to deliver margin expansion, supporting strong cash flow and our compelling sustainability story. So thank you very much, ladies and gentlemen. I'm happy to take your questions.

Samir Shah Executive

I was just going to say for anybody who asks a question, please do state your name. Thank you.

Peter Welford Analyst

I'm Peter Welford with Jefferies. Can we -- just going back to the geographic mix and the mix of the business, you talked a lot about biosimilars and how obviously that naturally is going to grow. Can you just talk a bit about from a geography point of view, how you think the split by geography could potentially evolve over the next, well, say, midterm 5 years? Because obviously, the U.S. has been under a lot of pressure.

But I mean, do you see biosimilars as being catapulting the U.S. as a proportion of your business? And then just secondly, on the biosimilars sort of manufacturing and the deals you outlined. And apologies, this may not be the right time for this question, but you talk a lot about obviously the free cash flow going up 2.5x and free cash flow conversion, and that all makes sense. But I guess what about from the CapEx point of view, presumably, isn't this going to be quite CapEx intensive over the next few years, given that portfolio of biosimilars you've outlicensed.

So how does that fit in still with the free cash flow items?

Richard Saynor Executive

Okay. Thank you, Peter. Perhaps the second part first, I think Glenn and Colin will cover quite a lot of the detail in terms of CapEx, free cash flow, the investments in terms of stepping that up. Clearly, we'll continue to use Novartis over the midterm in terms of our supply, particularly around biologics. That's going to be done on an arm's length basis, but it still gives us a cost leadership platform to drive and support the business.

The bio mix, we don't break out the proportion of bio by geography. But clearly, we're launching potentially 4 biosimilars in the short to midterm in the U.S. That's a significant sales and margin opportunity. I mean clearly, adalimumab launch is on the 1st of July, it's the single largest LOE in the history of the industry. And I know Keren will take you through quite a lot of the details in terms of that expansion.

It's also worth noting 3 of those 4 biologics will also launch in Europe over the coming few years. And again, there, in Europe, we already have a strong leadership position. We have 8 biologics already launched every single product we developed, filed, we've launched and every single one, we're either #1 or #2 and continuing to take share even many years after we actually launched those assets. So I think Europe will continue to drive strong growth. Clearly, there's an acceleration expected in the U.S.

And then International, it's one of the things I'm really proud of what Paco has been able to do is launch biosimilars in market so the originators couldn't even be bothered to do. So we're bringing biosimilars to unserved patients and growing. So it's -- and a significant proportion of its business now in terms of the acceleration is going to come from biologics as well. So it's a nice mix. I guess the short answer is it will be everywhere, but you're right, disproportionately in the U.S., given the opportunities that we see over the next few years.

Unknown Analyst Analyst

[indiscernible] with Credit Suisse Pharma team. Just -- on the U.S. market, how do you view the future for biosimilar uptake in the U.S.? We have seen some rebate walls impacting the ability for some biosimilars to gain market share here. And what impact do you expect from changes to the industry from the IRA?

Richard Saynor Executive

That's a great question, but perhaps if I delay those in line and Keren will cover quite a lot of those later on today. So I don't really want to steal her thunder, I'll give her the opportunity to

explain that. And then again, we can dig into that a little bit more in the Q&A, if that's all right.

Mark Purcell Analyst

It's Mark Purcell from Morgan Stanley. Again, I don't know if it's the right time to answer the question, but could you more broadly talk about the sort of benefits and the challenges from the separation from Novartis? I'm sure you're going to these topics in more detail, but just at a top level to begin with. And then the second question is on biosimilars. Do you believe it's becoming a more attractive or more challenging market?

The question over there was on the U.S., but do you expect it's already a consolidated market? Do you see further consolidation, fewer players? You talked just about the geographical separation, which -- segregation, which I think is on Slide 118, but it will be really helpful to get a top down from you.

Richard Saynor Executive

Yes, sure. Yes, in separation, I mean, it's -- I mean, I guess, unlike Alcon, Sandoz has never been a stand-alone business within Novartis. It's been a stand-alone commercial organization, development and supply organization broadly, but a lot of the infrastructure, IT, tax, treasury, investor relations, all of those things were all managed by group. So clearly, that's one element over the last year, 18 months with Colin and the rest of the team we've been building to have that stand up capability. I think the biggest over the next 18 months, 2 years, a lot of the tech services will still be linked to the -- or there is a TSA between Sandoz and Novartis to allow that system, the systems and processes.

But I see that as an opportunity. It's something like 1,500 shared software platforms between Novartis and Sandoz. We don't need 1,500 shared software platforms. So there's a significant opportunity to simplify and effectively shift those to being fit for purpose to run a generics company. I would say also, I mean, Novartis has been a good parent.

This is about creating 2 great companies. Clearly, Novartis is going to continue on its own journey to become a world-class and innovative science company. But what Novartis has done over many generations is invested in the business. I mean they had the foresight to invest in biosimilars and give us the technical capabilities to do that. I think which is what happened now is we've got the scale.

We have the momentum in the business. We have the depth of the pipeline, I mean it's now time for us to stand on our own 2 feet. So then we'll become 2 completely separate organizations. In terms of bio, actually, I'm pretty bullish. I mean, for a number of reasons.

I mean, if you look at our bio business today, it's a few years since we launched a new asset in a market in a region like Europe, yet it's still growing 7, 8, 9 points depending on the quarter. So that's -- something is going on that says, well, why would a biologic that you've not launched for 3 years still deliver 7, 8, 9 points of cash growth. And there's something else happening. So when you launch a biosimilar, a lot of the time, those drugs are so expensive, they're third or fourth line treatment. So a market like Poland, if you've got rheumatoid arthritis, it might take you 5 years to get best-in-class therapy.

What happens when biosimilars come, the price point clearly goes down. Margin is still very attractive, but then it means that patients get treated much earlier in the treatment cycle. So you get a much more significant portfolio -- or a patient population expansion that drives growth. And then looking forward, it's still technically difficult. A lot of the partners want to work with us because it's not an easy thing filing into the U.S.

for a product like natalizumab. It's not easy having a site capable of doing that. And it's also complicated. You have a REMS program. We have testing and compliance programs and all sorts of things.

So there's all sorts of opportunities and barriers, but that's an opportunity for us to create share. So I think the journey for me has been how do we have the broadest and deepest portfolio. So we started with about 8 3, 4 years ago, now we have 24. That journey needs to continue, not all of it in-house, but clearly through partnerships and development. And so it gives us many, many opportunities to create value.

And the fact we're launching 4 biologics in the next few years is a significant growth driver. And clearly, we'll continue to look at expanding and doing that. So I'm pretty bullish. I think not necessarily more consolidation, but I do see signals that some of the Korean players want to go in a slightly different direction in terms of [innovator light] or those kinds of directions. And some of the other players that launched biosimilar portfolio to complement their [innovators'] portfolio, that cycle is coming to a close.

So a number of the players, I don't see them necessarily expanding that. So I guess it's consolidation, but not necessarily through acquisition or merger more just through divergent strategies.

Mark Purcell Analyst

That's very helpful. And just to the first question, I get the operational benefits in separation. In terms of strategic benefits, I guess there's no surprise that you've done more deals more recently, long-term strategic deals like [indiscernible] as you approach separation. Can you help us understand the freedom from a capital allocation perspective the separation provides, the strategic flexibility for being a separate company, maybe an overview there or -- I'm sure [indiscernible] details later.

Richard Saynor Executive

Sure. I'll give you just top line and then I'll let Colin give you through the details. I think -- we've tried to outline our capital prices really clearly investing internally into the organic growth of the business. So to the question around manufacturing and development, clearly key as we set up a stand up -- stand-alone Sandoz. M&A is further down the list of priorities clearly behind returning capital back to our shareholders.

The pipeline that we have, the plans that we have are here to deliver the growth. There's always a low level of BD and M&A. I was to say about $100 million a year of sales coming from that. But that's always been there. So we're not really targeting at this point any transformational M&A to either strengthen a geographical footprint or strengthen a pipeline or a portfolio.

What we have is currently in the plans. We'll continue to look at expanding it. But -- and I think then the M&A phase is probably 18 months, 2 years further out as we sort of got the structuring set up separated from all the systems from Novartis, driving up the free cash and then start thinking about how we deploy it. If there's no more questions, I suggest we take a quick -- a cup of coffee. Okay.

Thank you so much. [Break]

Richard Saynor Executive

Thank you very much. We're going to try and keep the same timing because there's about 400 people online. So if we have a little bit more time over Q&A, we'll still keep to the original timing. So thank you for bearing with us. Okay.

Now we're going to move into the commercial part of our segment, really looking at our leadership and scale across our 3 main regions. We're going to start with Region Europe. As I said, 50% of our sales coming from Region Europe, a real champion. We're in the #1 biosimilar player, and we have a phenomenal capitalization in terms of our portfolio and footprint. Region Europe is run by Rebecca.

She's been President of Europe for the last 3 years. She has over 16 years' experience in the pharmaceutical industry and 25 years overall working, I mean, Roche, MSD and 16 years within Sandoz. We're then going to go and spend some time looking at North America, clearly, in many ways, probably the most challenging geography for the generics industry but still the largest pharma market and a significant opportunity we see going forward. U.S. is led by Keren.

Keren is a veteran of the industry, worked in what comes from Teva originally, was head of BD and M&A for them, head of the BD and M&A function for Novartis and has done a phenomenal job stabilizing and really energizing the U.S. business and now in a position where we're potentially launching 4 high-value assets in the coming time period. And then lastly, Region International, a diverse geography, but under Paco's leadership, who's had more than 35 years' experience in the industry, has worked in many geographies, worked in, in both Novartis and in Sandoz. Really, he has been able to target significant market opportunities and significant part of our portfolio and driving very attractive top line growth, but in a very executed and disciplined manner. So delighted to welcome the 3 of you, Rebecca, the stage is yours.

Rebecca Guntern Executive

Thank you, Richard, for the introduction, and good morning, everyone. It's a great pleasure to be here with you today. As Richard said, my name is Rebecca Guntern. I'm 16 years with the company and since 4 years, the President of Region Europe. And the last 4 years have been an exciting journey.

And together with Richard and my colleagues, we have been working hard on our ambition to become the world's most leading and most valued generic company. So today's presentation, of course, is a highlight and a key opportunity for us to get you equally excited about our equity story and how we're going to drive value in the future. In my role, of course,

how do we do this in Region Europe? Before I'm going to take you how we have built the success in Europe, let me start to say that I feel truly proud to lead Sandoz in Europe. I do have an amazing team.

And with over 1 billion packs sold, there is almost no other company who impacts the health of so many Europeans today more than ever. And that's exactly why we feel proud to say that we do take care of Europe, and we're passionate about what we're doing every day. And this is really what kept me and my team going day by day to give our very best. So let's have a look at Europe at a 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 with commercial presence in over 40 markets. Critically, we're a top 3 player in over 80% of the markets we're operating in. And as you can imagine, this gives us huge scale, which is important in the off-patent industry, but also a strong and unique footprint. And together with our broad portfolio and leading go-to-market capabilities, this translates into a very powerful commercial platform led by a highly committed and experienced leadership team. The business has delivered sustainable profitable growth over the past couple of years and is accounting for 50% of the total Sandoz turnover at $4.5 billion annually.

We will build further in the future on the strong foundation and leadership position to continuously deliver growth in Europe. So let's have a look at the market. The market in Europe is attractive, it's sizable and it is growing. Important to know the off-patent industry plays a very critical role being the backbone of the European health care system. We account for 70% of all medicines dispensed at 30% of the expenditure.

And we have dramatically increased access for patients in Europe, namely in core therapeutic areas like cardiovascular and diabetes by over 100% without increasing treatment costs over the same period. We expect, as you can see, the market to continuously grow, primarily driven by 2 factors: first, loss of exclusivities. We do see an LOE value of over $100 billion in small molecules and biosimilars. With a higher shift to biosimilars, now accounting for 15% of the market, we see this doubling over the next decade to 30% by 2031. Sandoz in Europe is in a very strong position to capture on this market opportunity based on our broad LOE coverage and strong pipeline.

Second growth driver, volume growth, fundamentally driven, as mentioned by Richard, by a growing and aging population, but equally also cost containment measures, which will further accelerate and drive generic and biosimilar penetration. So what is the role and the position of Sandoz in Europe? As you can see on the slide, we are the undisputable market leader with 11% share. We do have a strong and broad foundation being the leading company in 6 out of the top 10 largest European markets, like, for example, in Germany, Spain and Italy, just to name 3 of them. What is also important to know, we're the only top player with a very balanced portfolio between generics and biosimilars.

And this is a key differentiator for us, which will enable us to capture on the future LOE value, important with the shift to biosimilars, but equally offers a very attractive value proposition for our customers. We have been outperforming this market over the last 3 years, which is reflected in the evolution index of 104. We doubled the gap to our second largest competitor

moving from 2% to 4%, driven by a strong and above-market performance in biosimilars and also equally first-to-market launches. And this brings me to biosimilars. And let me say that this is a true success story, biosimilars in Europe and fundamentally specifically for Sandoz in Europe.

Sandoz was the first company to launch a biosimilars back in 2006 with Omnitrope. Today, we are the leading biosimilar company with 8 commercialized products being ranked #1 in 5 out of 8 products. And what is impressive is the fact that despite 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 market leadership position across the markets in Europe. Richard has already shared the example of Omnitrope, which is amazing to see after so many years in the market, and it's also true for Europe.

We have further expanded our market leadership position in the last 12 months to 38% share. I would like to share another example, which is Hyrimoz. Launched back in 2018, we are now #1 in 19 markets across Europe with Hyrimoz. We have doubled our volume share over the last 3 years, and we're delivering year-over-year growth. Just in 2022, Hyrimoz grew by 23%.

And this is what is truly exciting when it comes to biosimilars is the fact that there is a great opportunity to further expand the market by treating more patients and by treating them earlier. And we do have the commercial capabilities to do so, including contracting and pricing excellence but also pull through share of voice markets. And this has exactly enabled us to expand our leadership position from 22% to 27% over the last 3 years. So based on what you can see here on this past performance and strong performance, I feel very confident that we will successfully launch and drive value out of our next 4 pipeline assets targeting an LOE value of $4 billion in Europe. This brings me to the financial profile of Sandoz in Region Europe.

We are present in 2 business segments: generics and biosimilars. We have doubled the biosimilar business over the last 5 years now accounting for approximately 30%. In 2022, the business grew by 6%. We saw strong volume growth, both in biosimilars with plus 70% and in generics, plus 7% backed on a post COVID recovery and strong market demand. We have been able to capitalize on this market growth, growing again above the market and further expanding our leadership position by 60 basis points.

So what is the success factors in Europe? Let me say that I see 2 main points. The first one is our strong commercial platform and the second one, our leading go-to-market capabilities. And this, in combination, makes us really a partner of choice in Region Europe. Now looking at the building blocks of this commercial platform, I like to call it the hardware.

I do see 3 main elements. The first one is geographical footprint. We do have a huge scale and strong presence with being in 40 markets in 32 with our own legal entities. And this gives us, of course, scale and a unique footprint. Second, with over 2,500 sales representatives, we have one of the largest field force in Europe, and this is even beyond the off-patent sector.

And last point is the portfolio. With over 900 products, we have one of the broadest portfolio among competitors, which is important for our customers to address those needs they have for the patients they treat. So these 3 elements fundamentally are core. And that's why we are

ranked consistently among the leading companies across the major markets in Europe, as you can see here. And beyond the hardware, what is important, we know how to play, and we know how to win across those market architypes which are tender, share of voice and pharmacy substitution.

And this brings me to the software, our leading go-to-market capabilities. So talking about our leading go-to-market capabilities, this truly covers all elements which are important for successful commercial execution. And we do have strong proof points and a track record when it comes to commercial execution, starting the first step, market access. And while Europe is one region, we do have 40 markets, 40 markets with different pricing and reimbursement policies. So absolutely important to understand how do you enter a market to get price and reimbursement and, of course, that you can sell it at the end.

And we know how to drive market access. We have been frontrunners in driving policies and shaping the market environment to ensure sustainability of the industry. We have been leading when it comes to defined criterias for tenders beyond price and fundamentally also introducing gain-sharing models in biosimilars, namely in Spain and in France. Then launching. We know how to launch a product, being first to market in 70% of the products we're launching.

And in combination with our broad LOE coverage, this is truly the core skill set of an off-patent company. Last but not least, selling. We know how to sell, and we know how to sell across market architypes. In tender, we have a high win rate. And we're winning many tenders not because of price but criterias which are product features, quality and supply.

Then in share of voice, we're leading in face-to-face share of voice, which is super important to really drive prescriptions at physician level. When it comes to pharmacy substitution, where the pharmacist can switch an originator to a generic product, we do have a very broad and strong access to pharmacy networks, which is enabling us to drive broad distribution and the fast uptake specifically for launched products. So bringing it together, both the commercial platform and on top, our leading go-to-market capabilities are really differentiating us from our local and global competitors. And it is very difficult to replicate them in the way Sandoz has built them over decades, being a very trusted brand for payers, for customers and for patients. So looking at the future, I have talked you through now how we have built a success in the Region Europe, and I'm very confident that we are well positioned to continuously deliver sustainable growth in Europe.

As presented by Richard and as outlined here, in essence, it is a continuation of our growth strategy. We're going to do more of what we have done successfully in the past, namely relentless focus on commercial execution. We want to leverage our unique footprint and our scale, maximizing our pipeline value. We do have a very attractive pipeline with $20 billion of LOE in the next 5 years to come, and we can leverage our first-to-market capabilities. We're going to see continuously a product mix shift to higher margin biosimilars.

We will build strong strategic partnership, leveraging our commercial platform. And on top of that, we will continuously invest into the breadth and depth of our pipeline. So to conclude, Sandoz in Europe is a true commercial champion. We're operating in a very attractive sizable market with market proximity and the reach, which differentiates us from our competitor. We

do have an outstanding track record in commercial execution and an ability to win across market architypes, something my experience tells me is absolutely key to win in Europe.

With those core skill set and strengths and I would say with a highly committed and capable team and a very clear plan in place, I'm very confident that we will continue the success in Europe, and we will continue to deliver growth in the future. Thank you. And let me introduce Keren, my colleague, who is President of North America.

Keren Haruvi Executive

Good morning, everyone. Thanks, Rebecca. Thanks, Richard, for the introduction. Great to be here. I joined Sandoz 2.5 years ago, and it was a special opportunity to join a company where my personal why and my professional why are coming so well together.

My personal why is all about people and making difference and impact in people life. And at Sandoz, we have an amazing opportunity to make a huge difference in patient lives every day. I'm privileged and inspired to lead this organization every day. I was reflecting when I was preparing to this session and how I'm going to share the North America journey that we've been through. And I was thinking about our story and our story think about as a book have 3 chapters.

Every chapter, each chapter in our book has one key message that I want you to take away from this session. The first chapter is about we stabilized the business. The second chapter, we have the right team and strategies in place. And the third chapter, we are ready for our exciting upcoming launches, and we are entering our growth phase. Before I go into my book, let me give you a bit of an overview of our market.

The North America market, it is a $75 billion market, which includes 2 countries, U.S. and Canada. As you can imagine, given the size and dynamics of the U.S. market, most of my presentation, I'll focus on the U.S. The market is expected to grow 10% over the next 10 years.

And as you can see, tremendous growth in biosimilars, 24% of the gross expected in biosimilar. Now this is a unique opportunity in the United States because the access for biosimilar is not where we want it to be. And this is an opportunity to serve patients early and give them the opportunity to get into the biologic drugs that without introducing biosimilars, they will not get access to. If you look at a small molecule market, it's also growing with 6% CAGR, driven by LOE opportunities. And the market is already well genericized in the U.S.

As you are well aware, 90% of the volume in the U.S. is filled by generics. This 90% account only for 3% of the overall U.S. health care expenditure. That's why it's so important to continue and serve patients.

As you heard from Richard, we're uniquely positioned to be this pure bio -- pure-play sorry, biogeneric company that will be there to serve patients in both generics and biosimilars. We have a leading position in both U.S. and Canada but let me start with Canada. We have a very strong business in Canada. We have experienced and committed team that continue to grow share in the market for the last 7 years.

We are committed to the patients in Canada, and we'll continue to do everything we can. And as you can see, we were the one -- the only company that grew in 2022, and we'll continue to consistently grow and close the gap to be the #1 in Canada. As I mentioned, most of my presentation would be on the U.S. today, and this is where Chapter 1 begins. We stabilized the business.

This is our evidence. We are 1 of 2 companies that were able to grow in the market in 2022. We had strong sales of $2.1 billion, 80% coming from generics, 20% for biosimilars, and we declined 2% versus previous year. As you remember, this is a business that came a long way. This business suffered from lack of portfolio investment due to our decision to divest in 2018, our [derm and] oral solid portfolio.

We decided to divest its portfolio and the transaction didn't go through, the FTC didn't approve the transaction. We reintegrated the business in 2020. But as you can imagine, it takes time to rebuild your portfolio. I'm very proud, and I'll tell you, of course, in more detail of all the work that we did with Claire and our team to rebuilding our portfolio in both generics and complex generics. But we didn't want to wait for the portfolio.

We wanted to make sure we're stabilizing the business. And in order to do it, that's where my Chapter 2 begins. We talked about having the right team and the right strategy. Let's start with the team. You cannot turn around a business without having the right team in place.

We have a very skilled committed team that is working every day in the market to win share. And as I said and as you saw in my previous slide, we were able to do it. And I'm very proud. The culture that we have in our company and the people that we have is the one thing I'm proud the most. Now there are many things that go in to turn around a business, and I was thinking what will be the best way to share them, and I focus on 3 elements.

The first one is commercial execution and focus. We have a very broad portfolio. And in order to increase share, we thought what we can do, as I said, pipeline would come later, right? We know that it takes time to build pipeline. So what we decided to do, we looked at the entire portfolio and we decided to act and execute when we feel that we have a competitive advantage.

It could be from a price, from a cost or from a supply perspective. And we worked hard to focus on this portfolio where we can win. And as I mentioned, we had a lot of success, and we were able to grow our share. The second thing is to focus on our launch excellence because as you know, we have a significant number of exciting launches, and we wanted to make sure that we are making it perfect. We have a very strong experience and skilled launch team that work very hard every day and well equipped to bring product to each one of the channels.

If it's the bio, retail or hospital market. The second thing that we did is looking at our customers. When I joined the U.S., there was this perception that the only thing that matters is price. I can tell you it's not correct. But again, having this relationship with your customer, building this trust, it's taking time.

I'm very proud. And as I said, the only way you can do it is having the right team. You build trust with people, not between companies. And that's what the team did so well. We had the right conversation, not always the pleasant conversation, also being able to have the tough

conversation, but doing it in a very respectful and transparent way made a huge difference for us.

Now beyond that, we said price matters. But Rebecca talked about it in her presentation. It's these 3 elements that really makes a difference in our market. It's price, it's quality, and it's supply, very proud of our quality heritage, and I think there is no doubt that the Sandoz brand give a lot of quality heritage. But supply, that's what I'm proud the most.

We were the first company to introduce biosimilars to the United States. We introduced biosimilars in 2015, and I'm very proud that we had 100% supply reliability into this market. And that makes a huge difference for patient because what access mean at the end of the day is that the patient can get their product when they need them at the right time and at the right cost. And last but not least, and this coming back to the pipeline. This is the lifeblood of our industry.

The only way to offset the price erosion in our industry, specifically in the United States, it's to launch products. We had focused the U.S. portfolio in a very attractive pipeline from both small molecule and biosimilars. We worked very hard with Claire and our team. We doubled our [end of submission] in the United States and we focus on opportunities when we can be first to the market.

70% of our portfolio is the opportunities to be first. It's either exclusive [indiscernible] file, first-to-file or first-to-market. And again, this pipeline is coming very soon, and the exciting part of this pipeline that I want to take time and share with you is that -- is where actually Chapter 3 begins. It's our launches, our upcoming launches. We have 4 upcoming launches, which account for $30 billion of loss of exclusivity.

We are very excited for what we can do for patients in the United States. As you know, in the United States, there are 2 channels to sell your biosimilars, the medical benefit and the pharmacy benefit. Our first launch adalimumab, which we are very excited, and it's around the corner, it's into the pharmacy benefit space. This is a unique opportunity for us as an industry to write a chapter in the books of history. This is $18 billion loss of exclusivity, the largest ever loss of exclusivity in the United States.

We are just coming off our launch meeting, and I can tell you the excitement and the enthusiasm to be able to bring patients this drug, it's just inspiring. If I could show you the videos and the energy, it's just hard to describe. Now as you are well aware, this market is going to be very competitive in the U.S. But we feel we're uniquely positioned to be leaders and win in this market, mainly because of 3 reasons: our formulation, our high concentration, citrate-free formulation, which we believe is the best formulation for patients. Our experience and leadership outside the U.S., and you heard from Rebecca how well we are doing with Hyrimoz in Europe.

We are #1 in Europe. We are #1 in Canada. We have 120 million days of patient experience in transitioning patients from the brand product to the biosimilars. That's critical when you enter a market, patients feel very comfortable and physician that they know that the company that they are working with has this experience and capabilities, not just to transition the patient, but also to support them throughout the disease journey. We know those are chronic patients

that need the support, not just a day or 2 in their life, every day.

And last but not least, our supply. As I mentioned, the most critical element in this launch is to be able to supply the market and we feel very confident that we have the supply that we need to support the market. And as I mentioned, our 100% supply reliability so far, we just -- we'd not just have the confidence, we know that we did it in the past, and we'll continue to do that. Now the 3 other biosimilars, they are going into the medical benefit space. It's a very different channel in the United States, where we have tremendous experience.

Our biosimilar portfolio, our [indiscernible] portfolio is in the medical benefit space. And we were the first company to launch in 2015 after the BPCIA was introduced. We launched our own Zarxio, and we still have our leadership position in the market. So 3 launches, all of them will come to the market upon FDA approval and IP clearance. As you are well aware, the IP landscape in the U.S.

is complex. Litigation is part of the business. In order to bring biosimilars to the United States, you need to litigate, and we are in this process, as you can see in the footnote for all of them. Now in each one of them, I want to leave you with a key message. Let me start with natalizumab.

Natalizumab is the biosimilar to the reference product Tysabri. We have a unique opportunity here. We are the first to get into the market and potentially the only one. So we are not aware of other competitors that are expected to come in the near term. Secondly, Tysabri has a very complex profile from a safety perspective.

And we have the experience and the right support system for patients to make sure that we continue to serve patients safely. The next one is denosumab. We expect to launch into both the oncology and osteoporosis space. And here, we're going to leverage our experience and skills. As I mentioned, Xgeva is into the oncology space where we already have our portfolio.

And with Prolia, we believe that we'll have a lot of synergies with our Humira -- with our adalimumab launch. And last but not least, aflibercept. We launched -- we are going -- we will launch both the prefilled syringe and [the vial], and we have a unique opportunity here to continue to put patients in the center. As you can imagine, when you inject a medicine into your eye, you want to work with a company that could be there, and you trust. And we are very proud to be this company.

So as you can see, many launches in many therapeutic areas, which will help us serve patients and continue this journey, which I'm very proud of. Coming to the cliff notes of my book. We'll continue to execute on our sales, we'll maximize our upcoming launch, which have a significant opportunity to serve patients and introduce significant opportunity from a dollar perspective, $30 billion LOE in the biologics space and $53 billion in small molecule. We will continue to improve our product mix, thanks to those launches and leverage our strategic partnerships to ensure we get products either organically or from externally. But we need to remember our patient, they don't care where the product come as long as they get it at the right time and at the right cost.

And last but not least, our lifeblood of our industry, we'll continue to invest in our pipeline, both in small molecule and bio. So just to conclude, remember the 3 key takeaways that I

want you to take from this session. We stabilized the business. We have the right team and strategies in place, and we are ready for our launches and entering our growth space. I can't wait to update you on our next chapter.

Thank you. And with this, I will hand over to my colleague and friend, Paco.

Francisco Ballester Executive

Hi. Good morning, everyone. We have been during the last few minutes listening our business in Europe from Rebecca, pretty strong commercial footprint. And also, we heard from Keren [indiscernible] turnaround together with her team, the business in North America. That has been this outstanding story.

What I'm going to do in the next 10 minutes is share with you what we have been doing in Sandoz International Region that is covering the rest of the world beyond Europe and North America. My name is Francisco Ballester. I'm known as Paco, that's the nick name and I have been in the industry for the last 35 years, 32 in Novartis, the first part in innovation and the last 11 years as part of Sandoz International Region. And this is my responsibility to share with you the past, the present and the future of Sandoz International. Sandoz International is covering geographies that is up to $68 billion business.

And this is a growing business, very attractive that we are running in the global scale. We have been doing in the last few years, a lot of focus and dedication, as Richard mentioned before. We have been reporting $2.5 billion revenues in 2022 with a 7% growth, not only in '22, but also during the last 4 years. The growth that we delivered in '22, and the previous years was based on a very clear strategy. We made some decisions 5 years ago when we created Sandoz International Region.

Sandoz International Region was a newly created region among several geographies in the world, which were clusters or subregions at that time. And when we put them all together, we make 3 decisions. Number one, we decided to focus on people and culture, working on a winning culture in order to make a difference. Second, we decided to operate in a very lean approach working with a generic mindset. And the third one, we decided on 5 pillars, 5 pillars of strategy that I will share with you in the next 2 minutes.

First of all, we decided on specific geographies we wanted to play and geographies that we wanted to exit, and we went from 120 countries to 26 focused countries in this period of time. The other one, we decided not only to operate in specific geographies, but also to decide which were the segments where we wanted to play. And the segments we wanted to play within the specific countries or geographies because we knew that we didn't want to play everywhere in every country, and we wanted to decide where to invest and where to make the difference. The other one is that we also streamlined our portfolio. We decided to select the specific products where we were competitive.

And as a consequence, we were able to make a difference versus our competition in the local specific markets. And I will also mention how we did it and how we streamline our portfolio in the next few slides. The next one is we also focus on our launches, making sure we were doing more launches, more frequent, more successful and expanding our first-to-market opportunity. We moved from 10% first-to-market launches to 25% in '22, and we're looking

forward to expand up to 50% in the next 2 years. And the very last one, we did both, a combination of leveraging our global portfolio and bringing that to the geographies that we have selected together with BD&L opportunities.

That means signing contracts with third parties in order to do business development and license contracts with third parties that are -- most of them multi-country in order to do the simplify approach and do not make a lot of deals across the world. These multi-driver that I've mentioned before to you are the ones making the difference in Sandoz International and delivering this consistent 7% growth or above in the last few years. The market is attractive. That's another question. Market is attractive because it's $68 billion, as I mentioned before, and this $68 billion is equal to North America or Europe.

So it's big, sizable and growing 5%. This is based on the economies that we are operating. Also, it's based on the population, it's based on aging population. And beyond that, there's an expansion on the health care coverage in the different geographies of the world. We have, obviously, as I mentioned before, to you selected the specific pockets of faster growth within the geographies where we are operating.

We don't play everywhere because where you invest matters. We decided where to invest, where not to invest in the specific geographies that I will cover later. One clear example is biosimilars. In the case of biosimilars, we will be growing in the next 10 years 4 to 5x faster than the standard small molecules, and that is obviously a focus on a target audience for us. The segments.

I mentioned to you that we are operating in the specific geographies. But beyond that, we select the segments where we can be competitive, and we can make a difference. We select these specific segments, one of them is substitution, pharmacy, INN. The other one is share of voice, share of voice that could be either in a specialty or general practitioners or we go to tenders, tenders that could be -- we choose multi-country, or we choose -- tenders that are multiyears or we choose tenders that are either national or regional. And we make that decision where we can be attractive and competitive.

And then we can also choose either hospitals or OTC. These are also options that we eventually decide in the specific geographies. These decisions are based on patient needs, market size, market growth and the value creation, how we can grow over the next few years, not only considering what it is today, but what we can do in the future. There's another point here about the number of countries that we serve through third-party distribution. I will cover this in the next slide.

How we did expand our business in growing 7% in the last 4 years? We did it with a lot of focus on the attractive markets I mentioned. We also implemented an effective successful approach with satellite countries. These are the ones that we serve through third-party distributors. In the satellite countries, we serve through third-party distributors, we do it with a similar portfolio that we do in the mother country, the country supporting the satellite.

We did that approach because then as a consequence of that, we simplify our portfolio. We have similar regulatory framework, similar portfolio and SKUs and as a consequence, which we leverage our volume, simplifying the portfolio and improving our outcome in the supply

that we do in the geographies. Harmonizing this portfolio. As a consequence, it is an enabler in order to get a better COGS and as a consequence, serve with higher margin in the future. The other reference I want to make, it is the first-to-market.

I mentioned that we have expanded from 10% to 25% in the last 3 years. But this number, I want to highlight that is creating significantly more value. We create value 3 to 4x higher in top line but also in margin every time we do a first-to-market launch versus when we get [late to the market.] Beyond these comments, we also did a couple of inorganic acquisitions in the last 3 years, and I will mention them and the details in the last slide before we close. Two specific examples of this model where we target the country, and we target the segments and we make decisions in order to be consistently growing over time during the next few years.

One is Australia. These 2 markets are fast growing, 15% per year in the last 3 years, but they are not the fastest growing, but they are sizable. So as a consequence, they are representative of the decisions and the outcomes we made in the last few years. In the case of Australia. In the case of Australia, we decided to go from a local approach to a global approach.

We maximized launches. We went to the global portfolio, and we selected the ones that we were able to launch in Australia. The last 3 years, we launched 3x more products in Australia than what we did in the previous 10 years. So we massively expand our launches in Australia. Second one, a consequence of our new portfolio and launches that I mentioned, then we went to more key accounts, and we were able to access more pharmacies and change in the market.

And that was a significant growth versus what we did in the previous years. And the last one is biosimilars. And the launches in hospitals and biosimilars was significantly more efficient because we understood that the growth in the future was going to be biosimilars. So we overinvested in that area in order to be successful as we did in the last 2 years. Second example, Brazil.

Brazil was 100% focused on the pharmacy business a few years ago. And we shift from that one to a model where we now have our 3 pillars. Number one, we remain with the pharmacy, but we deliver at lower scale. We went to the branded generics and specifically, the last example is what we did in antibiotics. And then beyond that, we have been investing in biosimilars.

The case of biosimilars in Brazil is through a third-party distribution with the government and a consortium, and we have a 10-year deal with the government. This supply agreement with the government increased reliability in Brazil. And as a consequence, it is more predictable that other cases that we go for tenders year-over-year in different geographies. So all in all, it is decisions we made in the different geographies. This is just an example illustrative of what we have been doing over the last few years.

Two examples of acquisitions. One is the business that we acquired in Japan, the Aspen business. We integrated in the last couple of years, and this business has been successful. Beyond the success, this was a strategic asset because it gave us access to the channel in

the hospital where we didn't have before. According to the complex products that are coming to our portfolio, we have been leveraging that opportunity in order to be able to access the hospital business in Japan in the next few years.

The second example is the antibiotics and cephalosporin. This is branded, which is according to our strategy in International. Beyond that, we have the opportunity to create synergies with our commercial footprint around the world because we are leaders in antibiotics in many countries. And beyond that, obviously, we will integrate the antibiotics in our manufacturing setup across the next few years. In summary, I'm very confident that we will continue to be growing in Sandoz and in Sandoz International Region in the next few years.

Why? Because we have the right [pillars.] We have the right team, the right culture. We have the right countries. We have selected the right segments within the countries.

And beyond that one, we are doing more launches, more frequent and first-to-market, creating significantly more value. Then the mix, we are expanding to complex products, and we are expanding also to more launches in biosimilars. And as a consequence, the margin expansion, it is -- will be helping us to deliver better outcome for the shareholders. And then the last 2, we are maximizing the opportunities to partner with third parties. We are the partner of choice.

We are multinational present in the right countries across the world beyond Europe and North America. Last one is portfolio. We are doing more and better every time in our portfolio. You will hear that from Claire and Pierre in the next few minutes. And then because we are doing more and better maximizing and launching first-to-market across the world is giving us the opportunity to create more value and more access for patients in the world.

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

Richard Saynor Executive

Thank you so much. Thank you, Rebecca, Keren and Paco. Now happily take your questions.

Peter Welford Analyst

I'll start with one and then -- I guess, I don't know how much any of you are going to be able to say necessarily on this, but particularly Keren, but I guess the obvious one is we've obviously seen with adalimumab biosimilars in the U.S., a number of different strategies that have been employed or will be employed. Not expecting you to say what you're going to do on July -- 1st of July. But can you just talk a little bit about, I guess, your interpretation and how we should think about this and how they could play out in the U.S. and how you're thinking about the adalimumab market evolving for you over the course of, I guess, this year and next? And maybe on a similar vein in Europe, I guess, could you just talk a bit about how the pricing and the dynamics have changed since they were originally launched in Europe?

I know obviously, there's been some very aggressive tenders initially. I guess, what was some of the initial pricing? Is it eased somewhat? Or is it just continuing if anything to get even more aggressive over time? And if you can talk a little bit about how you see that evolving in the future?

Unknown Executive Executive

Keren, do you want to go first?

Keren Haruvi Executive

Yes, sure. Thanks for the question. Look, as I mentioned, there are 2 channels in the U.S., right? And in the pharmacy benefit channel is where we have less experience as an industry. So I think it's not a question for me of the kind of if it's going to happen, it's more the win.

And we see a lot of different strategies, as you mentioned, which is expected when you have such a competitive market. We do believe that it will take time to market to form. We don't believe it will happen this year. I think we also -- that Humira will continue to be in a preferred formulary and the biosimilars that will be introduced by the payers will be in a parity position. So I don't think that there is real opportunities for biosimilars, again, as an industry when you are in a parity position to the innovators.

But I'm 100% confident that the payers will displace Humira. When it will happen, it's -- we don't know. We assume it will be in the mid- to short term. What I can tell you is that when it will happen, we are very confident that we have the right strategy and the right pricing to be able to win in this market. And as I mentioned in my presentation, we have a lot of discussions with payers.

There's 3 things that makes a difference for them is the formulation is -- our experience and ability to transition patients and then, of course, our supply reliability.

Unknown Executive Executive

Rebecca?

Rebecca Guntern Executive

Yes. So let me quickly frame your question on pricing in Europe. So fundamentally, I think the price impact we're seeing is dependent on the competitive landscape. This is one element. And the second element is the archetype.

So roughly 50% of our business is tender. The rest is share of voice. And in many cases, like Germany, we have still a big part, which is share of voice. What we're seeing is pricing depends, of course, on the majority of the portfolio, and we do see stabilization. I would say high single digit in average is the price erosion we're seeing in biosimilars, and it has been stable.

If I look at the last year and compared now to Q1, it's stabilizing. This has, of course, to do that we work very intensively with government and also with the authorities and procurement partners to go and to define criterias beyond price. If you take France, for example, over 50% of the tender is already beyond price criterias, like product features, supply, quality, which is a big part, if you think it through, and we see more and more countries going into multi-slot tenders and really shaping these tenders to make it more sustainable because they understand that they need to change the thinking. It's not just price. You need to have the product to treat patients and have the impact on the system.

Richard Saynor Executive

And [indiscernible] continuing to get the volume expansion that you don't get it from small molecule. So you still see strong underlying growth for biologics years after they're launched in a way that you wouldn't see the small molecule.

Mark Purcell Analyst

It's Mark Purcell from Morgan Stanley. Three topics, if that's okay. The first one is on biobetters. Could you sort of help us understand the importance of this in your different regions. So I guess in the U.S., the concern investors have is if the branded innovator squeezes down on price, but you have differentiation in terms of your product offering, how important that is.

And I guess, in Europe, the best example I can think of is Omnitrope. It was a biobetter from the beginning and took share from the innovator. So the importance of biobetters in your strategy that would be great. The second question was on IP success. In one of your slides, you talked about success with [pirfenidone].

Is this marking or representing a shift in the balance of power when it comes to IP? Or is this just a product-specific situation? I guess there was a topic -- a question earlier around IRA. I'm just wondering if I IRA potentially changes the dynamics when it comes to settlement agreements, where obviously, you're on the wrong side of a situation with Enbrel, which locked you out of the market until 2028, which comes in the scope of, I guess, the direct price negotiations we're about to face based on IRA in certain markets or certain products for them. And then the last one is interchangeability, just following on from Peter's question.

How important is interchangeability in your 3 separate regions?

Richard Saynor Executive

Okay. Perhaps we'll break the questions down, I'm going to ask Pierre to answer your first question because I think he can then look at that as a landscape. Clearly, we have strong life cycle management. And I don't recognize it in sense of a biobetter. We're not trying to be [innovator light] or clinically differentiate.

I think where we can innovate and change is maybe the formulation, presentation or delivery mechanism to all us. Pierre will pick on that. IRA, clearly, I think Keren is extremely well positioned. I think the last bit on the patent landscape, look, I think it's one of the things that's clearly we have a stand-alone Sandoz part of the reason for being of a generics company is to challenge and push that. As we become an independent company, clearly, that will be part of our strategy.

[Pirfenidone], I think, is a really great example. A lot of our competitors [indiscernible] not challenged. We challenge, we won, we launched. And I think we will continue to do that. I think the team that Ingrid has built is extremely capable.

And clearly, we will continue to challenge patents in the U.S. and other territories. Do I see a sea change? I don't necessarily on the patent landscape, the U.S. It's always been a feature of that.

Interchangeability, I'll perhaps speak at a macro level. And then again, we'll close them with Keren on the U.S. I mean Europe is already -- biologics are interchangeable anyway, it's a non-debate. So we don't really see that as a key differentiator. The patent you get -- you're approved and [indiscernible], the assumption is it's interchangeable.

And I think the acceptance in Europe broadly for most markets is there. I think the U.S. then we'll pick up separately. But perhaps Pierre, do you want to start with the differentiation?

Rebecca Guntern Executive

Thank you, Richard. So on our strategy, our strategy clearly is to follow the biosimilar room for our product selection and for development. And I'll explain why we're confident in that and what that means. We're confident in that because that means that we can follow the biosimilar development pathway, which is efficient, well defined, well characterized. And within that pathway, there's a lot that you can do to ensure that you've got meaningful differentiation for your product where it matters.

That can be the device, that can be the shelf life, that can be out of [indiscernible] stability data that can be needle gauge and other features and benefits that come with the product. And in my later presentation, I'll give you very tangible examples of where we've done that and really to Rebecca's point about tenders, we're able to win tender criteria based on those [advantages.] Now on the biobetter aspect, here, this is from a strategy perspective not in scope because ultimately, it follows a different regulatory pathway usually resulting in a product that is so meaningfully different that you have to follow an innovator pathway, invest in a large clinical trial, which typically would be hundreds of millions of dollars. That is not in our strategy. We feel very confident with our pipeline that we can deliver meaningful success with the biosimilar defined strategy.

Unknown Executive Executive

IRA?

Keren Haruvi Executive

Yes. So on the IRA, I will start and say that it's very different, the view from the generic and the biosimilar industry versus the innovative medicine in our industry. And there are pros and cons in the IRA. Where we are concerned is the unintended consequences and how it would look at the incentives to continue to innovate and bring -- and for us, biosimilars, as you heard from Richard, it cost a lot of money and it takes time. So you need to make sure that you have the market by the time you get there.

But again, as I said, there are also pros. So we are still assessing. I think for me, the guidance of CMS, the final guidance and how we'll implement IRA, that's what will make a difference. There are still a lot of open questions. We'll continue to work with them very closely.

We need to remember that at the end, this is just in the government setting, right? It's not the commercial business. It's just on the Part B and Part D. So of course, we'll continue to work with them. The negotiation is the part that we are concerned the most.

As I said, the unintended consequence, then it's coming back to my presentation, we do a

very good job as an industry to reduce pricing in the market. So we believe that the best [try] to reduce price is competition, and our industry is doing a great job, 90% of the volume and 3% of the value. That's in the IRA.

Unknown Executive Executive

And Keren, interchangeability?

Keren Haruvi Executive

Yes. So in the interchangeability, what I want to [pick] specifically for the U.S. We need to remember, interchangeability is not a better product, right? It's not from a quality and not from a safety perspective. It's just a regulatory designation.

The importance in the U.S., I would say, time will tell. It's very different feedback from different stakeholders. We believe that you could win and be very successful in the market with the attributes that I mentioned in my presentation. We don't believe that interchangeability is a key attribute, but it's -- but we definitely recognize that it's one of the attributes out there, and it does allow pharmacies to switch without calling the physicians. So it does give an operational benefit.

We believe that we are equipped to win in the market without it.

Unknown Executive Executive

Anything you want to add, Rebecca?

Rebecca Guntern Executive

No, I will just -- for Europe is clear, right? Because EMA in April '22 gave out a statement that any product which is approved by EMA is interchangeable with originator and with other biosimilars. So in Europe, it's basically what we see in practice is also now confirmed by EMA with an official statement.

Unknown Analyst Analyst

You look surprised.

Unknown Executive Executive

[indiscernible] nervous.

Unknown Analyst Analyst

I have 3 questions from Balaji Prasad from Barclays, who wasn't able to join us in person. The first one for Rebecca. What disadvantages, if any, would Sandoz face in Europe by not being part of Novartis? That's the first one. And then 2 for Keren.

In North America, how is Sandoz geared to differentiate itself from peers and offset the pricing dynamics that most of its peers' face? And the second for Keren is what are your thoughts about the direction of EBITDA from North America in the small molecule generic segment? Will it face a similar upward trajectory as the rest of the business?

Unknown Executive Executive

[indiscernible], could you repeat the last sentence?

Unknown Analyst Analyst

Will it face a similar upward trajectory as the rest of the business?

Unknown Executive Executive

Rebecca?

Rebecca Guntern Executive

It isn't. We have been -- I think, looking at the disadvantages have been actually operating pretty separately already in the past from a commercial point of view, right? I mean, different when you think about supply or development commercially have been independent almost. So we see this now also there's almost no detanglement. So I don't see actually a disadvantage from a commercial point of view.

Keren Haruvi Executive

Yes. Thanks. So for the first question, the best way to offset the price erosion is launches, as I mentioned in my presentation. And we have a very strong portfolio, both on the small molecule and the biosimilar side, so the way that we will offset and differentiate ourselves from the competition is by execution and by launching product. That's this commercial engine that we have, and we'll continue to launch products.

For the question -- for the second question on the EBITDA and the small molecule, again, we will continue to improve because we've introduced more complex products. And again, Claire will cover it in her presentation. But in the small molecule, we have great portfolio, both from oral solids, but also from a much more complex product that will help us to continue and grow our EBITDA. We need to remember that we have this unique scale. We have a large portfolio and infrastructure in small molecule.

So the additional -- bringing more portfolio is just using the scale and infrastructure that you already have. So from a margin perspective, it's allow you to really grow once you introduce more products into the market.

Unknown Analyst Analyst

This is [indiscernible] from JPMorgan. Just 2 quick questions. One on Tysabri, anything you can say on the litigation front in terms of dates for any court trials? And what gives you confidence maybe in that patent that will go your way? And then the second question is, so on the oral solids business, I think in the presentation, you mentioned you tried selling that business at some point.

As you -- sitting where you are today, like do you see that as a core piece Sandoz? Or is that potentially something you can again explore kind of either divesting or doing something else?

Richard Saynor Executive

Okay, perhaps I comment on the first part, and then I'll let Keren just talk about the thoughts about the synergies between the businesses. We -- I mean, clearly, we're going through a patent dance. It's a normal part of the process. We wouldn't normally disclose any specific details around that, other than clearly, we're confident we have a great product, and we look forward to clearing the landscape and hopefully bringing that to the market the latter part of this year. So I guess, watch this space and we'll see what happens.

The -- I guess the Aurobindo thing was an interesting one. Clearly, it shows that some of the challenges trying to divest in this environment. And I don't think that environment has got any easier, actually, with the current FTC. So I think actually in the end, what we've ended up with now is an intimacy and a scale in the U.S., particularly around how we supply our pipeline, the relationships with customers and our credibility that having that broad portfolio, clearly took some time to wash it out, stabilize it. But I think now you're also starting to see an environmental change in the U.S., clearly supplies in the [indiscernible] a lot at the moment.

So having a broad portfolio and a relationship actually I think gives us more strategic advantages. But I think Keren is clearly the expert.

Keren Haruvi Executive

Yes. Thank you. We definitely have a lot of synergies in the business. And it goes from IP capabilities, which, again, definitely goes in both small molecule and biosimilars into market access into supporting patients. We talked about all our ability to support our patients with the biosimilars that launches, but we already have those hubs.

We have a lot of complex generics products that we already bring those support to patients and, of course, the existing bio portfolio. Now other than I would say, we will continue to leverage the expertise, some of the expertise like contracting, we're doing together. Some of our customers are the same. The payers are the same. So it's -- there are a lot of synergies when you look at it from a business perspective.

And we're very proud the way we operate now in 3 channels when we have bio, retail and hospital. But our back end is really consolidate because we do have a lot of synergies, we can use the teams to work with each one of the channels.

Unknown Analyst Analyst

Carson Lo from Credit Suisse. Just 1 for Rebecca. You presented that the European generic penetration rates are significantly lower than -- and there's still quite some significant revenues from branded off-patent products. Do you envision that the European market can ever change to move towards the U.S. in terms of generic utilization?

Then 1 for Karen. U.S. generic pricing has gone through a number of cycles. What do you see as a sustainable pricing trend for both biosimilars and small molecules?

Rebecca Guntern Executive

It was not so easy to understand, but I understand the question was the generic penetration in Europe and whether we see this an acceleration in the future, correct? Yes.

Richard Saynor Executive

And would end up looking like the U.S.

Rebecca Guntern Executive

Like the U.S. Europe, and I think this is also the beauty in Europe. We have 40 different markets. So which makes it attractive in terms of the mix of architypes you have and most probably the risk profile, which is a bit lower because you have really these different market policies and frameworks. So fundamentally, we do see a difference in generic penetration in Europe.

And of course, the tender markets by definition, you would see higher penetration. And if you go to share of voice, it takes a bit more time to pick up on the generic penetration. But we've seen acceleration overall for the reasons I presented that, of course, we see cost containment pressure coming in, which will drive generic and biosimilar penetration. And you're going to have an aging population. So by definition, you're going to see volume growth, which will go into the generic penetration.

Will we become U.S., I would not say that's going to happen really fast because you have very strong stakeholders in the market, like physicians, pharmacies, and I don't see that we are moving so fast in such a consolidated framework like what we would see in the U.S.

Richard Saynor Executive

There's a couple of things to think about. I mean, clearly, Europe doesn't have -- seems like a PPM. I mean it's a completely alien concept. So I think to Rebecca's point, it's highly diverse, different reimbursement systems, governments are under no desire to harmonize that. Were you clearly have harmonization regulatory licensing, which actually we can play to that synergy.

The other thing that's worth thinking about in Europe when I first started at this industry, someone told me you only need to know 3 things to run a generics company: be the cheapest, be first to market and have the best supply chain. Now reality is the relationship between those 3 things, and the Indian players, particularly generally are good at being first to market and generally have low cost. Yet they have no presence really in Europe, less than 5%, 6% share. So there's something else going on. And I think that's really what Rebecca explained is that the relationship with the market, your proximity to your customers making your portfolio.

So if our German business feels very German, our French business feels very French, and that's such an asset that our competitors just really struggled to get that kind of scale. And then the economies of that scale really flow through. So when we launch more products, we don't need more infrastructure. It just flows through the organization. So it's something that's very, very different between the U.S.

environment, which is generally a different kind of framework, and then a European one.

Keren Haruvi Executive

Yes. I also had a bit of difficulty, but I think you asked on price erosion going forward. That was the question? Yes. So I'll not try to guess pricing in the market.

I would say that definitely, as you are well aware, there is price erosion for both small molecule and biosimilars in the United States. And I would say that it's the regular part of the business. I would look at it as a business as usual. You talked about a cycle. So definitely, we've been through a difficult cycle, and I'm very optimistic.

But we need to remember that market do not erode the specific products that you erode, right? So if you look -- if I look at our portfolio, I can tell you that we're very confident that we have enough launches to offset the erosion that we're going to see in the market, both in the small molecule and the biosimilar. And we expect to significantly grow going forward.

Unknown Analyst Analyst

Thank you, I got 2 more questions. On -- for Europe, could you run through the example of Rixathon what happened there? When we looked to the prescription data, you're second to market, you quickly became the leader in Europe, other, which I guess is a more diversified, tougher place to succeed. And then you moved into Europe, top 5 and did incredibly well. Now you're #1.

I was just wondering, you mentioned how commercially Sandoz and Novartis have been operationally distinct. I can imagine having Novartis as a parent company with an oncology portfolio may have helped at some level in terms of commercializing and developing Rixathon. And then the second question is along the same lines but maybe for the U.S., if you look at these hybrid companies that are farmed around generic companies who can offer a portfolio of products across both Rx and Bx and Gx, is it an advantage having broader contracting just outside of sort of generics and biosimilar sort of operational setup? So I'm just going to give a company like Amgen where they have obviously -- they were present in Biologics, they're present in immunology. They have both biomes and generics.

Does that give them an advantage versus you? Or is it just the different strengths and weaknesses for the 2 different business models.

Rebecca Guntern Executive

So thank you -- thank you, actually, for the question because I did not have the chance during the presentation. It's a very important point, both in Hyrimoz but also equally in reality have not been first to market in all the markets around Europe. Nevertheless, as you look now Hyrimoz, which I presented, 19 markets, we're #1. It's pretty similar if you look at reality, right? So there must be something which we're doing well and I would put it back to the platform we're having, but then the commercial capabilities.

In this case, this is absolutely critical to win. So it's this ability to really have this deep customer understanding, our contracting pricing excellence. And then the team in the market who really pull into deep customer understanding. So this 1 I would really pull. Again, I said this advantage of having a separation.

I would not link it to the Novartis oncology portfolio because if you think about the reality is

immunology, right? I would have other examples with Omnitrope, I mean we have different examples where we prove that we really have these commercial capabilities to know how to play, know how to win across market architypes. And it's across all the markets. So it's not a single market across. So the people in the teams in the market is really key success factor during differentiate for [indiscernible].

Richard Francis Executive

Keren?

Keren Haruvi Executive

Yes. Thanks. Look, on the pharmacy benefit, that's where you kind of you refer to, there is an advantage to have a portfolio, right, when you're negotiating with your payers in the U.S. In the medical benefit, it's very different. I would say that the way we look at it, we don't have the portfolio of an innovator, but what we do have is a very broad portfolio across different therapeutic areas.

And payers have a lot of respect and commitment to work with companies that are bringing those products into the market. So we don't have this innovator approach of, again, replacing the brand or bundle products, but we do working in a very broad portfolio, and we believe that we have excellent relationship with the payers, and we'll continue to be successful and bring those products to the U.S.

Unknown Analyst Analyst

Maybe a question for the international markets as well, given U.S. and Europe. Could you help us understand for biosimilars, the relationship between price and volume? So I'm just sort of thinking that as prices come down, volumes might accelerate relative to where they were before, thinking about affordability and things like that. We've seen examples where, I guess, [indiscernible] antibiotics that reduce prices historically in Asia and they gain more volume share and they get sales overall went up from a mix of volume going up dramatically versus prices coming down.

So I guess, we took something like a Herceptin, for example, in your regions where the split between adjuvant and metastatic in the U.S. might be 2/3, 1/3. I think it's the other way around in your regions. And so as prices come down, presumably, the use in the adjuvant setting, which comes with a longer fixed term, could potentially go up to volumes go up in response to prices coming down?

Francesco Balestrieri Executive

Good, so I understand the question is related to the biosimilars in the rest of the world, especially in countries where the price could be with high erosion over time. It's correct?

Unknown Analyst Analyst

Exactly, prices coming down to open access to drive volumes up.

Francesco Balestrieri Executive

Yes. Thank you for the question. I think that's interesting one. It's part of the way I was presenting today in some countries where we understand already in advance that this is going to happen. Eventually, we decided not to play.

And we basically allocate resources, effort, promotion and our volumes to the countries where we see more predictability. In the case of Brazil, this is a perfect example. We understand exactly what's going to happen in the next 10 years. In other geographies within Asia, we have a very predictable environment in Hong Kong, but we have obviously a different pricing versus others but it's predictable over time. We have a 2 to 3 years agreement -- so this is a way of the way we approach this pricing, where we get long-term sustainable, attractive price versus where we get a lot of volatility.

We eventually decide not to play. So that's part of my presentation. We decided not to play in some geographies because they are not either reliable, attractive or long term.

Richard Saynor Executive

If you look at the region, I mean in our markets like Australia, where we're only driven biosimilars. Japan, we have a strong platform. So you've got sort of more regulated markets that are much more like Europe and the rest of the world than markets like Brazil, where we have partnerships with the government through PDP structure.

So then we look at them working with government to open up a market clearly. So then your argument is fair in terms of by bringing down the price and affordability, there's a volume expansion. And then you've got everything in between. I mean a lot of markets, some of the smaller ones, originators may not have even launched. So they're fairly small volume, but good margins.

It's interesting to talk about the antibiotics business to use around that franchise. And a lot of that actually was about promotion. It was about actually positioning it. So in India, it's the world's largest market for clavulanic acid, but it was about the brand promotion rather than getting the right price point, but not necessarily the cheapest price point. And I think that's really the strategy that we've taken with international is we're not promising to be the cheapest.

We're a high-quality biosimilar, but it does open up markets at a different price point to the originator.

Francesco Balestrieri Executive

If you want, I can give you building on Richard's comment specifically in the case of Australia and Japan, Rituximab in Australia and Japan. In the case of Japan, we have a 70% market share. In the case of Australia, we have an 88% market share. So that is the share we have in the market in the last couple of years since we launched.

Richard Saynor Executive

I think we're out of time. So thank you so much for your questions. We now have 1 hour lunch break and we'll back in exactly 1 hour and a half from now, if that's okay. [Break]

Richard Saynor Executive

Thank you, everybody. So now we'll get into the operational part of our journey. And really, I want to sort of reflect on 3 areas. So Pierre, Pierre heads up as the Chief Commercial Officer. In his role, he's responsible really for the end-to-end platform, identifying our pipeline, working with Claire and Glenn to ultimately realize that and then bring that to the business.

For the last 3 years, Pierre has headed up the biologics organization, so a lot of the expansion that we see today is really down to the hard work of Pierre and his team. And he's had 20 years of working in Innovative Pharma, Alcon and Sandoz. So he will come and talk to you really about how we define and drive our pipeline. And then in terms of developing our pipeline, I'm delighted to introduce Claire. So Claire is our Chief Scientific Officer.

She has a distinguished career in both originator pharma but also in generics pharma and has really transformed the development organization within Sandoz. And lastly but not least, we then look at the supply chain and the operational opportunities that we see, both to deliver and support our pipeline, but also to expand our margin as a business going forward. So Glenn will take you through that. Glenn joined us about a year ago. He has many decades of experience in Innovative generic pharma in many geographies around the world, and we're delighted to have him as part of the team.

So with that, Pierre, the floor is yours.

Rebecca Guntern Executive

Thank you, Richard, and hello, everyone. It's really a pleasure to be here to present to you today. As Richard said, I've been with the company actually for 21 years or the group of companies across Novartis, Alcon and now Sandoz, and I've had the privilege of working across biosimilars and generics. And in this role, I cover pipeline strategy, portfolio operations, key launches, M&A, licensing divestments and other key global commercial functions. And so what I'd like to do is begin with a big picture, a big picture summary of this morning.

Richard talked to you about the very unique position Sandoz is in as a scaled global leader across both generics and biosimilars. And the region heads have presented to you on our excellent commercial platforms and how we lead with market proximity, launches at LoE and having a portfolio of scale for the right portfolio in the right area. So I'm going to build off those 2 elements and share with you looking forward, 3 main areas, what's our strategic framework for pipeline management and definition? What is our highlights, if you will, of both our generic category and our biosimilar category in terms of pipeline. And then last but not least, what is the launch value outlook over the next 5 years?

And why are we so excited about that potential. So moving to the strategic framework. This is very critical and will flow through the next slides that I take you through and it's very critical for us in terms of value delivery and operating process. And so I'm going to highlight a few additional highlights that are here a little bit more than what's beyond this slide. And so if you look at the selection frame, what I'd like you to take away from this element is that Sandoz is a company that has built a pipeline for products that will launch at LoE.

That is incredibly important to highlight because those are what will drive the most value for us. And you've heard all the reasons why from commercial platform presentations. So in essence, to be very clear, we will not be pursuing building a pipeline of launching products that are already existing in market with many generic competitors. We will do the opposite. We will launch products and majority build for products that launch at LoE.

Second aspect is the commercial lens. You heard about the distinct differentiation of the Sandoz commercial capabilities and platform. That's very critical because that commercial platform is ultimately used and leveraged in all our pipeline process and governance boards. We get our insight direct from business leadership who are included and involved in all reviews and decision-making on pipeline. Ultimately, for the simple reason that what we build in pipeline, we want to ensure we succeed when we launch in market.

The other area that's really important to point out is scenario valuation. You're going to notice through the presentation that 70% of Sandoz pipeline is geared towards complex generics and biosimilars. That means we are selecting programs 7 to 10 years before they launch. And so having very good line of sight on intellectual property scenarios and really good line of sight on what product do we need to develop now, so that 7 to 10 years from now, that is a winning product on day 1 of market formation. And then last but not least, the 2 areas of technical lens.

My colleagues, Claire and Glenn will present to you in the upcoming sessions, and their expertise in advisory is critically important where they hold decision rights and have presence with their teams across all our boards, not only to ensure that we have conviction on the pipeline that we're developing, but also that we have clarity and alignment on network strategy, capabilities and the efficiency that we can drive with that. And then last but not least, I want to bring to your attention the overall point of the operating review. We have a very high level of discipline and diligence with monthly operating reviews, including all presenters that you have met here today being part of a monthly executive governance forum on both pipeline and launches. And so overall, this really for us sets a very confident tone on the next slides that I'll present, and why we're so excited about the pipeline that we will deliver. So clearly, the big picture is that we're moving to a more complex phase of delivery of pipeline assets across both complex generics and biosimilars.

And we have a very broad pipeline. As Richard pointed out, more than 400 generic programs and 24 biosimilars in the pipeline. And it's important to point out that this mix shift with 70% contribution from higher and more complex technologies, is ultimately going to allow Sandoz to grow but also to mix shift and to provide even more value with the launches ahead. And so what I'm going to do now is spend a little bit of time on the generic pipeline, afterwards followed by the biosimilar pipeline with a view of the key launches that are coming up.

So on the generic side, clearly, we're very excited to have complex generics that are covering $44 billion of loss of exclusivity out of a total portfolio of projects, 400 projects covering $145 billion in LoE. Now before I speak a little bit more on complex generics, I'll explain to you our approach for standard generics, where we have a very disciplined and focused approach. So when we look at standard generics, we see a few lenses that are very critical we target high-value assets in market. We target launching at LoE in those asset categories. And then

last but not least, we look to maximize scale in those asset launches.

And let me give you a live example of a product that we launched only 3 weeks ago. There's a large product called Farxiga. Farxiga is an originator brand with more than $4 billion a year in growing sales in the diabetes space and is an oral product. We developed a generic. We launched on day 1 of -- in the Canadian launch to ensure that we're in a position at market formation so that we can succeed and we're going to scale that launch globally across Europe, the U.S.

and international markets over the next 3 to 5 years as market formation occurs. And so here, you've got a great recipe of going after value, going after scale and being there at day 1 in all the key geographies, leveraging our internal development and manufacturing network really efficiently. Now moving to complex generics where clearly, with 1/3 of the value contribution and $44 billion in LoE coverage, this is a very important strategic segment for Sandoz. We have a multitude of different technologies here, covering complex, high dose injectables and IVs, complex peptides, drug device combinations and oligonucleotides. Some of these are emerging technologies that will only see the LoE pattern occur 2030 and beyond, but it's very important that we have the capability and the early planning to succeed here.

And my colleague, Claire is going to present to you on our capabilities in his segment in the development section, as well as real examples of highly complex products that we've already launched in market and succeeded on. And so now I'll switch to biosimilars where I want to point out a few important facts. Bringing you back to Richard's earlier presentation, today, Sandoz has 8 in-market biosimilars, and they are generating $2 billion in annual sales with a very healthy growth rate behind them. What we're really excited about is then adding 24 additional biosimilar launches over the decade to come as part of our pipeline execution, and really putting us in a position to be the undisputed industry leader in this category. And so clearly, it's a complex category.

It's a category where you're planning 8 to 10 years in advance. And so as we look at the cost concentration and the planning, we look forward many years in advance to understand what product are we developing, with what features and benefits and why will we win 10 years from now in that category? And I'm now going to show you the 4 upcoming launches we have, and I hopefully give you some examples of how that strategic process has played out into winning proposition for the upcoming launches. Okay. So here's the big slide on the global launches, the 4 major biosimilar launches that are going to occur in the next few years.

Let me start with the first product, adalimumab, which is a reference biosimilar to the originator of Humira, covering a very large LoE of value and a total value of $21 billion globally. Now clearly, this is a very competitive field, and Sandoz is in a very strong position of already having had FDA and EMA approval for the high concentration formula. Now a few things that are really important for you to know about this launch: As my colleague, Keren, pointed out, first and foremost, we have a high concentration formula. Why is that important? Because the originator has shifted 85% or more of its volume from its low concentration formula to high concentration formula.

And so far, only 3 companies have an approved high-concentration formula offering, Sandoz being 1 of the key companies. This is a really critical point. Second aspect that Keren

mentioned is ex U.S. supply reliability and record of excellence. We have 5 years of supply reliability information across being #1 in Europe, #1 in markets like Australia and Canada, and the confidence that can transmit to U.S.

customers is unparalleled in terms of our ability to ensure that we will be positioned as a partner of choice and a good strategic partner for not only the short-term rollout, but the long-term rollout of the launch. The other aspects that are potentially unique and really interesting for you to know about are 2 aspects. One is that we have a very unique device, and they have some important differentiating features. First and foremost, it's an ergonomic design. So it's got a triangular design, which for rheumatoid arthritis patients is very helpful and very much appreciated by customers and not offered by all companies in this segment.

The other aspects of the auto-injector include a large viewing window, thin needle gauge as well as a double-click presentation feature. What does this lead to? It leads to real-world evidence in the last 5 years that this is a best-in-industry device, and again can ensure customers that when they transition patients from the originator, they will have an equal or better experience on the device compared to what they had prior. And last but not least on adalimumab, one very important differentiating feature. We will be one of the only unique companies to have a starter pack.

Now this was part of our strategic planning several years ago in anticipating that customers may not only want to transition existing patients but may want to obviously start new patients. And if Sandoz had a starter pack, we may be having a unique offering. And so we will have that at our U.S. launch, and we anticipate that this might be a differentiating feature for the company. And so overall, very large LoE, and I would point to the fact as well that the high concentration formula will be rolled out ex U.S.

where we already have a leading position in a business that is growing double digit, as you heard from Rebecca, over the last year, and we have a leading position. So a great asset, very confident on our position. Okay. Now moving to a very different launch and a very unique one with natalizumab biosimilar or a proposed biosimilar to the originator Tysabri used in multiple sclerosis with global sales of $2 billion, largely split $1 billion in the U.S. and $1 billion ex U.S.

Now this is a really exciting and unique opportunity where we expect to be first and potentially alone in the market because we don't see anyone initiating clinical trial activity. We at least feel very confident that for a 2.5- to 3-year window, we will be the sole entrant in the market. Very exciting market for a few reasons. You know that the MS market, multiple sclerosis has been growing for many, many years, but it's also seen a lot of innovation disruption. Many new therapeutic agents have entered the MS space in the last decade.

What's really interesting about Tysabri is despite all the innovation disruption that's occurred, Tysabri has largely held a 10% share in most major markets. And so it's really well positioned as a high-efficacy treatment, used in patients with highly active disease in a second and third-line setting. And we look forward to bringing a biosimilar with all the attributes needed by patients and customers to be able to succeed. The next really exciting launch is denosumab, the third line that you see on this graph, a biosimilar proposed to Prolia and Xgeva, filed already in Europe, U.S. and Canada.

Now here, I want to point out a few things. When you see the $7 billion figure, it's important to point out that 2/3 of that revenue base is in osteoporosis, and that's seen continued growth over the last several years. Now this is a twice yearly injectable in osteoporosis. And this is going to build on a point that Richard brought earlier. Richard explained to you that when biosimilars come to market, they can greatly expand the original position of the originator brand because of more accessible pricing.

Well here, only 15% of patients in public health care markets today, such as the EU 5, have access to denosumab. We see the potential for really significant market expansion to be able to bring this therapy to more patients with more accessible pricing and the great commercial platform that we have. And then last but not least, we have an aflibercept biosimilar program to reference medicine Eylea. This will see a readout of the Phase III clinical trial in Q3, upcoming shortly. And we're excited for this space for a number of reasons, and I'll bring you back to the strategic framework here.

Several years ago, we identified that this would be a very competitive market at entry. And we determined that ensuring that we could launch with a prefilled syringe in addition to a vial offering would be very important to our success. Now it's important to point out that the original brand has a prefilled syringe, and it's more than 80% of their revenue. But it's a very high technical hurdle to achieve FDA approval for the prefilled syringe. In fact, the originator brand faced a CRL and a delay in bringing their brand to market when first attempted.

We are leveraging a platform of an already approved prefilled syringe technology across both development and manufacturing, and we feel really confident to enter this market with a winning target product profile in a market that is large and growing. So hopefully, this gives you a sense of 4 great examples leveraging our strategic framework to ensure that we're launching biosimilars, all of these market formation and all of these with differentiated and/or highly competitive profiles to ensure success and ultimately winning conditions for Sandoz with customers and patients. And so wrapping up to my last slide, here's a great summary of why we're so excited about the pipeline. And you're going to see here on your left-hand side that in the last 5 years, Sandoz has launched $1.6 billion in value in terms of new launches and medicines. And the makeup of that was approximately 1/3 biosimilar.

Look forward to the next 5 years on the right-hand side of this slide, and we have nearly doubled the pipeline potential value already in our existing pipeline. In addition to that, you see a mix shift in line with our strategy of having approximately 50% contribution from biosimilars and having a higher proportion of complex generics contributing 35% of a contribution in the generic space. So we're really excited about this pipeline, really excited about the future. And with that, I'm going to pass to my colleague, Claire, who's going to take you through our development network strategy capabilities and operations. Thank you very much.

Claire D'Abreu-Hayling Executive

I will start by introducing myself. I'm Claire as already spoken about. I have had 35 years in pharma, always in R&D [Audio Gap]. And the last half of spent 15 years in Teva, looking extensively on the generic portfolio, specifically in complex injectables in the last 10 years and have been with Sandoz since October [Audio Gap]. Taken us through a very eloquent

description of a deep and wide pipeline, biosimilars and small molecule generic products and -- as a scientist, I'm truly excited to have the opportunity to find my passion for science, people and being able to get products into patients' hands.

And I want to take some time with you this afternoon to take you through the Sandoz Global Development, [indiscernible] which is an organization that sits at the heart of Sandoz and is the engine that really drives the growth of Sandoz as we move forward, delivering the current pipeline and also delivering the future. I've already said that I've spent time in innovative and generic R&D. So that gives me a very unique perspective on what a generic mindset truly is, and the opportunity that we have as we separate from Sandoz to really optimize that generic mindset, build agility into the way that we would look at cost optimization and speed of development and most significantly lean into our regulatory and IT capabilities to create competitive advantages for Sandoz in the market greater access for patients, our products. I want to give you an introduction to the organization, which is a development and regulatory organization. Where we have 1,700 still highly experienced, scientific, clinical, medical and regulatory associates very passionate about delivering the portfolio.

They are located in our 6 development centers, which is a quite cost-efficient footprint. And it's really important to recognize that we are well equipped in terms of our infrastructure, in terms of our capabilities, in terms of use of digital tools to accelerate the development process. And that has led to both in the past and moving forward, our very strong track record of success in getting products to the markets. I'm particularly proud to say, and as Rebecca has already said, that we have 100% success record in bringing biosimilars to market, and we are very smart in our clinical approval. I'm particularly excited about the fact that we have small molecule generics and biosimilars under the same [Audio Gap].

From a skills capability and knowledge point of view, there's a lot of synergy between having the 2 together. I think it makes it smarter in the way that we work. Some key examples that Pierre just shown you the device for our adalimumab product, our device development capabilities, a platform that's common across our complex injectables and our biosimilars, as well as our regulatory knowledge and the need to do analytical characterization is something that we can tap into and take advantage of for both parts [Audio Gap]. Generic industry continues to be a very rapidly evolving and challenging one. And the fact that we have highly skilled, very experienced regulatory associates, but really no regulatory requirements in each market and are able to lean in and work very closely with regulators to shift the regulatory landscape continues to give strategic advantage to Sandoz as we bring new products to market.

And lastly, the last point on this slide really is recognizing the breadth of technology and the span [indiscernible] move pipeline, it's not practical to expect that we can do everything internally both from an infrastructure capacity point of view. But Sandoz, because of its scale, reputation and credibility in the market, is actually a very desired partner, and we work with high-quality external partnerships to succeed in delivering our entire portfolio. Keren, Rebecca and Paco spent time this morning taking you through the commercial platform. We are really proud of the development and regulatory organization and the track record it has in generics. And in each of the markets, which have their own complexity, Europe, over 40 countries.

Paco has already spoken about selectively playing in 26 countries. In America and in Canada, recognizing that we have one regulatory.

The capability to understand the development needs, regulatory landscape and the IP landscape for these markets have allowed us to be able to bring over 120 unique submissions in Europe, a similar number in international. And we've been very assertive in increasing the number of files that we've put into the U.S., working collaboratively with Keren to bring the rebalancing of the U.S. profile as we move forward. Another part of our key focus as a development organization being very incentive in our system market strategy. We say, you have to be first.

You have to be first. You have to be first and you have to be fast with respect to generic. And again, for our European countries, over 80% of our products are launched with the market. In the U.S., we have increased the number of first-to-market launches that we have. And I'm particularly proud in international, where we have moved from 10% to 25% first-to-market opportunities in the last 3 years.

And that is a profile that we will continue to do, and we continue to work very closely with our commercial colleagues to ensure that we're meeting the needs of the market, both present and future. That is well showcased as I show you some examples of our complex generics, which Pierre mentioned earlier. Taking a step back, one of the things that tempted me to come to Sandoz when Richard approached me 20 months ago was the fact that Sandoz was first to file with ferumoxytol. They then succeeded in getting it to market. And that really tempted me as a scientist and as a professional because I thought, wow, there's some serious capability in this organization.

We're able to bring this because it's a complex API. It's an IM-based product, which is then developed into a solution formulation, but the analytical characterization requirements for that product and a very high barrier of clinical requirements that the FDA have posed to get approval and get to market with something that Sandoz was capable of succeeding with. Similarly, the 2 examples, they have fulvestrant and albuterol, where the drug device combination capability and the fact that we have invested in a device organization, really showcases already established capabilities in the organization to do that type of product, but also for future technologies, the capability to continue to meet drug-device combination products. And lastly, the last example there, which is transdermal, which is launched in Europe buprenorphine again, has its own complex and regulatory requirements. This platform of capability and understanding of the development and the regulatory requirements.

You can't hear me? Means that we have been very successful in the past, and that's a future platform for future successes. In combination with that level of capability on the generics, we already have a significant success record in bringing biosimilars to market. We've already hit about the 8 biosimilars that are in Europe, where we have #1 position in 5 of them. That pioneering spirit of Sandoz in being the first to bring a biosimilar to market in Europe, Japan and Canada, opening the U.S.

market particularly excited about the planned launches that we have of the 4 molecules that Pierre has already shared with you. But that increased success rate of understanding the development time lines, which is 5 to 9 years, the cost of development, the speed of

development and the ability to ship regulatory guidance, create advantage in the market for biosimilars, gives me significant confidence that for the remaining 24 products that we have 16 in early development, 8 already under clinical and regulatory review, we will succeed in bringing those, and that will underpin our growth as we move forward. So just taking a step back, and I really want to talk about the key technologies and some of the end-to-end development capabilities and how everything works together across the organization. The development organization has the capability to deliver every technology platform. But focus is so critical.

We focus on 4 particularly biosimilars, all solid injectables and respiratory. Working in an end-to-end manner with Pierre to understand what assets we're going to be working on; with Glenn to ensure we have a good understanding of the manufacturing infrastructure in which we have to develop and manufacture these products to be able to launch successfully. So that end-to-end approach is something that we work on in a very smart way. Similarly, when we look on our development aspect, you can split it into several areas. There's early development around analytical in formulation, the later phase around the clinical and regulatory and then launch.

We've been very specific and strategic and vertical integration, and deciding where to play and where not to play. Specifically for biosimilars, we have our own drug substance development capability, similarly for anti-infectives. However, for our small molecule generic portfolio, we took a decision that we would partner externally with API suppliers, which gives us access to API early. It allows us to bring the products to regulatory review first to mark -- first to file and later on be first to market release opportunities.

Similarly, that regulatory and IP framework is a key part of understanding what our development strategy is and working very closely with our IP and legal team. We're in the business of busting patterns. That's what it means to bring products to market at loss of exclusivity or even before loss of exclusivity when we were able to work in such a way that we were able to bring the right formulation early on. Our capabilities and our people sit in 6 development centers, which are highly equipped both in terms of equipment but also in terms of digital capabilities and the use of artificial intelligence, which we have started to lean into quite significantly to accelerate the time of development. And there's a strong strategy around the design of our network.

Both from a point of view of access to talent but also from the point of view of cost optimization. And having some of our centers situated in low-cost economies, as well as ensuring that we can actually find the balance between talent and cost. Our Solids Oral, which is the primary base for our generic portfolio, is actually based in 3 locations. We have our injectables based in 2 simple injectables and complex injectables. And as I spoke about previously but there's actually a lot of synergy between the complex injectables and the biosimilars.

And because of that, you will see that we centered Kundl and Ljubljana as the place where we will be building our biosimilar capability as we move forward. Another key area for us is the respiratory space where, again, we have end-to-end capability, both in terms of development and manufacturing and having both capabilities located at our Rudolstadt site in Germany.

Complementing our development centers, we also have centers of expertise where we focus on key topics, which are of significant interest to the regulators. Nitrosamines has been a key area of focus in the past and will continue to be a key area of focus, being able to understand how we do biosimilar analytics, and also something like leachables and extractables, again, has been a very key area of focus from our regulators. So we complement our internal development centers by having centers of expertise for knowledge sharing best practice development.

In parallel with our highly skilled scientific community, we also have a highly capable regulatory team, which shapes the industry landscape through advocacy and scientific discussion. This is particularly important. We spoke about we have a current pipeline, but we continue to do significant industry intelligence on what technologies are coming our way. And for some of these new and emerging technologies, the regulatory guidances have not yet been defined. So actually having skills and capabilities in regulatory where we were able to speak into the scientific guidance on complex products define and work very closely with the regulatory agencies to shape the clinical programs that are required and also build on the guidance with analytical similarities through representation from our subject matter experts on some of these industry panels like AAM, biosimilar form, et cetera, continues to create a competitive advantage for Sandoz and has been part of the reason that we've been able to succeed in the past with being very smart in how we leverage our products into all the markets globally.

Similarly, recognizing that synergy, again, from a regulatory point of view, we've integrated our regulatory teams across generic and biosimilars. One of the changes I've made to the organization, recognizing the strategic importance of regulatory is I have brought one of our leading regulatory leaders into the organization to again speak to this particular area. I've already shared with you our internal capabilities, and maybe to sum that up, I think we have a lean, efficient, highly-skilled, very experienced organization of scientists, regulators, clinical, medical, patient safety that sits in our 6 facilities. That is complemented by working very closely with high-quality external partners.

Again, I said that we cover such a range of technologies. We don't have the infrastructure to do everything internally. Glenn and I have worked very closely to define what our technologies platforms are, where do we play internally both from a development and manufacturing point of view, where we partner externally to allow us to have access to technology, capacity or people and expertise. And I'm particularly proud of a recent relationship that we've established with Just-Evotec, which I think is very disruptive in the biosimilar space, which gives us access for the artificial intelligence capability to deliver and develop drug substance for biosimilars, which will then be put into their continuous manufacturing framework.

Just-Evotec is an organization that works very closely on early development with several innovative companies, and they have already started conversations with the FDA on acceptability of their continuous manufacturing platform. So we are highly confident that we will be able to succeed in delivering many of our products with this Just-Evotec relationship. Similarly, we will continue to have that relationship with Novartis, who currently are working with us on execution of some of our technical laboratory work and some of our existing

biosimilar form projects. In conclusion, therefore, I'm very confident that we have a strong base as a development organization to continue to deliver our portfolio. Both the 400-plus generic molecules we are already working on as well as our 24 biosimilars.

We continue to have the breadth of capabilities to cover the full range of technologies in every discipline within our organization. We will build on that strong track record of success, and we will continue to work exclusively and extensively with very strong external companies partnering with them to ensure that we can have access to flexible network, both internally and externally, to deliver our current portfolio, but more significantly to continue to pioneer and deliver new technologies for our upcoming portfolio as well. Thank you.

I hand over to my colleague, Glenn.

Glenn Gerecke Executive

Thank you, Claire. So good afternoon, everyone. My name is Glenn Gerecke, and I lead Sandoz manufacturing and supply. This means that I am responsible for delivering all of the products that our commercial platform heads discussed with you earlier today, as well as all of the development products that Claire and Pierre just discussed with you in the last 2 sessions. That also means that I am responsible for delivering 350 basis points of core EBITDA improvement over the time period between now and 2028.

So I'm going to take you through exactly how we are going to do that. It is perhaps useful to look at the organization as it was at the end of 2022, so that you can have a basis for understanding what I will talk about as we go forward today. I selected some numbers, and I selected some data for this slide that I believe are really differentiating for Sandoz and I will take you through some of that. The first is 160 regulatory inspections of our facilities over the last 4 years without a critical or major observation. This is differentiating in our industry.

It speaks to the way we run the network, and it speaks to our ability to continue to deliver these high-quality products for years to come, it's a basis and its fundamental in our operations. The next number I'd like to show you is 90% of our products delivered on time and full in 2022. Given such a broad array of in-line products, this is really an incredible accomplishment. This means every line item on an order delivered the day it is supposed to be delivered, 90% on time. And I will remind you, this is coming out of the COVID era when supply chains have been extraordinarily stretched.

1.7 billion packs delivered in 2022 in a very asset-light network only 18 manufacturing sites. And I think you will find this to be quite differentiating when you look at large-scale generics. So I will talk you through why I'm so extraordinarily proud to lead this network. When Richard asked me to join Sandoz partway through last year, I gladly did join, but I did not know all of this information. And when I came to the company, I became incredibly impressed with the way that Sandoz technical operations has been operated.

And it gives me tremendous confidence to know that going forward, we will be able to build on this success and execute the plan, which I will describe for you as we go on today. So we said that we would move the company in 2028 to 24% to 26% core EBITDA margin. And we said that 350 basis points of that EBITDA margin would come from operational improvements. Those operational improvements fall into 4 categories. They are design of the

internal and external network, focused vertical integration.

So this is vertical integration where it makes sense. And there are some places it does make sense and there are some places, it does not, and I will take you through that.

Operational excellence. Operational excellence, I defined is getting more value out of a given asset base. We have a long history of operational excellence, and I'll explain to you how we will take it forward. And finally, external spend optimization. These 4 levers put together will deliver that 350 basis points of core EBITDA margin improvement.

So let me start with the internal network. You can see that the internal network is composed of 18 different manufacturing sites. I would characterize this network, first of all, as being highly utilized. We are getting extremely good value and volume out of quite a limited fixed cost base. The network is also characterized by well-maintained facilities, very modern equipment.

A group of colleagues that operates this network that is not only well trained, well qualified but most importantly, highly engaged in our business. The network is capable of making all of our oral solid products, in addition to the complex generic products that Claire described to you and biosimilar drug products.

If you look at the left-hand of this particular slide, you will see that we have reduced the size of this network by 7 sites over approximately the last 5 years. This does a couple of different things for us. The first thing that it does is it limits our fixed cost exposure going forward.

The second thing that it does is it limits the amount of maintenance capital and recapitalization that we need to do going forward. And all of this leads to cost competitiveness and cost efficiency. And I will point out to you that this network has changed, although the volume output has increased. So let me talk now about where we will go with both our internal network and our external network. You see on the left-hand side of the slide, just staying with the internal network a little bit longer that we have already announced that we will reduce over the next couple of years, 3 more sites.

Again, limiting fixed cost exposure and limiting the amount of CapEx that needs to be put into our internal network.

As a general operating principle, we manufacture internally where we believe that we bring competitiveness, and we bring differentiation. So we look at each of the technology platforms that Claire described too earlier, strategically, and we look at each of the products in the portfolio from a business case perspective, and we decide will we manufacture internally or externally. Always through the lens of are we the best at this or potentially our external providers better than us in a particular technology or with a particular scale or with a particular portfolio. So let me bring us now to the external network. You see that we have 700 external supply points today.

This is part of an asset-light philosophy, and this is part of a maximized value philosophy that we have in Sandoz. Of the 700, a little more than 200 are actually active pharmaceutical ingredient suppliers. And as Claire has said, we choose the active pharmaceutical ingredient supplier who can allow us or enable us to be first to market, first to launch. We then often

switch API to do life cycle management of our products to make sure that the products are kept competitive with API being a very large part of the product cost. So we rather like having 200-plus suppliers.

It enables us to be very flexible. It enables us to have very little fixed cost. And it enables us to make sure that we keep this market competitive for our good and for the good of our customers and our patients.

The other 400 or so plus sites are actually finished dosage manufacturing sites. And here is an area where we believe we have tremendous opportunity. So the idea with this part of the network is that we will concentrate our external spend with suppliers where we can build strategic relationships, win-win relationships and actually very much improve our competitiveness for the finished dosage side of our business. I think it's important that I speak with you about Novartis as an external supplier to Sandoz. As we spin Sandoz away from Novartis, Novartis becomes a CMO.

The main message that I want you to remember from this slide is that we will sign agreements with Novartis that will enable us to supply all of our in-line biosimilars, and all of our near-term launch biosimilars as they were described by Pierre.

Novartis over the years has shown to be a highly reliable, a very high-quality supplier of biosimilars for Sandoz and this will continue. And in this agreement or in these agreements that we will sign, we will also be able to maintain a highly cost competitive position that will give us the commercial flexibility that we've been talking about so far today. Of course, we will look to diversify away from Novartis over time. We have already mentioned Just-Evotec. So manufacturing tends to follow development.

And while Just-Evotec gives us tremendous development capability with a brand-new technology platform, it also gives us the option on this very same manufacturing capability. And there are other examples, which we'll bring to you at a later point in time.

So staying with biosimilars, now let me shift gears a little bit into where we do want to be vertically integrated. So Richard has already discussed and you've already seen our press release that we will build a biosimilar drug substance facility in Slovenia. This is a fully end-to-end, fully integrated biosimilar drug substance facility, starting with cell bank management, through manufacturing, through quality control, storage and distribution. We will begin construction late this year. We will complete construction and have the facility ready for technical transfer in late 2026.

Key point on the slide is when this facility is built, and we are ready to transfer products into it, it gives us a step change in cost competitiveness even over the Novartis network, which I've mentioned to you earlier.

Now I'm going to stay with focused vertical integration, and I'm going to bring you another example, and this is in antibiotics. So we've not talked about antibiotics a lot today. But as Gilbert mentioned in his introduction, when Sandoz introduced the first oral penicillin in the early 1950s, it was groundbreaking for the practice of medicine. Ever since then, it's been an extraordinarily important part of our portfolio, really a cornerstone of our portfolio, and it has remained a mainstay in the practice of medicine. We are the leaders in antibiotics worldwide.

We are #1 in value, and we are #1 in volume, and we have continued to invest in this business to make sure that we remain #1 in cost competitiveness. So this $250 million that we've invested and over the years will enable us to make sure that our network remains the best in the world, fully integrated and fully in Europe. Most of this money has already been spent. 2 of the 3 sites that I said we will be closing on a previous slide will be a result of this investment. So you get an idea of how we continue to develop our network.

Next, I will move to operational excellence. Again, operational excellence, getting more value out of a finite set of assets. I've mentioned to you our strong foundation in terms of quality, in terms of reliability, and I would add in terms of safety. Operational excellence is really in the DNA of Sandoz. We will continue to find ways to maximize our asset utilization and to improve our processes, both the technical processes in terms of manufacturing the actual product, but also our supply chain processes.

We have a plan that we continually execute. We build our challenges from an operational excellence perspective into that plan and we monitor it constantly, and we do very well with it. We also benchmark ourselves. We know that we're good, but we know that we can get a lot better. And this gives me a lot of confidence in telling you that between now and 2028, we'll be able to continue to deliver value out of our network.

And finally, external spend optimization, procurement optimization. On the left-hand side of this slide, I show you a bit about our external spend base. We spent $4 billion externally as a company. It is spread out amongst 13,600 different suppliers. If you do the math, that comes out to about $300,000 per supplier.

It tells us that we have a huge amount of opportunity to do a much better job with external spend optimization. As part of Novartis, this has been done by a fragmented procurement organization from different parts of Novartis, not necessarily focused on what we need as a generics company.

So what will we do differently? The first is we will leverage our scale. And this has to do with not only the direct materials that go into our products, which, of course, are a large part of the product cost, but also all of the indirect services of the company, which have largely been untouched. We will reduce complexity. This is through internal demand reduction, but it is also through business process simplification.

We need to have business processes and demand that is appropriate for a generics company and a biosimilar company, not an IM company. So tremendous opportunity here.

And lastly, we have built already a fully integrated procurement organization, which is focused on Sandoz with a brand-new Chief Procurement Officer, who has selected a tremendous team.

So in summary, we already have a high-quality global supply network. It works really, really well, and I've showed you all the data to support that. I've also showed you that we have 4 main levers to drive optimization in the near term and certainly over the period that we're covering today, which goes up to 2028. And we have tremendous internal and external capabilities through the teams we've built, the partnerships we've built to support our ambitions. So thank you very much for your attention.

And Richard, will lead us in Q&A.

Richard Saynor Executive

Thank you very much. So Claire, Pierre, Glenn, join. So we open up the floor to any questions.

Mark Purcell Analyst

Mark Purcell from Morgan Stanley. I have 3. The first one is a very broad one. Richard you talked at the beginning about the cost of biosimilar development being between $100 million and $200 million. Could you help us understand that range and if the costs are coming down?

Secondly, on biosimilar Eylea? Can you help us understand what you're seeing around the high dose formulation, time lines there, IP, et cetera, so that opportunity?

And then lastly, the importance of cell lines, clearly, for long-acting products like Stelara and specifically, in your case, [indiscernible], it's important to have the originator cell lines. It seems in terms of some of the things we're seeing with the regulators. So I think with [indiscernible], I think with [indiscernible] cell line. So can you confirm that you're using the originator cell lines and provide any comments around that side of the dome?

Richard Saynor Executive

Pierre, do you want to take that?

Pierre Bourdage Executive

Yes. So I can take the Eylea high-dose question maybe to begin. So on Eylea, there are a few things to think about when we see the market and the opportunity. First and foremost, there is innovation and disruption happening in the market from -- mainly from 2 sources. You have high-dose Eylea that is expected to enter.

And clearly, that is going to move the opportunity for patients instead of -- and kind of an 8-week cycle of dosing, they could move to either 12 or 16 depending on patient reaction to the dosing and the label.

And there's also Vabysmo from Roche, which has also extended the dosing interval and the innovation in the market. So we see that in 2 ways. Number one, innovation is something we always face when we enter a market. If you think about adalimumab, it's facing competition from several classes of new immunology launches and yet we not only convert the originator, but we see underlying market growth, as explained by my colleagues, in particular, in Europe where we have deep experience.

And number two, we look at the ophthalmic market across the 3 primary indications, and we see Lucentis and off-label Avastin accounting for 45% to 55% of the market in both the U.S. and in Europe. So our view of the 8-milligram dosage for Eylea is that, first, it will be still continue to be a very large market with an $11 billion LOE. It will face competition, but there's an opportunity to expand utilization ultimately against the 2 reference agents that I mentioned. Beyond that, for competitive reasons, I wouldn't mention any internal planning on high dose.

And on intellectual property, our policy as well is to not disclose that until we have a firm statement to make.

Richard Saynor Executive

Do you want to comment about cell lines?

Pierre Bourdage Executive

Yes. On the cell line side, natalizumab in particular, as referenced, is developed by our partner, Polpharma Biologics. They lead on both development and manufacturing. This has been submitted to authorities, the file itself for both U.S. and EU.

I can't comment specifically on the cell line, we'd have to engage with the partner to discuss any disclosure that we would make. What I would say is that the program itself had very good and early scientific validation with both the FDA and EMA, and we feel very confident about the filing status.

Mark Purcell Analyst

So it was [100 million, 200 million] cost -- average cost of the biosimilar. What defines that range? And is it coming down?

Richard Saynor Executive

Mainly the cost of this -- clinicals. Now Claire, it's encouraging that you're seeing the regulators, particularly in the U.K. now started recognizing enhanced data package rather than necessarily that. And really, the bulk of that cost is to originate the samples in order to do those studies. But clearly, we see opportunities to see those costs coming down.

I don't know Pierre or Claire, do you want to comment?

Claire D'Abreu-Hayling Executive

Yes. I think we have been working collaboratively with the regulatory agencies that be smart about the design of the clinical programs for as long as there's a requirement for clinical programs. Ultimately, we'd like to be able to influence that analytical characterization and similarities enough to eliminate the need for this clinical programs. We also manage the cost very closely by ensuring that not just with the individual regulators but across all the different countries that we submit that we try to align and have 1 clinical program that serves all of our markets. And this is the true power of leverage.

And again, it helps to manage and minimize the total cost of development for each biosimilar asset.

Unknown Analyst Analyst

I've got 4 questions, I think, please, if that's all right. I'll maybe [indiscernible]. But maybe, first of all, just on the Just-Evotec relationship. Curious, are there any plans to also look at potentially using their AI technology, et cetera, to make the lower cost? Because you mentioned it was best-in-class low cost to make your current biosimilars and near-term

biosimilars actually a lower cost option?

Or is it purely because you sort of mentioned to develop it in the future? But is there any plan to potentially improve your current COGS? And I guess sort of related to that, the Novartis contracts that you're going to sign are those perpetuity? Or is there -- or how do we think about who has control there, I guess, what your aim would be on your side with regards to those contracts?

The second or third question, if you like. You mentioned -- I thought how many it was now, but a lot of people -- there are a lot of sites that are providing you externally with API. Just curious what -- from your side, given you mentioned that competitors and there's a lot of issues with quality, et cetera. What do you do to safeguard, I guess, from your perspective, that -- given the significant number of external suppliers that you're going to be okay given you seem to be quite heavily reliant outside of those on third parties to supply what you need?

And then finally, curious on antibody drug conjugates, I guess this is an R&D question. Clearly, potentially a massive class over the next decade. Is it an area you feel is viable? Is it an area you're looking at? And is it something you think potentially could be an opportunity?

Or is it just too complex given the challenges on, I guess, both manufacturing, R&D and everything else?

Richard Saynor Executive

Okay. Perhaps if we do it this time, I'll do with the Novartis contract. Pierre, Just-Evotec, Glenn, our suppliers and then Claire ADCs. So a distribution of labor. I guess your question predominantly relates to biologics rather than small molecule supply.

So we have, I guess, a medium- to long-term supply agreement with Novartis, which we can then choose to extend over a period of time. So it's a supplied at arm's length, but it's a very modest cost increase over the current costs that we have. So part of the benefit of I guess, continuing with the relationship. So effective at the moment, it's a 5 plus 2 plus 2 agreements. So we've got plenty of scope to extend it.

And then also we'll look at tech transferring and a lot of that pipeline then into the Slovenian facility once that's up and running. So I think it gives us the flexibility, gives us the assurance of supply and the confidence in terms of our cost base going forward.

Okay? Pierre, do you want to take Just-Evotec first?

Pierre Bourdage Executive

Sure. And Claire had mentioned that we worked together on end-to-end. So I'll cover one part of Just-Evotec and then transfer to Claire for the second part. Let me speak about the scope and terms of the contract. So we have 8 assets partnered with Just-Evotec and these are pipeline assets, not in market assets, where we will partner with Just-Evotec on the development and ultimately, all the way through a commercial manufacturing for several of the assets.

And what we're really partnering on here in a shared economy structured deal is the artificial

intelligence and data lake capability that they've built in early drug substance development scaled through ultimately being able to work then with Claire's team on regulatory and clinical strategy. And then ultimately, we will have access to their commercial manufacturing capability, which they have through their continuous biomanufacturing sites of which they've built too for some of the select assets.

And maybe I'll pass to Claire a little bit as to why is this technology interesting and...

Richard Saynor Executive

I guess just the question as well is would we use them for our existing pipeline -- portfolio of launched assets.

Claire D'Abreu-Hayling Executive

I'm happy to take that. I think for our existing portfolio of launched assets. The original question from Mark around cell line. We already have our cell lines well established. We've already established all of our processes and to try now to bring Just-Evotec on board with our existing portfolio is going to require establishment of new cell lines, significant technology transfers, reiteration of our regulatory process, we would have to consider whether we need to redo any clinical programs.

I think the cost and time line that is implied there makes it prohibitive.

Richard Saynor Executive

Okay. Claire, thank you. Glenn?

Glenn Gerecke Executive

Yes. And so the question relative to our external small molecule API supply points. So we have a close relationship with these suppliers. Often they come to us through Claire's organization, and then they get transitioned to be commercial suppliers. So often, they are actually -- we are involved with them in the API development process.

During that period of time, we thoroughly examined their quality management system to make sure that they are able to operate in a high-quality manner going forward, not just for the products they produce for us, but for their product portfolio because it's a system of quality management. It's not product by product by product.

We have an external supply organization, which manages them constantly, okay? And we do have audit rights. So this is, I think, a very comprehensive way of making sure that they remain reliable, they remain high quality. The other thing I should mention is we often -- because of the way we manage the life cycle we often have more than one source of supply. So we double up on the critical products to make sure that we are not left without an API source.

Richard Saynor Executive

ADCs, Claire?

Claire D'Abreu-Hayling Executive

Okay. I think ADCs is a very interesting technology. It's certainly a space that we are evaluating in line with all other opportunities as part of the portfolio review process that Pierre alluded earlier. And at the point at which we take a decision, whether we commit to ADCs or not, we're already confident we have the foundation capabilities within the organization to pursue that particular technology as well.

Umer Raffat Analyst

Umer from Evercore. I have 3, if I may. First, I saw you have a settlement on a peptide, Victoza for next year. But I didn't see much conversation in your R&D review section on that. I'd be curious why that is.

Second, among the big biosimilar opportunities through 2028, 2030 time frame, the big 3 that come to mind, KEYTRUDA, ENTYVIO, DUPI, I didn't see much mention on that. So I'm curious where you guys stand on those. And then finally, on the manufacturing side, I see a voluntary action indicated on an Austrian facility, which happens to make devices. Is that where the HUMIRA biosimilar injectors made?

Richard Saynor Executive

Okay. So Claire, do you want to take the peptide question first?

Claire D'Abreu-Hayling Executive

Yes. So yes, I mean, the GLP-1 peptides is an area of interest for Sandoz. You already alluded to the fact that we have a settlement on that peptide. It's currently under regulatory review, and we continue to work very closely with both the organization and the regulatory agencies to finalize the approval and bring it to launch.

Richard Saynor Executive

Pierre, do you want to comment on the bio pipeline?

Pierre Bourdage Executive

Yes, sure. So biosimilar pipeline, we have 24 assets in the pipeline. And our policy and disclosure, which is in line with industry norm is we'll disclose specific target assets once we bring them into clinical trial phase. And so right now, you have the 4 near-term assets that we've described today. And as we bring more products into the clinic, we'll be disclosing them as we do that.

Typically, that would occur 3 to 5 years before LOE, and we do expect to bring a few new assets to the clinic over the course of the next 12 to 18 months. Other than that, I won't comment on specific assets other than to say that clearly, our position is to be an industry leader in the space, and 2/3 of our pipeline is immunology and oncology which are the 2 therapy areas that you mentioned.

Unknown Executive Executive

And then to address the voluntary action indicated question, voluntary action indicated is that when the agency has observations but does not consider them to be critical. So the company is allowed to respond, of course, in an appropriate and responsible manner but there is no impact on business.

Unknown Analyst Analyst

[indiscernible] on Credit Suisse. On the point that you have to prepare 7 to 10 years prelaunch, how do you prepare for a technology required by increasingly complex pharma pipelines while also managing reduced capital intensity, what's the improvement you're targeting for your free cash flow conversion?

And then second, can you remind us how many of your biosimilars are currently partnered. And if you have to share economics, does that limit your pricing flexibility if you have to pay royalties?

Richard Saynor Executive

[indiscernible], if I take the first part and then Pierre, second. Sorry, could you just repeat the first question here?

Unknown Analyst Analyst

Sorry, what was it?

Unknown Executive Executive

Could you just repeat your first part of your first question?

Unknown Analyst Analyst

On the point that you have to prepare 7 to 10 years prelaunch, how do you prepare for technology required by increasingly complex pharma pipelines while also managing reduced capital intensity with the improvement you're targeting for free cash flow conversion?

Unknown Executive Executive

Look, in a sense like Claire and Pierre and seems doing a really good job of showing how we've reduced the footprint, particularly around the small molecule network. I mean a company of our size with now 15 manufacturing sites is pretty lean. And I think our intention as we invest going forward, we will invest in technology platforms where we believe that's gives us a strategic advantage. So clearly, we're investing in the site in Slovenia. And similarly, going forward, if we need to invest in specific technologies.

We could -- the partnership we have with Just-Evotec would allow us to make different kind of investment decisions further down the road whether it's into ADCs or whether it's then into the biologics pipeline.

I think what actually recall to the purpose of Sandoz is in many ways, we have the scale to do those. I think 15 years ago, we did that with biosimilars. We should be considering doing that with ADCs and other platform technologies. So in a sense where the innovator goes we have

the scale, the technical capability, the legal capability and the clinical capability and then finally, the commercial capability to bring those assets to the market that a lot of our competitors either don't have those skills or the funding to do it.

Richard Saynor Executive

Okay. Pierre?

Pierre Bourdage Executive

Yes. And on the bio partner question, clearly, there are pros and cons to any partnering strategy, but here, we have a few really strong reasons why this is a critical part of our strategy. So first and foremost, it takes 7 to 10 years to develop a biosimilar internally. And so you can imagine that of the 24 assets we have defined that means that anything we have uncovered in the market becomes a licensing opportunity. And Sandoz is positioned as a very attractive partner because you've heard from my colleagues about the commercial performance and scale that we have.

And so when we pursue licensing opportunities, clearly, the deal framework is well evaluated looking at financial threshold, fair value return for shareholders and external competitiveness, we feel really strongly about that aspect of our partnering.

And it's right now at about 1/3 of the pipeline, which allows us to capture opportunities we can't capture otherwise, and where and if allowable leveraging our balance sheet to expand the pipeline.

Unknown Executive Executive

I have 3 questions from Graham Parry from Bank of America. The first one how does 1/3 of U.S. generics first to file compared with industry in the U.S.? How high can this go? And what is the IRR on development cost for FTE versus day 1 launch versus late launch?

Second one, in terms of being selective in terms of virtues to develop biosimilars, what factors go into selecting which to develop? If we think of big commercial markets that will go generic biosimilar by early 2030s, are there any you wouldn't go after and why? So for example, IL17s, IL23s GLP-1, PD1-L1. For instance, are these in the business plan?

And the last one, probably for Glenn, how much of the 350 basis point margin upside from operational improvements are more readily achievable due to the separation, could this have been achieved as well as part of Novartis?

Richard Saynor Executive

I think actually the last question -- I think actually cover quite a lot with Colin. So perhaps we can part that to Colin, conscious that we only got a couple of minutes left. Pierre?

Pierre Bourdage Executive

Sure. So what I can say on the U.S. pipeline is that you'll remember when Karen presented that she talked a lot about going through a period of restabilizing the business and rebuilding the focused pipeline for the U.S. What I can confirm is that the pipeline that has been rebuilt is

more than 2/3 focused on opportunities that meet the criteria of first to file across different categories of that bucket. On internal rate of returns for those kind of projects, our policy is not to comment on individual return rates on either assets or geographies.

And then on bio selection as to what biosimilar do we choose or not choose and why for targeting for development or licensing. We use a very comprehensive strategic review process first and foremost, looking at the lasting power of that agent in the therapy area. So for example, when you're looking over a 10-year period, you may assess gene therapy disruption. You may assess new originators coming to disrupt the position of the biologic that you're targeting. We do a very deep assessment using competitive intelligence as well as publicly available resources to assess, and we continually monitor at every milestone along our strategic pipeline framework.

I wouldn't comment as to which ones we would target and which ones we would not, other than to say that our framework and operating process gives us very good line of sight.

Unknown Executive Executive

Just one more question from Balaji Prasad of Barclays. Can you comment -- maybe this is for Pierre, can you comment on the future next 5 to 7 years of biosimilar competition? Do you anticipate newer entrants into the biosimilar market in Europe or U.S.? Or will it be largely incumbent company?

Pierre Bourdage Executive

Great question. Actually, I can comment on that because most of the assets coming within the next 5 years are actually have clinical trial activity, we're publicly identifiable competitors in the arena. And so typically, we see an entrance of between 5 and 7 competitors in each primary competitive field. It could be larger. So there are typically 10 to 12 companies developing, but we think in the higher regulated markets with very high threshold for success particularly in the U.S.

and in Europe, we would see 5 to 7 competitors. And most of those are quite similar to some of the familiar names that you see today with a few exceptional new entrants.

Richard Saynor Executive

I think we're at time. So thank you very much [indiscernible]. Thank you.

So now I'd like to move on to the financial outlook and the compelling sustainability story. So before I talk about the sustainability story, I'd like to invite Colin to come to the stage. Colin has been our CFO for just over a year. Previously, he was CFO for Vifor and Evotec SE. He is a Board member of Siegfried AG and has deep capital markets experience, particularly in terms of the Swiss stock market.

So Colin, the floor is yours.

Colin Bond Executive

Thank you, Richard. As Richard said, I joined Sandoz and Vifor Pharma. And I think what is relevant that in 2017, I led the separation of Vifor from Galenica onto the Swiss Exchange,

and I feel very privileged to be here doing something similar with Sandoz. You've heard from Gilbert, Richard and my colleagues throughout the course of the day about the uniqueness and exciting potential of Sandoz. And it's my job now to summarize that from a financial perspective and what it all means.

The best way to do that is to look at 3 distinct time periods. Firstly, the past '21 and '22, where there was a challenging economic environment. Secondly, the present 2023, which is a year like no other, when we're separating the company to be stand-alone. And then most excitingly, the future, the period from '24 to '28 when we will exploit our potential as a pure-play generics company.

Looking at the first of these periods, '21 to 2022, we all know the economic events and macro developments that dominated this period. The pandemic, the war in Ukraine and subsequent supply side inflation. But I think what was really impressive was how strongly the business recovered coming out of COVID and we continue to invest in the pipeline and commercial initiatives throughout the period.

My next slide is a summary of the key financial highlights for '21 and 2022. And starting with net sales, on a constant currency basis, they grew strongly by 4% in 2022 versus '21. Core EBITDA margin declined by 0.9%, but this was due to inflation, which occurred in the second half of 2022, and that is a known industry-wide issue. And then thirdly, free cash flow as a percentage of net sales declined slightly, but this was due to a positive reason we needed to build up inventory in support of the strong top line growth.

Looking at the net sales development between 2021 and 2022, we will report in U.S. dollars and restating the 2021 sales for 2022 currency rates. We grew 4% in 2022 on a constant currency basis. This growth was driven by strong volume, which was approximately 10% or contributed $0.9 billion to the top line. This was offset by price erosion of approximately 6% or $0.6 billion.

It's important to highlight the price erosion is a part of the generics business, and that 6% erosion is absolutely consistent with what's occurred in previous years.

This slide, Richard presented this morning, but it's significant, and I'd like to cover it again. It shows the distribution of our sales between the 2 businesses. Firstly, generics, in 2022 was 79% of the total business. And what's key from a financial perspective is that generics is diversified, stable and a cash-generating platform, as Richard highlighted this morning.

Biosimilars, which currently account for 21% of our business grew very strongly 9%, which is absolutely consistent with where we want to go with the pipeline of 24 assets that Pierre just described. Looking at the distribution of our net sales in 2022 by region. Richard covered this slide this morning.

But really importantly, our European champion, which accounts for 50% of our total sales grew by 6% and international despite the challenges in Ukraine and Russia grew 7%. And as Karen described, after many years of significant decline, the U.S. business stabilized in 2020 to ahead of the key biosimilar launches that my colleagues have described.

Looking at the EBITDA bridge between 2021 and 2022, there's 3 bridging items that I'd like to

highlight. The first 1 is the operational improvements, which contributed 80 basis points. That came from procurement savings and conversion cost reductions. That really is a proof point for the margin expansion that Glenn spoke about in his session.

Secondly, investments. These had a negative impact, but they were related to positive business developments and there were 2 factors. Firstly, investing in commercial initiatives that drove the strong top line. And secondly, the integration costs related to the 2 acquisitions the Aspen business in Japan and GSK Cephalosporins that Paco talked about during his session.

And thirdly, inflation, occurred in the second half of the year, and that [caused] that 120 basis points decline in the margin. But as I said, that's a known issue and an industry-wide challenge.

Looking at the second of the time periods, the present 2023, as I said, it's a year like no other. We're separating the business. What's really exciting is the 2 bio launches timed in the second half of the year. We will continue to invest in capability, capacity and pipeline and we have some investments to make to operate as a stand-alone company.

Looking at the quarter 1, which we published, we continued the strong momentum and Richard spoke about the 6 quarters of continuous growth. We recorded an 8% growth in the quarter. And what was really encouraging was to see a 16% growth in Europe champion and also a 17% growth in biosimilars, which is the core of our strategy going forward.

Looking at the EBITDA bridge, there will be a decrease in the EBITDA in 2023 versus 2022. We will decline from 21.2% between 18% to 19%. Two very clear reasons for this. Firstly, the cost to operate as a stand-alone company will have an impact of approximately 100 basis points and then inflation on the supply side will be up to 10%.

What's really encouraging is that we start to see significant signs of that inflation, modifying which is really encouraging as we go into 2024. Then most excitingly, looking at the future, this period of 2024 to 2028 when we will operate as a standalone generics company.

What we're committing to is mid-single-digit growth. That will be driven by what you've heard from my colleagues, the 400 assets in the generics pipeline and the 4 biosimilar launches. We will have a core EBITDA expansion to reach 24% to 26%. And you've heard from Glenn about the operational improvements that will drive that.

In addition, we will have the volume impact of leveraging a bigger business over the infrastructure, a mix shift and also operational efficiencies from managing the business differently. Cash is fundamental, and I would just like to use this slide to highlight what's going to drive our cash over the midterm. You've heard from my colleagues throughout the course of the day that we're in a super attractive market. We have scale in a leadership position and multiple levers of top line growth.

Secondly, our margin will expand. You've heard of the drivers of margin expansion. The mid-single-digit volume growth, the mix shift, the operational improvements that Glenn described and organizational efficiencies. And those 2 together will drive free cash flow. But on top, we will make better use of our working capital as we operate as a stand-alone company.

Looking at the top line development over the period from 2023 to 2028, we're committing to a mid-single-digit growth, and this will be balanced across both businesses. Firstly, with generics, given the scale, we will grow that part of the business. And then most excitingly, on biosimilars with the 4 launches, we will shift the proportion of our sales in biosimilars from 20% to 30% over the period, and that will have a positive impact on our margin.

Looking at the distribution of the growth by region, 50% of the overall growth will come from the U.S. That shouldn't be a surprise given the 4 biosimilar launches and the other 50% will be equally distributed between the European and international regions.

This slide is really key. It's the margin expansion, the quality of our business, and I'm going to spend a little bit of time on it. We're committing to go from 18% to 19% in 2023 to 24% to 26% by '28. It will be driven by 4 things. Firstly, volume and price.

Let's assume 5% growth a year, mid-single digit. That will generate approximately 30% additional volume of which we can then leverage over the existing infrastructure.

Secondly, product mix. I highlighted that the proportion of bio sales will increase from 20% to 30%. Historically, the gross margin on biosimilars has been roughly 20% higher, and that will then lead to 100 basis points improvement in the EBITDA margin.

Operational improvements you heard from Glenn will contribute 350 basis points, approximately 60% of that coming from procurement. And then organizational efficiency will deliver 150 basis points, and that will be through automation, standardization and redesigning the organization. The obvious question is how is that margin expansion phased over the period between 2023 and 2028.

And I'm happy to go through each of the 4 components here. So let's start with volume. We think that will be broadly linear over the time period, that margin improvement coming from volume. Similarly, product mix, we think, will be more or less equally phased over this period.

Operational improvements, we think procurement will be more skewed towards the front end on -- and the other 3 components of operational improvement, network design, vertical integration, and operational excellence will be more skewed towards the second half of the time period.

Organizational efficiency we see as being more towards the front end of the time period skewed more towards the front end. So hopefully, that gives you some color for the modeling that I know you now need to undertake.

Looking at our CapEx investment over the period. When you look back over the past, we've spent approximately 2% of sales annually on replacement CapEx, and we expect to continue at that rate going forward. That results in $1.1 billion of CapEx on replacement over the time period.

Secondly, the bottom left-hand corner in the pie chart, generics expansion with a 30% growth in our volumes. We will spend $0.6 billion in support of that expansion. And then the top left-hand part of the pie chart, the biosimilars investment, $0.6 billion, you've heard from Richard and Glenn, the majority of that is in support of the Slovenia Lendava biosimilars

capacity investment.

Looking at cash flow generation and Richard covered this during the morning session, we expect cash flow to increase by more than 2.5x between 2022 and 2028. And clearly, that is coming from the top line growth of 5% per annum, mid-single digit. The margin expansion from 18% to 19% up to 24% to 26% and a more efficient use of our working capital. We currently invest about 35% of our sales in working capital to support that. We think there's an opportunity to significantly improve that.

In the short to midterm, the period '24, '25, we do have some investments to make. First of all, in bio capacity, $0.6 billion that I spoke about previously and onetime separation costs of $0.7 billion.

Richard covered our balance sheet and capital structure this morning, but it's critical, I'm going to highlight and go through it once more. At the separation, we will finance the company through bank debts. We will then access the capital markets in the months following the separation and refinanced the company. What we're anticipating at the separation, the net debt to core EBITDA ratio will be in the range of 2% to 2.5%.

We're targeting an investment grade and we're in the process of securing 2 investment grade ratings. And we think that with this strong balance sheet and the investment-grade ratings, we're going to be clearly differentiated from our competitors and in an extremely strong position to do inorganic deals going forward.

Capital allocation is my next slide, and Richard spoke about this during the morning session, capacity expansion is our first priority to invest in the organic business, and I've spoken about the $0.6 billion for generics growth and the $0.6 billion in the biosimilars capacity and capability.

Stand-alone capabilities, the $0.7 billion that we need to invest to operate on a stand-alone basis. And DNR is currently in the range of 9% of sales. We're going to keep it at that level and shift the proportion of the spend more from generics into bio during the planned period.

The second priority for our capital will be to return the capital to shareholders, and we're going to do that through a progressive dividend policy, and I'll come to the details of that in a moment.

And then thirdly, as Richard explained this morning, when the right opportunities present themselves going forward, we will be able to leverage our strong balance sheet to execute on those possibilities. The guidance is my closing slide, and Richard presented this during the morning session. It's critical starting with the top line. We're committing to mid-single digit for 2023 and mid-single digit in the midterm to 2028.

On core EBITDA, I've explained very clearly how we're going to expand the margin from 18% to 19% in 2023 to 24% to 26% by '28. And then dividend policy is a percentage of core net income, 20% to 30% in 2023, expanding to 30% to 40% by 2028.

And as Richard also highlighted this morning, we will pay a full year dividend for 2023 even though we will only separate in the second half of 2023. So EBITDA -- top line growth EBITDA

will really drive the margin expansion, the bottom line performance and on top of that, we will increase the payout, and that will lead to a very healthy expansion of the dividend. With that, I'd like to hand back to Richard.

Richard Saynor Executive

Thank you, Colin. Okay. I'd just like to now spend a little bit of time reflecting on our compelling sustainability story. As I started the presentation this morning, clearly, we have a very strong sustainability story -- access and clearly, as much of the focus of our business is really our purpose for existing and our core focus in terms of how we want to drive the business particularly around how we democratize biologics, how we bring biologics to patients couldn't hope to aspire to have those in many markets around the world.

Clearly, as we step away from Novartis, we have a strong environmental framework, which we can build on. And again, we'll communicate specifically in terms of what those objectives and goals will be in the early part of quarter 1 next year.

And as an organization, we will continue to champion our people to drive diversity, equity and inclusion. And as Gilbert started this morning, we have an incredible Board and a great organizational setup as we come out of Novartis in terms of compliance and our risk management and our overall corporate covenants.

And of all of the slides today, this is the 1 that I'm most proud of. Because this is really what it Sandoz is about. It's about driving access for our patients around the world. So significant health care savings, $17 billion direct savings just to the U.S. and Europe, nearly $200 billion of savings in terms of our social impact every year and reaching over 500 million patients every year for the products we manufacture and serve.

As we brought and become a leading player in the biologics market, we've opened up markets. We have 90 markets where we've launched biosimilars. Many of those, the first time those products have been available in the market. We have 8 biosimilars currently marketed and an unrivaled pipeline in '24 assets, which allows us to continue that journey in operating transformational medications to patients.

We have a huge pedigree around antibiotics. We have over 50 different molecule antibiotics. That's 1 of the broadest and deepest pipelines in the industry. We're the only remaining vertical manufacturer left in the Western world, that gives us leverage to government to patients and a responsibility in terms of how we support that.

We educate over 40,000 physicians a year, and we continue to invest in this critical medicine going forward. This allows us to have very strong engagement with our stakeholders. As Julie said, I'm the Chairman of the IGBA and CEO Advisory Committee; Rebecca is Vice President for Medicine of Europe; and Karen is also a Vice President for AAM, again, the Affordable Medicines Group in the U.S. This gives us a very strong voice with government, with payer frameworks and across the industry.

As a company also, we pioneer at for biosimilars, helping payers, physicians and patients understand the opportunities that biosimilars can bring, opening up markets and really driving change. As a manufacturer, we engage heavily with all of the regulatory authorities,

whether the FDA, the EMEA.

We're investing in technology platforms to support the AMR antibiotic resistance agenda. And as a manufacturer, we're part of the AMR Industry Alliance, which really looks at green manufacturing, wastewater management, et cetera, particularly in the antibiotic space. We've come a long way in terms of our environmental responsibility as part of Novartis.

We have significantly reduced our greenhouse gas emissions by 49%, our water consumption by 42% and our total waste by nearly 60%. And as we think about these areas going forward, clearly, we'll consider our programs around decarbonization, our waste and water management and our sustainable supply chain.

As I said, we'll provide guidance on these in quarter 1 next year. With the 22,000 associates we have in our organization, we will continue to champion diversity, equity and inclusion. We have a very diverse workforce with 47% women representation in management. We have engagement and connection to our purpose as we attract and retain our talent and we're continually retaining and upscaling our talent.

And when you look at our Glassdoor scores and our own industry internal metrics, we are certainly ahead of the industry, significant and a leader in our sector. We're committing going forward to transparency and pay equity with 100% of associates covered by pay equity studies by 2025. We want to maintain our strong gender balance throughout the whole organization and continuing building an inclusive and open and collaborative organization through its leadership and its talent.

All at the same time, building on our very strong governance framework. So clearly, a world-class Board led by [indiscernible] fully independent board members with 40% female representation. A high, strong corporate governance in built in our organization with a strong culture of doing what's right, clear and robust code of ethics and an integrated risk management platform that we will inherit and take from Novartis.

And we will continue to commit to best practice reporting. And as I said, we will give guidance the Q1 2024 when we publish our annual report in terms of GRI and TCFD and other rating agencies. I guess just into conclusion. So you've heard a lot of -- from my colleagues today a lot about the business, and thank you for your questions.

Just in summary. So this is a proposed subject to Board approval and subject to the shareholder vote, a 100% spin-off separating Novartis and Sandoz. There will be 2 completely independent companies. We propose to list on the Swiss Stock Exchange, and we will headquarter -- our headquarters will remain in Basel in Switzerland.

As Colin has said, we will target to maintain an investment-grade credit rating that differentiates us from our competitors, but also allows us to invest for our future and for our growth. We will publish our second half year results in line with Novartis on the 18th of July, and we're on track for the second half of 2023 for the execution of the spin.

We covered a lot of things today. And these 6 areas really focus about our attractive market fundamentals, our leadership and scale, our multiple growth drivers and margin improvement, strong cash flow and our compelling sustainability story.

But perhaps in summary, I'd ask you to about 4 things. First question, really, has our U.S. business stabilized and prime for growth. And I think Karen has done a phenomenal job building a business that now is at scale and with the pipeline that we see in front of us can position us and accelerate our growth as an organization going forward.

Can we continue our broad growth journey? Again, we are a champion in Europe, very strong performance in international. And coupled with the stabilized U.S., we're confident to deliver at least mid-single-digit growth over the planning period.

Can we expand our margin from high teens to mid-20s over the planning period? And again, Glenn and Colin, we see significant opportunities to simplify our network change our portfolio mix and drive execution to expand our margin to return capital back to our shareholders and to allow us to invest in our organization.

And lastly, are we a biologics business? At harsh -- at heart, 20% of our business today is from biosimilars. We have an unrivaled pipeline of 24 assets and a leadership position with 8 assets already launched. So we're extremely confident about the opportunities that we can present will not only drive growth but help drive and expand our margin. So thank you so much for your time today.

Ladies and gentlemen, I present you Sandoz. Okay. Final Q&A.

Mark Purcell Analyst

It's Mark Purcell from Morgan Stanley. Just 2. First 1 on the competitive environment. Samsung Biologics and Pfizer announced today a partnership $411 million contract for Samsung to manufacture biosimilars for Pfizer. So given the unprecedented number of second wave of biosimilars coming up towards the end of the decade, do you expect the competitive environment to increase as people see the same attractive opportunities you've described?

And then secondly, obviously, some parts of the business when it comes to IP, pricing, et cetera, there's this risk and there's also a lack of visibility. It'd be great for you to help us understand on the IP side of things, how we should think about that in terms of where we have certainty of launch?

I guess the Enbrel situation is 1 ended spectrum. Humira in the middle and others, you've been successful. So how should you -- how should we think about the timing and IP? And also operationally how do you run scenarios around that. So whether there's an on-time launch a 2-year delay, 4-year delay, how do you sort of manage your operation in the business.

And then secondly is just around pricing. If the environment were to become more competitive or the originators were become a lot more aggressive in terms of cutting their price? How should we think about the impact on your business, I guess, across the column on margins, et cetera, but more detail there would be helpful, too.

Richard Saynor Executive

First, if I take pricing first, then I'll ask Pierre to comment on the first 2 questions. I understand your logic, but I think let's take a step back. There's -- today, as I said, 5 players account for

80% of the market already. It's already consolidated.

Pricing is always a factor, but we've not launched a biosimilar in Europe for 3 years. Yes, the business is growing at 16% in cash terms, 3 years after that launch at a very healthy margin. So even with a low -- high degree of competition, the margin expansion and the opportunity is still quite significant.

So I don't think you're going to get the same level of commercial intensity that you would say in a small molecule environment, which -- because I think the dynamics are very different. And also, if you look at the pipeline going forward, if you look at the 4 launches we've got probably maybe 2, certainly 1 of those will see no competition for quite a period of time.

Others, there's a lot of competition. But we're a generic drug company at the end of the day, we used to competition and we're used to leveraging and creating value. And I think particularly in region Europe, even when we weren't first to market, we end up as a leader in the market because of the commercial scale.

So I can understand the logic, but I just don't see it evolving in that way because the capital needed, the complexity. And also then the breadth of the portfolio means that there'll be some assets that clearly many players, so like ADA but there'll be other assets with much lower levels of competitive intensity. And then I think if you look at things like the human growth hormone, 15 years later, we're still #1 and it's still attractive. So it's that fundamental that to me makes this [above] sector so exciting. Pierre, do you want to perhaps add some comments?

Rebecca Guntern Executive

Thank you. As to the question I think was Pfizer related in their announcement about an hour ago, related to their partnership with Samsung. I did see that as well in my e-mail. Thank you.

I think I would refer to their public comments that they previously made from a capital allocation and development strategy. Pfizer has clearly made a statement in the last 18 months that they actually plan to lower or limit their investment only opportunistically in a biosimilar space. So until we learn further information, I would read today's announcement as a transfer of their in-market portfolio into a consolidated third-party player to be determined once more information plays out.

I think the larger question was, where is the industry going in terms of competitiveness and entries. And there, we continue to always have line of sight on the next 5 to 7 years because of clinical trial activity. We continue to see most markets with 5 to 7 primary entries of high-quality, high likelihood companies that will enter a time of LOE. And over the long term, as Richard said, there are very high technical barriers to entry, in addition to financial barriers on development costs; and lastly, capital investment barriers in terms of the ability to invest in internal manufacturing.

I think the space will continue to be a very difficult in our carrier. The second question was on IP visibility and timing related to some of the assets. So I'll reference here that clearly adalimumab, we have a U.S. settlement and are entering the market in early July as part of that wave and settlement.

On natalizumab and denosumab we're in active litigation on both those assets. And as a matter of policy and good practice, we don't comment in areas of active litigation other than to say that we're very confident in our position. We look forward to resolving it as soon as possible and ultimately, bringing the product to market as quickly as possible.

And then lastly, where we are engaged in litigation, there is active industry litigation with aflibercept. One of the first filers on that brand is an active litigation. We monitor the litigation, and we'll keep you posted when appropriate on the outcomes of those with 1 of the key outcomes expected to be a trial decision in the latter half of this year related to 1 of the patent families related to aflibercept.

Ultimately, the thing to remember as well is that whenever we create a biosimilar pipeline is clearly laid out, we create 1 global pipeline, and we scale. And so natalizumab will be launched in Europe. And there, we have a very high confidence and conviction level on our ability to launch in the latter half of this year, as will other products. So I would remind you of that as well because it's part of our balanced distribution of risk and opportunity.

Peter Welford Analyst

I've got 2 very boring financial ones, I'm afraid. First of all, the tax. There was no mention at all about the tax rate and tax structure. Any thought -- I mean, I guess, you've obviously been spun off, but is there any change at all intact that we should consider versus the parent when we think of Sandoz an independent entity?

And then secondly, just on the debt. So you're spinning off you say then you're going to refinance in the capital markets. So is there any plan to pay down the debt? I mean, are you quite comfortable with 2, 2.5x leverage sort of longer term as a capital structure for the company? Or if not, I mean, where do you see as a sort of sustainable long-term level of debt given your ambition stores have some flexibility?

Richard Saynor Executive

Yes. So tax, we expect to be very stable over the plan period at about 22% to 23%. In terms of the capital structure, given the strong top line growth, the mid-single-digit top line growth plus the margin expansion and the cash generation, we think that, of course, there's going to be a decrease in the overall net debt as a ratio of EBITDA.

And the way that we will structure the refinancing of the company is with a range of maturities over the midterm.

Unknown Executive Executive

I have 3 more from Balaji at Barclays. So first 1 for potentially if you'd like to comment or Richard. What are your thoughts around the significant gap between the social value that the generics sector provides and the equity value it gets which is driving a flight from future generics and biosimilars investment as you've seen some of your peers do. The first question.

Related to the last 1 that Colin got also, can you please discuss the landscape for M&A and BD in North America and Europe? What kind of deals would you be inclined to look at and the

size of the deals that you're comfortable with in conjunction with this, what kind of leverage are you comfortable for the company versus the leverage at the time of the spin, which you might have already addressed.

Lastly, in the EBITDA margin progression chart, which is rather compelling, I was curious to see that there are no headwinds to margin expansion. Is there anything you could -- is there anything that could pose possible headwinds to margins even if the overall direction is still positive and in line with your guidance?

Richard Saynor Executive

Okay. Subodh, do you want to go first? Or John my take it. Look, it's a great question. I'll perhaps comment first with all the information I have.

Look, generics, I think the positive -- clearly, there's a positive and negative side of the story. Generics are very much to be part of the solution in terms of global healthcare. In the U.S., 90% of the volume is generic healthcare, probably about 10% of the cost. I'll give you some numbers for the U.S. that perhaps explains the problem.

So our sales in the U.S., it gross are over $10 billion. Now somebody else is making $8.5 billion out of that money, then it's not us. So the payer framework and the systems are what's driving a lot of this challenge. So I think a lot of the issues that you just got to currently see today on things like oncology, is that the margins are squeezed as a supplier, bearability to see a fair return for that price is incredibly difficult.

Because unfortunately, the middle actors in this have a significant amount of buying power and even when you can be sold supply, you can be selling under water because of the portfolio effect and the leverage that they have. And I think that's now starting to be recognized by government and payers. I think it's less extreme in Europe to be brutally honest, and we're having very concrete conversations with governments and payers, particularly on things like anti-infectives that -- on 1 hand, they want a sustainable supply chain, yet we need to invest significant amounts of money to do that.

So actually, I'm encouraged by the dialogue. I'm actually encouraged by the signs we're starting to see in the U.S. But it does -- it goes back to why should we be selling a product to treat cancer for the same prices of pack of M&Ms. Quite honestly, it's terrible. So I think it's a significant opportunity to drive that.

We have the scale, we have the relationships to continue to talk and move that forward.

Unknown Executive Executive

And then to your second question, M&A deals I think we said right at the beginning, I think we have a plan here that doesn't require M&A or BD certainly of the transformational elector to deliver the plan over the planning period.

We do about $100 million a year plus or minus of sales from BD and M&A, small product deals, transactions. And that's always been in the business. So we've assumed that level going forward. Clearly, I think over the midterm, once the free cash increases, that would open up the optionality. Do I see assets?

I think the U.S. as we've seen firsthand, it's a difficult environment to transact with the FTC.

So I'm probably more interested in technology platforms or possible assets for the U.S. Similarly for Europe, given our scale, there's no obvious company that you would ever really consider acquiring. So again, it's more portfolios or technologies. And international, difficult to execute, but I think again there, clearly, we had required mature brands or we found assets. But again, it's probably more likely around the asset class rather than obviously in terms of companies, but that's very much more for the medium term.

I think in the short term, focus on our execution, focus on driving efficiencies in the business and stabilizing the business post the spin and driving on our agenda.

Unknown Executive Executive

And then to the margin expansion, clearly, we're at the start of a journey now, and we're committing to 24% to 26% in the midterm. When I go through the checklist of the different components driving that, what we've assumed in our model is that price decreases will be consistent with what we've experienced in the past. From 2024, '25 onwards we assume that inflation goes back to low single-digit levels. So that's consistent with what we've experienced historically.

On the volume improvement in the margin with our 400 generics pipeline plus the full biosimilar launches, we feel confident about that. Again, on the mix shift given the 4 launches, we're confident on that. On the operational improvements, the 350 basis points, given all the initiatives that are in Glenn shop, we feel confident about that.

And then the organizational efficiencies given that we have a 30% increase in the volume, and we can leverage the infrastructure and work fundamentally differently. We feel good about that.

Now the midterm is quite a long period. And of course, things happen, but the responsibility of management is to react to that and deal with situations as they present themselves. But based on what we currently know and can currently see compelling is a good word, the margin expansion looks compelling. Thank you.

Unknown Analyst Analyst

Just a very quick one. Katerina from JPMorgan. So just to follow up on your comment on inflation. So if inflation were to stay elevated or accelerate. How big of a headwind would that be, I guess, put another way, like how much of inflationary pressures can you pass on from a pricing perspective versus how much of it do you have to absorb?

Unknown Executive Executive

Yes. So clearly, we work continuously with regulators and health care providers to try and get a fair and sustainable pricing for the benefit that our medicines bring. But clearly, there's a lag between input cost inflation and getting that pricing and it's a continual working in progress.

As I said, in 2023, our expectation is that inflation could be up to 10%, but what's been really encouraging in the first 6 months of the year, we see significant signs of inflation decreasing,

particularly in areas such as utilities. And we do expect a normalization just as the ECB and the Fed are expecting a reduction in interest rates, we see that in our inflation expectations as well as the supply chain normalizes.

Richard Saynor Executive

Also, it's not a Sandoz specific. It's an industry. So -- but certainly, we have seen payers now having conversation. I think they see the nature of the supply chain, sending in a couple of markets in Europe now. We found mechanisms to either get coverage for inventory to better secure supply as a way of compensating for inflation with payers.

So I think we're having the dialogue not easy to take price, but certainly, we've seen -- and there are examples in the U.S. where Karen and the team have equally been able to do that as well.

Unknown Executive Executive

I have more questions from Graham Parry from Bank of America. So one, I mean, they're all for calling. U.S. business was down 2% in 2022 and Q1 '23. What growth is assumed in the U.S.

generics business in the business plan guidance? Is this essentially a loss leader for biosimilars?

Then second 1 on depreciation and CapEx. The depreciation cost was $200 million in 2022. CapEx program, $2.3 billion. What is the utilization rate depreciation years on PPE? And is it fair to assume depreciation costs of $400 million in 2028 to help reconcile with core operating income margin being reported by Novartis and forecast by the Street now.

And then maybe you also want to address the 1 that we asked in the previous session on 350 margin rate, how much would come if we would stay with Novartis.

Richard Saynor Executive

Could you say that last part.

Unknown Executive Executive

The last 1 was the 1 from the previous. How much of the 350 basis point margin upside from operational improvements are more readily achievable due to the separation would these have been achieved as part of Novartis?

Vasant Narasimhan Executive

Well, let's start with that one. I think what's really interesting as a standalone generics company, the cost of sales becomes 50% of our net sales. So it gets an incredible amount of focus in a generic company versus being an originator. And that's -- because we continually get asked the question without the scale of Novartis, will you be able to get better input costs. And we think, absolutely, you've heard all the things Glenn talked about, which is leveraging the scale, the 30% volume growth, about reducing complexity with a number of suppliers and focusing the purchasing and procurement organization.

I think the second question in reverse order that Graham had was around depreciation and CapEx spending. We do in the appendix to this Capital Markets Day deck, have a bridge between operating income and EBITDA. And what you see in there is that our depreciation in '22 and '21 was about $200 million, which is absolutely consistent with the replacement CapEx that I was indicating in the presentation that we spent 2% of our revenues, which, of course, were approximately $10 billion. So we spend about $200 million a year on replacement CapEx and our depreciation is currently $200 million.

And obviously, with the investment in capacity expansion and bio capability, we will have a increase in the fixed assets on our balance sheet, which will inevitably lead to an increase in depreciation in the midterm.

Richard Saynor Executive

And I think your point then about the U.S. growth, I mean, I think we went through a phase post Aurobindo, we were claiming a lot of third-party deals that established drove the business down. I think plus/minus 2% is really showing that this business has stabilized.

Do I see the biologic? Absolutely not. These are very valuable in the originator prices even with significantly steep discounting. These are highly attractive opportunities. So they're highly accretive.

They're also accretive because then once you have the infrastructure and the relationship with the payers adding more and more assets into that mix means that you can extract more and more value.

So as the sales drive the top line comes more and more flow through to the bottom line. And I think to the first part of that whether synergies with Novartis, could we extract them without the separation. I think actually a lot of it is quite difficult. If you look at things like IT platforms, systems and processes. We're a global -- a division of a global organization at the moment.

That just doesn't operate like that.

I think -- the opportunity for us is ultimately to have the right systems and processes for a generics business and not the systems and processes for a global pharma organization. So in theory, I understand the question, but I think the reality next be possible to execute if we stay within Novartis. Okay.

Unknown Executive Executive

There's no more questions. Thank you so much for your time today. Thank you for your questions and engagement. I appreciate the challenges of travel with the slightly bizarre weather I blame the Canadian to that one. And thank you all, and safe travels home, and good evening.

Thank you.