# Transcript
# Fresenius: Biopharma 'Meet the Management'

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## CORPORATE PARTICIPANTS

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## PRESENTATION

Nick Stone: Hello, everyone. Welcome to the inaugural conference call and webcast as part of our new Meet the Management series. Today, we're kicking off with a deep dive into Biopharma.

The presentation was emailed to our distribution list earlier today and is available on fresenius.com.

On Slide 2 of the presentation, you'll find the usual safe harbor statement. Unless stated otherwise, we'll comment using constant exchange rates or CER.

In preparation for this call, we asked our investor and analyst research panel about the priority expectations. In short, you told us that you wanted more details on pipeline insights and competitive position, including timelines, scale of pipeline opportunity, and differentiation relative to peers.

You also asked about the growth drivers and long-term value creation, including greater transparency, revenue, and margin impact, with a clear growth roadmap, which we've addressed in the presentation and supplementary materials.

Today, I'm delighted to be joined by Michael Sen, Pierluigi, Sang-Jin Pak, and the broader Biopharma team, who will now take you through our ambitions and the agenda on Slide 3 in more detail.

Today's call will last approximately 90 minutes, with the presentation taking around 45 minutes, with the remaining time for your questions. To give everyone the chance to participate, please limit your questions to 1 to 2. We can always come back for a second round, if needed.

Lastly, let me please take the opportunity to thank Otto, Felix, and Mara from the Investor Relations team plus the broader Biopharma team for their significant efforts in preparing for this event.

And with that, I will now hand the call over to Michael. Please go ahead.

Michael Sen: Thank you, Nick, and welcome to everyone joining us today.

Fresenius's powerful mission and vision motivates us every day. At the heart of what we do lies an unwavering commitment to providing the highest quality in clinical care, ensuring that every patient receives the best treatment possible.

Our vision propels us forward. We strive to be the trusted, market-leading healthcare company, uniting cutting-edge technology with genuine human care. Combining both allows us to shape therapies that push the boundaries, moving healthcare to new heights.

I am inspired by the dedication of #TeamFresenius who makes this mission and vision a reality. Together, we will continue to innovate, improve, and expand our reach to the benefits of patients globally.

The global healthcare sector is growing, and it is undergoing an unprecedented transformation, driven by technological advancements, demographic shifts, and evolving patient needs. We, Fresenius, are in a fantastic position to address the major structural challenges in healthcare.

As we face a significantly ageing global population, people are spending more years in poor health. Consequently, healthcare spending in terms of GDP will increase across geographies.

Let's take the US as an example. Healthcare spending is headed in one direction only, projected to crossing the $5 trillion mark in 2024 based on CMS data. At an expected growth north of 8%, this is the biggest increase we have seen in decades.

Now let's dig a little deeper. Although generic and biosimilar prescriptions account for 90% of prescriptions in the US, they account for only 17.5% of the country's spending on prescription drugs according to the Association of Accessible Medicines.

In other words, costly brand-name products account for the bulk of pharmaceutical spending. The generics and biosimilars industry bring costs down. Hence, we are part of the solution with our relevant products and services.

This is #FutureFresenius, a company that can capitalize on exactly these trends I just laid out. It is a much stronger, simpler, and focused healthcare company -- stronger by focusing on the core and deepening our businesses.

Our core is twofold: On the what I call products side, the 4 businesses within Fresenius Kabi -- IV generics and fluids as the basis and underpinning business and the 3 attractive growth vectors Biopharma, Nutrition, and MedTech; and on the care provision side, our Helios businesses, where we hold leading market positions with our hospital networks in Germany and Spain.

This new setup enables us to benefit from changing healthcare needs and translates this one into great financial traction.

The focus of today is on our ever more relevant growth vector Biopharma. From my talks with many of you over the last quarters, I am convinced that today's event comes

exactly at the right time. We will give you more clarity on our positioning and our ingredients to win in this highly attractive market.

We have started the next phase Rejuvenate, and this phase has kicked off with great traction and focus and will guide us for the next few years. This phase is all about upgrading the core, scaling our platforms to elevate our performance.

This means bringing new products and innovations to market, focusing on the needs of patients and customers, and infusing fresh energy into our leadership and management teams to deliver further value, expand ecosystems, and create more opportunities.

Biopharma is at the core of our Rejuvenate agenda, positioned as the next frontier for growth and patient access.

As a leader in innovative healthcare products and highest-quality patient care, we are expanding our biosimilars business to delivering value for payers and patients.

We made the deliberate decision to leverage Biopharma as the next frontier for growth and patient access. First of all, because it is a dynamic and highly attractive growing market, we see that the adoption and patient access is ever increasing quarter by quarter.

At the same time, the importance of biologics is evident. As just laid out, payers are under significant pressure to save, and we are playing right there with our portfolio of biosimilars.

Annual savings in the EU and US are expected to grow to €100 billion by 2030. We are, thus, part of the solution to reduce global healthcare spending, a fantastic position to be in, combining relevance with economic success, and good news for patients everywhere.

Biopharma is an absolute success story for Fresenius. Post the acquisition of a handful of molecules from Merck, we derisked the business and built a vertically integrated powerhouse.

We have now 11 marketed products across 9 molecules in a globally balanced setup. Our differentiated portfolio and R&D function combined with state-of-the-art manufacturing and an excellent commercial function gives us the right to win in that very marketplace.

This is translating into excellent financial progress and also momentum. In the first 3 quarters, the Biopharma business contributed more than €600 million of sales with a growth rate in constant currency north of 30%.

Profitability wise, we have seen already last year that we were EBIT breakeven. And this year, we are already looking at the structural EBIT margin band for Kabi from below, fantastic financial progression, and as you will see later by Pierluigi and team, there is more to come. Thus, we will allocate capital in this attractive growth vector to spur further growth.

To be clear, not via multibillion dollar transactions, but much rather, we will focus on further in-licensing, capacity extension, and in-house R&D developments. That is what I meant with upgrading the core.

This is our renewed management team. That is part of our Rejuvenate agenda -- infusing fresh blood, fresh pair of eyes, into the organization, such as with Sang-Jin, who joined us from Samsung as President of Biopharma -- a great team that will lead you through the presentation over the next hour.

So in conclusion, Fresenius is well positioned to seize opportunities in the highly attractive Biopharma market. Our Biopharma asset has the right ingredients to win over the next years.

With a strong presence in Biopharma underpinned by robust secular growth trends, we are committed to sustaining our momentum and driving long-term profitable growth and, of course, shareholder value.

These dynamics present a unique opportunity for Fresenius to deliver innovative solutions that improve patient outcomes, while helping to advance cost-effective healthcare systems. Our strategy remains centered on serving patients with the best products and being a trusted partner to healthcare providers worldwide.

By allocating capital to our Biopharma growth vector, we will spur further profitable growth.

As focus now turns to 2026 and, of course, beyond, we are committed to leveraging these strengths to deliver long-term sustainable growth, creating value for patients, partners, and of course, shareholders.

Now let me hand it over to Pierluigi and Sang-Jin.

Pierluigi Antonelli: Thank you, Michael, for the introduction, and hello to everyone attending today's call.

It is a great opportunity for me to provide you with more details about our Biopharma exciting business and the opportunity ahead

I will now give you a short overview of what we have already achieved but, most importantly, why we are convinced about our future success and our confidence in delivering our 2030 ambitions.

Afterwards, Sang-Jin and team will give more details on the attractive biosimilars market and will elaborate on our unique fully integrated setup with the right levers to win and ultimately create value.

Let me move to the next slide. And before we go into the specifics of Biopharma, I want to go back to the CMD we had in May 2023, when together with my team, we shared details on the Fresenius Kabi performance turnaround.

I remember quite vividly that, at the end of the presentation, the first 2 questions were about our confidence and ability to execute such a transformation.

Looking back, we now see a tremendous track record. Not only have we demonstrated rigorous operating execution but also consistent positive results, meeting or exceeding expectations quarter after quarter. And I believe that we have proven to you that we can deliver on our commitments.

If you look at the 2023 CMD targets we laid out, we delivered both on revenue and EBIT expectations for Biopharma. As a reminder, we previously said that our ambition was to multiply our revenues by 3× or 4× by 2026 and achieve EBITDA breakeven in 2024.

In fact, we multiplied sales by approximately 4× versus our 2022 base year, 1 year earlier, and we achieved EBIT breakeven in 2024, and that's -- I believe it's quite a great performance. And therefore, over the past 3 years, Biopharma has played a pivotal role in driving the strong and positive performance development that we saw for Kabi overall and for Fresenius.

Kudos to my Biopharma team for these great achievements, and naturally, a key driving factor behind the performances has been the quality of the new Biopharma leadership team. We selected a new BU President with Dr. Sang-Jin Pak, and we strengthened the overall leadership team with important external hires, who have brought significant experiences from across the sector. We now have a winning team, who I believe is ready to deliver on our newly announced ambitions.

Let's have a look at our great financial progression. For Fresenius Kabi overall, our EBIT margin trajectory has been excellent over the last 3 years. We improved our Kabi overall margin from 13.8% in '22 to 16.6% in the first 9 months of 2025.

And while Pharma is the resilient part in our portfolio, we delivered a strong increase in the growth vectors' profitability. We improved in fact the margin significantly from 8.5% in 2022 to more than 15% in the first 9 months of 2025.

More specifically, Biopharma delivered the most significant margin improvement. We invested significantly in our pipeline, reduced costs, and advanced our technical network. We are now reaping the benefits of our strategic and capital allocation decisions, and we continue to scale our business to make it fit for the future.

As mentioned, with a new leadership team, we significantly advanced the maturity level of the organization, while also delivering successful regulatory approvals, launches, and commercial successes across the globe.

So why do we think that we have the right to win in this exciting market? Because along the 3 pillars of the Biopharma value chain, we are very well positioned with a distinctive, competitive, and integrated value proposition.

Firstly, we have a differentiated and robust portfolio with a proven R&D engine. We aim to significantly expand our pipeline with 15 potential new medicines, enabled by our 2 strong in-house R&D engines at Fresenius Kabi and mAbxience.

In addition, we will supplement our pipeline through strategic in-licensing opportunities, ensuring we have the best mix between internal and external opportunities, in order to deliver the best possible return on investment.

We are also scaling development in our platform approach, enable fast-to-market and efficient commercial execution across multiple new medicines.

Secondly, we manage a fully integrated and cost-competitive manufacturing network which is anchored on mAbxience. Progressively integrating and internalizing drug substance manufacturing into mAbxience ensures supplier availability, quality, and increasing cost-competitiveness over time.

Through this integrated setup, we can scale efficiently and expand mAbxience coverage through targeted capital allocation and future investments, tech transfers, and network optimization.

And our demonstrated ability to manage this complexity represents, in my view, a meaningful differentiation and a source of potential competitive advantage over the long term.

Lastly, we have balanced global commercial access with an established presence in more than 35 countries worldwide. We'll continue to build on our strong Europe heritage by leveraging our commercial infrastructures and payer access, but we'll also expand the coverage in the US, and we'll keep leading selectively in international markets, such as

LatAm, where we have leading positions in 2 out of the top 3 markets, namely, Brazil and Argentina. And this broad footprint is a strength and ensures also resilience for future long-term profitability growth.

There is also one specificity that I believe represents a significant differentiation compared to our competitors. That is our presence, global presence, with our 3 business units across the globe, and that gives us recognized reputation and strong presence that we can also leverage when it comes to Biopharma.

And together, these 3 pillars define how we compete and how we believe we'll keep winning in this space. And they also provide the structure for the presentation that will follow.

Now we'll go to the important slide, where we are stating our ambition for 2030. So we are now increasing our ambition, and today, we are announcing our new 2030 ambition, which is, first of all, we aim to double our revenue from today's base, and this will be driven by further launches, by increasing also penetration and market share with our medicines.

And second, we are aiming to achieve an EBIT margin of around 20% by 2030. And this is broadly equivalent to our highly profitable Pharma business. And the main levers for margin improvement are to keep driving continuous cost improvements in costs but also to keep scaling our portfolio in globally attractive margin.

With that, I hand over to Sang-Jin and the team to share more details and give you more color on how we plan to transform this commitment into a reality.

Sang-Jin Pak: Thank you, Michael and Pierluigi, for setting the stage. It is great to be here.

We have the strength, capabilities, and levers to double our sales and double the number of molecules in our portfolio by 2030. When we look at the building blocks to reach this ambition, the path is clearly laid out. The significant increase will be largely driven by the continued strength of our existing and highly relevant business.

The core engine is the compounding growth across our 9 in-market molecules. Tocilizumab, adalimumab, denosumab, and ustekinumab are driving a large share of this excellent momentum.

These products are still in the ramp-up phase with accelerating strong adoption curves ahead, expanding access, and increasing share across key markets. This gives us a consistent, reliable foundation for our growth with great visibility ahead.

On top of that, we are constantly adding new launches which are already in late-stage development or secured through confirmed in-licensing. This includes aflibercept, vedolizumab, etanercept, and nivolumab. These are significantly derisked, with clinical development near completion, scale-up tech transfers underway, and commercial pathways clearly laid out and defined.

In this context, we see a CAGR of around 15% through 2030. The portfolio is already built, the assets are funded, and the highly motivated team is rigorously executing.

Beyond the 2× ambition, we see further significant upside potential. Our early-stage pipeline, including 6 new assets already in development and fully financed, will hit the market beyond 2030. Hence, we are confident in delivering not only on our short-term ambitions but also on our long-term growth momentum.

This is how we double our portfolio, double our revenue, and reach about 20% EBIT margins by 2030.

Looking at the highly attractive market environment, we see strong tailwinds supporting our ambition. These are exciting times. We are moving into the strongest LOE cycle the industry has ever experienced, with a 6× market expansion to €180 billion by 2035.

Even in the years 2026 and '27, which globally have a lower number of LOEs, we expect to continue our double-digit growth trajectory. We operate with a globally diversified and well-balanced footprint across Europe, LatAm, and the US. Hence, we naturally capture LOE windows that are staggered across different regions.

This minimizes our exposure to temporary years with lower LOEs in certain regions. For the short-term, we plan meaningful launches, including aflibercept and vedolizumab, which are expected to maintain our great momentum.

For the early 2030s. we see further significant upside potential beyond our 2× ambition.

The market momentum is not only driven by LOEs. Biosimilar adoption has entered a new phase of momentum due to favorable regulatory shifts. Adoption is accelerating globally.

In the US, we finally see a significant acceleration, driven by increasing payer familiarity, stronger incentives, and broader acceptance by prescribers and health systems.

Importantly, most molecules continue to grow for several years after launch. We are also seeing this pattern across our own in-market portfolio. Tocilizumab is still gaining traction each month, adalimumab remains a stable anchor, and ustekinumab is accelerating with interchangeability designations.

These adoption curves give us sustained tailwinds from assets already launched, a major contributor to the predictability and durability of our growth outlook.

We are seeing a great performance of our Biopharma franchise. In fact, we are the fastest-growing top 7 biosimilar player. This momentum is fueled by our consistent and broad-based execution across our 9 marketed molecules.

Being the fastest-growing among the largest competitors underlines 2 points for me: first, our operating model works end-to-end, from R&D and manufacturing to commercial execution. Second, we consistently gain market share in highly contested, mature markets, which is one of the strongest validators of our competitiveness.

What differentiates us is that we operate as a fully integrated biosimilar powerhouse, from drug development to drug substance and drug product manufacturing, all the way to commercialization in more than 35 countries.

We have built a platform and reached critical scale for future success. Today, we run 15 pipeline products, 3 drug substance sites, and a flexible network capable of producing millions of units across vials, prefilled syringes, and autoinjectors. Because we manage the full value chain, we control quality, cost, supply reliability, and speed.

Our ingredients to win in biosimilars are a strong and differentiated portfolio, cost-leading manufacturing, and world-class commercial execution. Our entire operating model is built around these 3 pillars, and this is why we are consistently delivering today and will also do so in the future.

We have established a broad and competitive portfolio with 11 marketed products across 9 molecules. Importantly, the vast majority of the molecules were developed in-house, demonstrating the strength of our R&D engine.

Our brands now span immunology, oncology, and endocrinology, showing that we can both launch and scale across very different therapeutic areas. Adalimumab remains an anchor, tocilizumab is accelerating strongly, and denosumab is differentiated with a prefilled syringe offering. Pegfilgrastim, bevacizumab, pembrolizumab, and rituximab complement this base and add diversification across markets and channels.

This breadth, combined with proven execution, gives us a strong platform to double the portfolio by 2030 and maintain sustained growth well beyond.

Looking from the portfolio to the supply side of the business now, in biosimilars, drug substance represents roughly three-quarters of total manufacturing cost. Because we have internalized DS manufacturing through mAbxience, we operate from a structurally advantaged cost base compared to the broader industry.

Vertical integration allows us to optimize productivity, scale efficiently, and continuously reduce costs through process improvements. It also makes our supply chain more resilient and agile, an increasingly important differentiator as competition intensifies and payers put more pressure on pricing.

This manufacturing advantage is one of the key reasons why we are convinced that we are very competitive and will win in highly contested markets like the US and Europe. This will ultimately lead to further expanding margins toward our 2030 ambition.

Our commercial model is balanced and well diversified across Europe, LatAm, and the US. In Europe, we have a deeply established direct sales presence in more than 20 markets, coupled with strong payer access and tender excellence. This allows us to consistently secure leading positions at launch.

In LatAm, we are the leader in Brazil and Argentina, supported by strong regulatory environments and local manufacturing. These markets also act as incubators for early launches, enabling us to build real-world evidence and execution muscle ahead of global rollouts.

And in the US, we are scaling rapidly with high double-digit revenue growth year-over-year 2024 to 2025. We are applying innovative approaches in contracting and distribution and are deliberately expanding our footprint in a market that will represent more than half of the global biosimilar industry by the mid-2030s.

This global balance significantly derisks our revenue and enhances our growth resilience.

The biosimilar landscape is evolving quickly. Regulatory frameworks are shifting literally as we speak, with Phase 3 waivers accelerating timelines and market dynamics changing as autosubstitution and payer-driven contracting intensify cost pressure.

We have prepared for this shift ahead of the wave. We already achieved approximately a 40% reduction in cell-line and process development time, giving us a meaningful speed advantage. Our cost leadership, driven by DS internalization and a platform approach, ensures we remain competitive even as prices decline. And our direct payer access, especially in Europe and increasingly in the US, positions us well in more centralized and value-driven purchasing models.

Barriers to entry in biosimilars remain high. Even after Phase 3 streamlining, total development time will still be around 6 to 8 years compared to 7 to 9 years before, which is fundamentally different from generics, where development takes only 1 to 2 years.

This level of complexity and long-term commitment creates a natural entry barrier, and we have all the capabilities needed to win in this environment.

To summarize, we operate in one of the most attractive categories of the pharmaceutical industry, and we have built a business with the right fundamentals to win. The biosimilar market is growing strongly, and we are perfectly positioned with a balanced portfolio, a growing pipeline, and a globally diversified commercial footprint.

Over the last 6 years, we have established a true end-to-end powerhouse, with proven capabilities in R&D, cost-leading manufacturing, and commercial execution across all major regions. These capabilities give us the strong conviction that we will double our portfolio, double our sales, and reach around 20% EBIT margin by 2030.

Our clear strategy, rigorous execution, and strong momentum across our in-market and upcoming launches, gives us significant upsides beyond 2030.

And with that, I am pleased to hand over to my colleagues, who will take you through the levers why Fresenius has the right to win.

Michael Hammer: Good afternoon. I'm Michael Hammer, leading Portfolio and Business Strategy for Biopharma. I'm joined by my colleague Fabrice Romanet, our Head of R&D.

In this section, we'll demonstrate how Fresenius Kabi is rejuvenating its biosimilar portfolio to drive long-term profitable growth. Our goal is to show you how our capabilities, track record, and strategic priorities are building confidence in our long-term portfolio execution.

Our portfolio rejuvenation is designed to deliver sustainable long-term growth. We've built a highly competitive portfolio and pipeline covering approximately €200 billion in originator sales.

Our proven R&D engines leverage complementary in-house hubs alongside selective in-licensing, which gives us the confidence to achieve our goal of delivering more than 2 new clinical development projects per year.

Over the past 3 years, we have already demonstrated our portfolio speed and differentiation, outpacing many peers in the number of US FDA approvals. Unlike key peers, whose portfolios rely heavily on in-licensing, Fresenius Kabi's pipeline is predominantly in-house developed, which in turn supports margin accretion and maintains strategic control.

Let's first examine the biosimilar market. This is set for significant expansion, expected to grow sixfold by 2035. Nearly 300 molecules will face loss of exclusivity over the next decade, representing a major growth driver. More than 60% of these loss-of-exclusivity sales come from oncology and immunology, areas where Fresenius Kabi has deep therapeutic experience and knowhow.

Our expertise in these areas position us strongly for upcoming launches, while we selectively expand into other attractive or adjacent segments to maximize long-term profitable growth.

Building on this opportunity landscape, let's look at how we select and execute our portfolio strategy.

Firstly, we start with over 1000 biologic opportunities, narrowing the universe to between 15 to 30 pipeline candidates that can be prosecuted based on several important dimensions, for example, cost, target, product profile, originator global sales, and competitive density.

A cross-functional team uses a proprietary approach to identify the right opportunities to progress further as we actively develop our portfolio for the future.

Each year, our goal is to advance more than 2 projects into development, ensuring a steady flow of innovation, with our immediate focus monoclonal antibodies. Our current disciplined approach leverages synergies between immunology and oncology and enables portfolio expansion through both in-house development and strategic collaborations.

However, as part of our active portfolio management and as new technologies emerge, we will continue to keep under evaluation other modalities, for example, biobetters, bispecifics or antidrug conjugates.

Let's compare our portfolio size and composition versus peers.

Our portfolio includes 9 marketed medicines and 9 molecules in the development, doubling our launched products in the coming years.

Peers report similar numbers, but not all potential new medicines are disclosed in early-stage pipelines, and many are in-licensed. Fresenius Kabi's strength is substantial in-house development with strategic oversight across the value chain.

Now let's zoom in on our marketed portfolio and pipeline in more detail.

We now include 6 further early-stage candidates, bringing our total to 24. This coverage of €200 billion in originator sales spans immunology, hematology, oncology, and respiratory to include marketed products, registrational, clinical, and preclinical candidates.

Our complementary Fresenius and mAbxience portfolios offer a broad and balanced pipeline, expanding to meet evolving market, prescriber, and patient needs.

With this strong foundation, I'll now hand over to my colleague Fabrice Romanet, our Head of R&D, who will take you through our exciting R&D engines and technical capabilities.

Fabrice Romanet: Thank you, Michael. It's a real pleasure to be here.

Our two R&D engines, Fresenius and mAbxience, complement each other, increasing portfolio breadth and competitive strength. Fresenius has a track record in developing high-quality biosimilars for highly regulated global markets, focusing on immunology; while mAbxience brings oncology specialization, large-scale production, and expertise in navigating diverse regional regulations.

Together, we cover the entire value chain from lab scale to clinical development to manufacturing and registration with global regulators, integrating feedback from our commercial organization to ensure our target product profiles to meet evolving market, prescriber, and patient needs.

These unique characteristics serve as a catalyst for potential strategic in-licensing, providing access to late-stage clinical medicines with proven data, thereby accelerating development. In addition, our IP expertise also enables timely and defensible launches.

Let’s see how these engines translate into successful commercial launches.

With over 15 years of biosimilar development expertise, we have launched 9 medicines and have 15 more in the pipeline. Our early-stage hubs in Eysins, Switzerland, and León, Spain, excel in small-scale state-of-the-art R&D, while scale-up hubs in Garin, Munro, and León drive process validation and large-scale production.

After preclinical chemistry, manufacturing, and controls stage, our internal capabilities allow us to design robust clinical trials that meet the latest and highest global regulatory standards. We leverage our in-house pharmacokinetics and biostatistics seasoned expertise.

Our track record is clear: 8 US FDA BLA approvals between 2022 and 2025, one of the highest amongst peers. We are recognized as a leading voice in shaping regulatory guidelines to support innovation and patient access.

Next, I will highlight how our technical development enables differentiated and fast-to-market launches.

Biosimilarity demonstration is first and foremost about CMC analytical similarity. It all starts in the lab, striving for the best cell clone producer with the highest quality combined with the strongest productivity.

Our technical development capabilities -- spanning cell line development, state-of-the-art technologies, and digital systems -- enable us to select optimal cell clones and establish efficient CMC blueprints.

Integrated CMC and intellectual property experts ensure high-quality manufacturing and formulation, while our platform approach for devices importantly reduces costs and enhances patient usability.

The impact is substantial: faster cycles, right-first-time quality, and launch readiness differentiation.

Let me share a couple of examples of success.

Our denosumab biosimilars Conexxence and Bomyntra exemplify our ability to turn R&D innovation into competitive advantage.

Our first wave launch secured early market entry, with differentiation through a latex-free and unique prefilled syringe in oncology. This approach prevents allergic reactions and positions Fresenius Kabi as a solo bidder in key commercial tenders, demonstrating our leadership in product innovation and commercialization.

Speed is equally important, as shown in our next example.

Our first-to-market launch of Tyenne, our tocilizumab biosimilar, highlights R&D speed and agility. Parallel clinical trials for subcutaneous and intravenous formulations means we serve a broad market, including hospital and outpatient settings.

We move fast and smart, ensuring our biosimilars are designed in constant dialog with global regulators and health authorities to meet high development and regulatory standards. We accelerate the delivery of our trials, our study reports, an all-important step prior to the final delivery of the regulatory dossier.

This achievement underscores our ability to deliver biosimilars rapidly and effectively with early-to-market entry.

In addition to our leading in-house R&D capabilities, we strategically identify opportunities to in-license potential new medicines to complement our internal pipeline. A recent example in our partnership with Polpharma Therapeutics is the in-licensing their vedolizumab biosimilar to further strengthen our presence in immunology while harnessing existing relationships with key prescribers.

We have a proven track record in clinical development with a demonstrated ability to achieve regulatory approvals while adopting IP strategies to deliver launch excellence. These skills, combined in a collaborative, agile, fully vertically integrated business unit, make us the partner of choice for biopharma collaborations.

Let's now look at the evolving regulatory paradigm.

Regulatory expertise is essential for continuous and reproducible success. Fresenius has been a leading company in the evolution of the regulatory guidelines, collaborating with global regulators and health authorities to deliver successful policy changes, for example, the recent waiver of clinical efficacy studies across Europe, US, and Canada. We anticipated this evolution and prepared for the increasing focus on CMC analytical and Phase I pharmacokinetic studies.

We are increasing our speed of cell line and process development by 40%, leveraging our 15 years of CMC experience with thousands of lab-scale batches and associated data. Our expertise in biostatistics, data management, and clinical operations has delivered more than 10 robust Phase I studies.

Our active dialog with global regulators and health authorities continues, as we seek to further harmonize approval frameworks while maintaining our competitive edge with AI-powered regulatory databases.

In summary, Fresenius's rejuvenated portfolio and pipeline cover €200 billion in originator sales. Our proven R&D engines, complementary in-house hubs, and strategic in-licensing are significantly contributing to our success. We consistently deliver speed and differentiation, as seen most recently in our Tyenne, Conexxence, and Bomyntra launches.

Our governance, milestone-driven KPIs, and culture of performance and accountability underpin our confidence in delivering our ambitions of achieving long-term profitable growth.

Let me hand over to Yannick Sorlet, SVP Technical Operations, Supply Chain and Projects at Fresenius Kabi, and Jurgen van Broeck, CEO of mAbxience.

Yannick Sorlet: Many thanks, Fabrice. Hello, I am Yannick Sorlet, and together with my colleague Jurgen van Boeck, we will guide you through the ambitious program we are driving at Fresenius to create significant value for the Biopharma business unit.

At Fresenius Biopharma, we believe in the power of a vertically integrated manufacturing platform which is the primary strategic driver of significant cost reduction for our biosimilars.

Our operating model is based on insourcing of all the manufacturing steps from drug substance to fill-and-finish operations.

We have already achieved significant reduction in costs of production for recently launched biosimilars through insourcing to our manufacturing sites, including our primary drug substance manufacturing platform mAbxience.

In parallel to insourcing of additional products or manufacturing steps, we are driving additional COGS reduction through other initiatives in the next couple of years along the manufacturing and supply value chain.

On top, we continue to invest into building additional state-of-the-art manufacturing capacity to support our longer-term profitable growth and sustain cost leadership position for the future.

Our current manufacturing footprint and technology is industry leading, enabling us to cover a broad variety of biologic products and all manufacturing steps. mAbxience operates as our internal platform for drug substance manufacturing with 3 sites (2 with mammalian cell culture and 1 with microbiological fermentation), with several independent production lines each, while our biosimilar fill-and-finish site is located in Austria.

We plan to invest more than €300 million by 2030 in new production lines in our existing DS and fill-and-finish manufacturing sites, with the aim to double existing capacity in some technology and steps and insource more products and volumes in the future.

Together with increasing the capacity and enhancing the technology, we are also maximizing the potential of economies of scale to enable another major reduction in costs of production within next 5 years.

To further reduce COGS, we have developed an ambitious program with diverse and complementary initiatives.

Along with our main strategic pillar of vertical integration, we are optimizing our manufacturing technology and scale, the productivity of our production processes, and the efficiency and effectiveness of our supply chain to outperform competition in terms of speed, reliability, and agility.

We have clarity on how to get to best-in-class COGS and are confident that we are doing the right thing to deliver significant savings through these initiatives.

While we have demonstrated our capability of managing a complex network of both internal and external sites, we will continue our journey to internalize of all manufacturing steps from API to finished product manufacturing.

Since this year, we have established a fully integrated manufacturing and supply chain for tocilizumab, which will deliver several million euros savings per year versus supply from Merck.

Our capacity coverage target is to progress towards 80% internal and 20% external manufacturing in longer terms.

I will now hand over to Jurgen van Boeck, who is going to tell us more about all the ongoing mAbxience biosimilar manufacturing cost-reduction initiatives.

Jurgen van Boeck: Thank you, Yannick. As CEO of mAbxience, I will now elaborate on how we are increasingly taking a key role as the manufacturing platform for Fresenius Biopharma while driving cost leadership.

How? Well, first, the internal manufacturing gives significant more supply reliability and less supply complexity.

Constant structured efforts to increase process productivity and efficiency impacts cost of goods of the tech-transferred products in the short term.

The increase of scale, which will be realized in the planned capacity expansion, generates a midterm COGS improvement and flexibility of production.

Lastly, several initiatives are analyzed to further drive supply agility whilst being cost effective.

We are not waiting for increased scale to optimize the cost of goods of the products. Continuous productivity efforts through improving yield, raw material costs, and cell productivity are already delivering for key products.

For example, for bevacizumab, we have already significant improvements, and this is already in the market.

In terms of increasing supply agility, we mentioned already that this is key in a dynamic biosimilar market, a one-third lead time reduction through further implementation of lean manufacturing principles in production and, on the other hand, through optimization of the supply chain itself. This needs to be realized in the coming years.

Our integrated manufacturing platform needs to be at the forefront of innovation and manufacturing potential. We are building a future-ready platform to deliver long-term profitable growth.

Therefore, a mid- to long-term plan was created to understand the capital investments required to achieve our ambition. We will continue to invest in automation and digitalization, including AI, while assessing the return on investment from potential geographic footprint expansion and the adoption of new advanced manufacturing technology. These initiatives are already in the planning.

To conclude, we operate a cost-leading manufacturing platform across the full value chain, including drug substance, drug product, and finished product along with global certification. This expertise supports our goal to becoming a global leader in biosimilars.

We have already achieved significant COGS reduction through the benefit of full vertical integration from drug substance to finished product manufacturing.

We'll continue targeting additional COGS reduction through product and process optimization initiatives on capacity, productivity, and supply chain efficiency.

With our end-to-end manufacturing network now established, we are investing more than €300 million over the next 5 years to further expand capacity and drive long-term profitable growth.

I will now hand over to Sang-Jin Pak and Molly Benson, our SVP Commercial for US, to talk about our third value creation pillar commercial excellence.

Sang-Jin Pak: Thank you. You have just heard how our portfolio, our R&D engine, and our manufacturing scale come together. The next natural question is: How do we translate all of this into commercial impact?

And that's exactly what our balanced commercial footprint across geographies delivers and what Molly and I will detail in this part.

We achieve commercial excellence by executing successfully across key regions, by using a targeted go-to-market strategy molecule by molecule, and by derisking our revenue streams through our commercial network and selected partners with milestone payments.

Another way to look at the expected doubling of our revenues is through the lens of our commercial model mix, which shows how we want to balance between direct sales and out-licensing over time.

Historically, a significant portion of our biopharma revenues came through out-licensing partnerships, reflecting the way we scaled mAbxience while building our own commercial network.

As this network expands, a growing share of our revenues will come from our own sales engine across different markets and channels. This shift will increase margins whilst reducing our dependency on milestone payments.

Looking ahead, direct Fresenius sales are expected to account for the clear majority of our €1.6 billion in expected revenues for 2030. This reflects the impact of the commercial excellence we are now embedding across regions.

Out-licensing will remain part of our model, used selectively in markets where partners can accelerate access, extend reach, or complement our capabilities. But the overall direction is clear: a deliberate shift towards a higher share of direct sales as we scale our own global commercial presence.

Our commercial model is balanced and diversified across Europe, Latin America, and the US. In Europe, we have a deeply established direct sales presence in more than 20 markets, coupled with strong payer access and tender excellence. This allows us to consistently secure leading positions at launch.

In Latin America, we are the leader in Brazil and Argentina, supported by strong regulatory environments and local manufacturing. These markets also act as incubators for early launches, enabling us to build real-world evidence and execution muscle ahead of global rollouts.

In the US, we are scaling rapidly with high double-digit revenue growth year-over-year 2024 to 2025. We are applying innovative approaches in contracting and distribution, and we are deliberately expanding our footprint in a market that will represent more than half of global biosimilar industry by the mid-2030s.

This global balance significantly derisks our revenue and enhances our growth resilience.

Europe is where our integrated commercial model is already fully operational and at scale. We have a direct presence in more than 20 European markets, covering both public and private provider systems.

This gives us deep access to procurement structures and clinical stakeholders. Our regional key account teams engage directly with decision makers, supported by long-standing relationships across a broad network of partnered hospitals. In total, we have partnered with over 25 leading hospitals and hospital purchasing groups for tocilizumab.

We also benefit from a clear competitive edge in tenders. Our pan-European tender framework harmonizes processes and systems across countries, allowing us to compete with speed and consistency.

We have defined tender playbooks including best practices and training. Combined with our expertise in multicountry and multichannel bidding, this creates a strong platform for upcoming tenders. And this year alone, we won 40 tenders in Europe.

Performance management is another differentiator. Our analytics solution brings together external sales data and internal customer-facing metrics to help us allocate resources precisely, refine our messaging, and focus actions where they have the greatest impact.

This disciplined approach is already reflected in our commercial results, most notably a 32% market share in tocilizumab biosimilars with Tyenne.

Overall, our results in Europe demonstrate the effectiveness of our scalable, integrated commercial model and how it can be replicated as we expand our direct presence in other geographies.

We have achieved a level of commercial excellence in two of the most important LatAm markets, Brazil and Argentina, and have demonstrated capabilities that we will leverage in other markets.

First, Brazil and Argentina serve as incubator markets. The IP and legal environments allow for early, low-risk launches, giving us the opportunity to gain commercial experience ahead of global rollouts.

Both markets also benefit from strong fundamentals. They are among the largest Biopharma markets in LatAm, and the public health system covers the majority of the population in Brazil.

We have engaged in Brazil for more than 40 years and thus built a robust value chain and trust. The Brazil public market allows for productive development partnerships. This is a 10-year supply agreement which guarantees us minimum 40% of the public market.

In Argentina, we also hold a strong market position. This is supported by our ability to leverage the local manufacturing sites that Yannick presented earlier. In addition, our experience operating within Argentina’s dual national-provincial tender structure has been a major driver of our tender-excellence capabilities.

Managing tenders across two parallel systems, national and provincial, has required a high level of coordination, which we are now applying across other tender-driven markets.

Brazil and Argentina will continue to serve as key capability hubs as we expand our direct commercial model and accelerate launches in additional markets in LatAm and worldwide.

So I will now turn over to Molly to lead us through the US.

Molly Benson: Thank you, Sang-Jin. Hello, everyone. My name is Molly Benson, and I am the Senior Vice President of the US Biopharma Organization.

The US market for biosimilars continues to be an attractive and growing market. If you take a look at the number of molecules that will be losing exclusivity in the next 5 and 10 years, it is significant.

Not only does the loss of exclusivity make it an attractive opportunity for growth but also due to the complexity of the reimbursement and a strong interest for the need for change by plans, providers, and patients.

In addition, there is an increased attention to policy for cost savings and the need to support biosimilars in the US.

These 3 factors -- the number of loss of exclusivity molecules, the need for change to reduce complexity in reimbursement, and the increased attention to policy -- are aligned to our commitment to biosimilars as an organization.

Looking at our showcase Tyenne, Tyenne is the first and leading biosimilar in this class and is available both in IV and subcue.

Our market share has grown to 14% through September, and when you include our partner agreements, the market share is now over 18%. This is a proof point of how we gain momentum while launching first to market in a very short time period.

The reason Tyenne is a highlight is because it is the fastest growing pharmacy benefit biosimilar in the immunology space in the US.

At the same time, the launch of Tyenne also expanded the market 15% year-over-year, which demonstrates the unmet need for access to tocilizumab therapy.

Our access coverage also continues to expand in 2026 from parity to exclusive coverage.

The US Biopharma organization is committed to biosimilars being a long-term sustainable solution for affordable and accessible medications to the US. We have the opportunity to bring our portfolio strength with a molecule-by-molecule strategic approach to adapt to the business needs of the market.

There are 3 pillars of our go-to-market approach. First, individualized contracting -- we have the ability to learn from our launches and adapt to our customer needs. This includes provider and payer initiatives with innovative agreements to increase share. An example would be with our adalimumab-aacf molecule that grew 74% year-over-year with the success of alternative agreements.

Second, access execution -- as mentioned, we have the opportunity to bring a customized strategy to the market. It gives us the ability to optimize our lifecycle management for a long-term and sustainable approach in the market and grows our opportunity to develop partnerships, an example with Tyenne and our increased formulary coverage with payers now covering more than 70% of the US market.

And third, evolving our capabilities -- as the market evolves, so must we. We have evolved our internal skillsets to adapt to the market with a hybrid approach. This gives us the ability to flex with our field and marketing pull-through initiatives based on molecule, market, and lifecycle, an example is how we activate our internal teams to support payers and providers with education and resources to optimize pull through

We have demonstrated the ability to bring value and volume to the market quickly with our alternative and innovative agreements. For example, with Evio which is a pharmacy solutions entity that was created by 6 owner plans, we have agreements expanding our biosimilar coverage to over 20 million members across multiple regional payers.

Also, Cost Plus is another organization that is committed to affordable and accessible medicines in which we now have multiple products added to their formulary to bring value and volume.

And with Civica Script, which is fully transparent distributor created by Blue Shield organizations across the nation covering over 100 million lives, we have announced an exclusive distribution agreement on our unbranded ustekinumab.

These are just a few examples of how we have evolved and adapted to the market and customer needs.

In summary, it is an exciting time for the US biosimilars market, and we have a long-term commitment to the success of biosimilars. The US market is attractive and growing market which aligns to our path forward.

We will continue to expand our portfolio strength with a molecule approach to evolve to the business. And we have demonstrated the ability to adapt, innovate, and grow based on the market and customer needs.

With that, I will hand it back over to Sang-Jin. Thank you.

Sang-Jin Pak: Thank you, Molly. Let me summarize how we achieve commercial excellence.

We execute successfully across key regions with deep payer access in EU and leadership in Latin America, while gaining traction in the US and scaling access in other regions.

We have a targeted go-to-market strategy molecule by molecule, which has proven successful, for example, with the first-to-market launch of our leading tocilizumab biosimilar.

And we will continue to derisk our revenue streams through our commercial network and selected partners with milestone payments.

What you have seen today is a Biopharma powerhouse with a clear value creation strategy, a differentiated portfolio and R&D engine, a vertically integrated manufacturing footprint, and a commercial model that wins across regions.

The market opportunity ahead of us is significant, and we are ready to capture it. The path forward is defined, the levers are in place, and we are well positioned to deliver on our ambition of doubling Biopharma revenue by 2030 with around 20% EBIT margin. We know exactly what we need to do, and we are already doing it.

Thank you for your attention, and we look forward to your questions.

Nick Stone: Thanks, Sang-jin. Great presentation by you and the team.

We're going to begin the Q&A session. Firstly, just want to remind everybody that this event is being recorded. Similarly, questions can also be submitted in writing via the Webcast portal. For the sell-side analysts that have joined the call that are dialed in, obviously, this is a simultaneous conference call, so you can also ask your questions live via the audio line.

For anyone that wishes to ask a question via the conference call, please do press star and 1 on the telephone. You'll then hear a tone to confirm that you've entered the queue, and if you wish to remove yourself from the question queue, you may also press star and 2.

For those obviously on the phone, please do disable the loudspeaker mode because, obviously, we will get a little bit of feedback.

In the interest of time, can I also just ask you to please limit yourself to 1 to 2 questions? As I said at the outset, we can always come back for another round. And then if you do need operator assistance, please do press star and 0.

So we're going to take our first question actually from the Webcast. And this question, in effect, is asking: Why does it make sense for Fresenius to be in biosimilars? What is the overall strategic rationale, and how different will the business look in 3 years from now, considering the loss of exclusivity and peak year sales in the next several years compared to 2030?

So maybe, Michael, we'll come to you in the first instance, please.

Michael Sen: Yeah, thanks, Nick. And welcome, everybody, again. And also, thanks for the first question after what I would call a really deep and interesting presentation, which will give you a lot to chew on and also for Q&As, not only today, but going forward.

Look, from what we've been seeing, I could make it very short by saying, because we are the best owner of such an asset in a highly, highly attractive and vibrant market. Obviously, it is also fitting with our vision and mission that we want to deepen of providing highest quality and cost-efficient products to patients around the world and help healthcare systems to be much more efficient and get to much better outcomes.

But what we've been seeing here today in the presentation, how vibrant it is, and if you look at what has changed in the last 2 years, it is an evolving, structurally attractive market when you only look at the loss of exclusivity and the need worldwide for, for example, oncology and immunology drugs.

By the same token, having a vibrant, attractive structural market, we are very well positioned. This was what it was all about that we have the capabilities through the entire value chain, what Sung-Jin called as building a biopowerhouse. And that is the strategy that, also in terms of resources, we're going to double down.

And for the overall company, it is even great because, next to our biosimilars business, we also have other growth vectors. So the future looks quite bright, I would say, if you're well positioned in this attractive market.

And how will it look like in the next couple of years? I think this is exactly what we alluded to. The direction of travel is clear, the momentum only going upwards.

Nick Stone: Super. Thank you, Michael.

We're actually going to take our next question from Veronika at Citi. So Veronika, over to you, please. Obviously, unmute yourself, and then hopefully, we can patch you in.

Veronika Dubajova: Excellent. Hope you guys can hear me okay.

Nick Stone: Absolutely.

Veronika Dubajova: Very good. Excellent. Good afternoon, and thank you so much for a very informative presentation. I have a couple sort of financial questions. Apologies for bringing it back to the EPS number at the end of the day.

But just one more to understand, I guess, the degree of conservatism, if that's the right term, in the guidance that you've given when it comes to revenues. Obviously, you've exceeded your targets. I don't know, Michael and Pierluigi, if you can talk about the process through which you've kind of built this assumption of doubling the revenues.

And I guess as you think about it, to what extent do you think the risks are balanced to the upside versus the downside, and if you can maybe talk through that process, just to give us a degree of confidence around that number.

And then my second question is just on the margin target. My understanding is you're already looking at profitability that's in the low to mid-teens from a margin perspective. Obviously, 20% is terrific, but I think the slide said 20% by 2030. So I'm curious as to what the shape of that margin curve looks like. Could we get there a lot sooner than 2030? What are the pulls and pushes? And that'll be it for me. Thank you so much.

Nick Stone: Michael, do you want to take the first question?

Michael Sen: Yes, yes. So Veronika, hi. Look, we've been expecting exactly that question and maybe even with the undercurrent which you've been given. Look, this is, for us, more important to give you the direction of travel, the direction and, let's say, the trajectory of the development of the business. And I think this is net-net-net all positive.

Now this industry is still in the making, a lot of things happening. Sang-Jin was talking about, Molly was talking about, for example, on the only regulatory front in the US, for example, a lot of changes only in the recent past, also what you need to do when it comes to the whole development piece.

So a lot of things still need to happen in the industry as such when it comes to payers, when it comes to regulators, when it comes to the adoption of, for example, new and innovative commercial vehicles.

So in such an industry, to even make a statement, I would say that is pretty bold and very self-confident. That is not a mature industry which we have been witnessing for the last 20, 30 years.

So I think, what we've been laying out is, with the things we have in our own hands, which is be great in development, be very cost competitive on manufacturing, and then be very close to the customer and then manage the complexity overall, but also other things which happening outside of the market, that that is the direction of travel, and that is the puts and takes.

So it's not wise and prudent to take a ruler and do a normal earnings conversion kind of thing in an industry like that. But I would say it is very bold because it's net-net-net very, very positive.

And if the adoption and everything works out fine, then there is obviously opportunity for more. It was more important to say this is the clear direction, not hitting a landing point in '31. If this is more, it's going to be more, and we'll update you along the way.

Nick Stone: Thanks, Michael. I think it's fair to say those comments would probably also apply to Veronika's second question on margin. So rather than repeat ourselves, I suggest we lean on those. Can we come to the next question from Oliver at Otto? So Oliver, over to you, please.

Oliver Metzger: Yes, good afternoon. Thanks a lot for taking my questions. So first, for clarification, so you talked about doubling portfolio. Is it based on the -- sorry, doubling revenues -- is it based on the existing portfolio, or does this doubling also include the new products?

And second, about the manufacturing process, so on one slide, you shared that mAbxience operates at around 75% of the industry cost base. So it would be great to have a little bit more flesh to the bone, so how it is calculated. Is it just to the own manufacturing, or are there other cost advantages?

Nick Stone: Okay. Yeah. Thanks, Oliver. We'll get -- exactly, Michael. We'll come to Sang-Jin on the manufacturing, please.

Sang-Jin Pak: Yeah, so I think, for the first question on, is this coming from our currently marketed molecules, or are there any new molecules involved as well in the doubling until 2030, so in that time frame and in that forecast, we have 9 market molecules. The main drivers are tocilizumab but also adalimumab, denosumab, uste, pegfilgrastim, and so on.

And there are 9 late-stage launches that are also contributing to the sales. And namely, I can mention aflibercept in ophthalmology but also vedolizumab, which also launches at the end of the decade and will contribute to this.

Nick Stone: Thanks, Sang-Jin. Shall we take our next question, which is -- let me do sort of a couple from the Webcast. So Falko Friedrichs at Deutsche Bank, you did ask a question with regards to phasing of the revenue margin development. I guess we've already sort of touched on that based on Veronika's question.

So the next part of your question was around, how competitive is the market environment for in-licensing deals? And then the other part of your question is really sort of, clearly, there's a lot of companies that are out there looking at these transactions. So I guess it's our confidence and ability to fundamentally be the partner of choice in terms of ensuring that we gain access to these attractive deals, and what does it take to win?

So maybe, Sang-Jin, we'll come to you from an on-the-ground perspective.

Sang-Jin Pak: Yeah, maybe first comment I want to make is that we have a balanced mix that enables us to secure first-wave potential and sale and launches. And so we don't rely only on in-licensing opportunities, but also, we have an in-house development machine with two R&D engines that enable us to launch first to market.

The in-licensing opportunities we take very seriously, and yes, the competition is high, but just recently, we have actually managed to in-license 2 molecules which are very promising. I mentioned already aflibercept and the second one vedolizumab from Polpharma.

And so we are very confident that, with our commercial footprint and our proven track record, that we are a very attractive partner for potential in-licensing partnerships.

Michael Sen: Maybe let me add on that one because, Falko, your first question was the same like Veronika, and there will be a couple of these as we have expected after the first kind of comments. What you hear already Sang-Jin saying is, when I say travel of direction, it is clear that we have been laying out with everything we know today.

That means that is pretty much, when you come to risk and opportunities, derisked from the molecules we know and have today. And everything which is then in outer years obviously has a bigger uncertainty. That's why I said it is a very bold statement -- I don't like the word conservative, but you can label it as you want -- a bold statement, derisked with everything we have today.

The second thing what Sang-Jin just said is it is about that we will go molecule by molecule. We are very well positioned for the in-licensing, gave you the logic of how we do it, but we do not need to do every deal. It needs to be very attractive for us, and then we're going to put in one molecule after other in the pipeline.

Nick Stone: Thanks, Michael. Can we take our next question from David Adlington, please, at JP Morgan. David, over to you.

David Adlington: Hey, guys. Thanks for the question. Hope you can hear me. Given the recent update on the US regulatory environment in terms of reducing costs and times to market, I just wondered how that influenced your thinking about the competitive markets, both in terms of number of competitors and also pricing over the medium term?

Nick Stone: Thanks, David. Sang-Jin? David, sorry, do you have a second follow on?

David Adlington: No, that's -- the other ones have been asked. Thanks very much, Nick.

Nick Stone: All right. Perfect.

Sang-Jin Pak: Yeah, so in terms of the recent policy changes that we've seen, especially on the clinical Phase 3 trial waiver but also the simplification of interchangeability, that, of course, has two impacts.

Number one, it can reduce the timing of the development timelines. And currently, it was somewhere between 7 to 9 years, and probably we can shave it off by 1 or 2 years.

Second, it will also reduce the cost of the clinical development because the Phase 3 trials are now not needed anymore. And that, of course, could invite smaller players, more players, to enter the market.

But we believe that there are still high entry barriers to this market because you still have the 6 to 8 years of development timeline. So the returns on your investment will only come after a long period of time.

You have high CapEx investments. You need to have analytical requirements. You need to have expertise in regulatory authorities and what the demands are from their side. And so you need a lot of expertise and capabilities and a lot of investment cost.

And so not everybody's able to successfully navigate through this. And so we believe, with our now mAbxience end-to-end vertically integrated manufacturing setup, we are now able to cover the full value chain from development to manufacturing all the way to global commercialization.

So we are very well positioned in order to thrive in this new environment, whereas probably smaller players who only cover maybe one part of the value chain will be disadvantaged.

Nick Stone: Super. Thank you, Sang-Jin.

Pierluigi Antonelli: I want to just have a quick comment on what Sang-Jin just said. One element which really distinguishes ourselves versus the competitors is also the fact that we have a very strong global coverage from a commercial standpoint, thanks to the other 3 business units. And this, I believe, it is really a distinctive strength because we can also leverage the infrastructures, commercial infrastructure that we have across the globe, including the US and therefore the strong recognition and perception that we have as a reliable player across the globe.

Nick Stone: Thank you, Pierluigi. Okay. I'm just going to pick up a couple of comments on the Webcast. So maybe, Sang-Jin, if I can come to you, just maybe a comment around how we think about the evolution of biosimilar pricing, what are we seeing potentially from sort of an erosion and competition perspective? I guess, really, how does this compare to what we've seen previously?

And then if I can also fold into that a little bit, I guess, linking back to sort of some of the comments around the pipeline and, obviously, the role of business development, can you also just comment on the early stage pipeline, which has obviously got the focus around immunology and oncology, but where might we look to go potentially in the future?

Sang-Jin Pak: Right. So I think we can see significant price erosions and also increased competition, but we cannot say definitely that it has translated into uniform price pressure across the whole portfolio.

So there are still, molecule by molecule, very profitable niches and pockets of differentiation. I want to give you 2 examples. Number one, of course, our bestseller, tocilizumab, which is in a market with probably about 2 or 3 other competitors, so it is fairly niche, and we are first to market, so we were able to do a lot of contracts in those key geographies.

The second one is around differentiation. And our denosumab biosimilar, especially for oncology, called Bomyntra, has a differentiating factor that no other biosimilar has. We're the only ones with a prefilled syringe of the 120 milligrams, and therefore, we're unique, and we've now seen already the first success in the UK where we won the national tender with this.

So in terms of pricing, yes, it is competitive, but unlike small molecule generics, because that's always the next question that's coming, is it going exactly the same direction? And I already mentioned no. The CapEx investments are different, the development lead times are much longer, and the entry barriers are much higher.

So there will be, in the future, more and more specialized players such as us, probably with a fully vertically integrated manufacturing network that will be successful in the future.

Nick Stone: And quick comment on pipeline of the future. I guess it's fair to say you're going to be agnostic, but maybe you want to --

Sang-Jin Pak: Correct. Yeah, it's true that we started to focus on immunology and oncology, but we are therapeutic area agnostic, and we are very opportunistic with where we place our bets. What's more important for us is the potential to be first to market than that we have the most competitive cost of production -- and that within our vertically integrated network -- and that it fits well with our regional geography go-to-market strategies. And so in the future, we will be in ophthalmology but also in hematology and respiratory, just to name a few.

Nick Stone: Super. Thanks, Sang-Jin. I'm just going to pick up one question, which is, again, sort of with regards to the timing of loss of exclusivity relative to the '26, '27 period related to the doubling of revenue.

Look, I think it's fair to say, as we've already said, that this is very much about what we already have in our hands, which gives us the confidence to deliver on our ambition to 2030. So yes, you're right. There is a, shall we say, trough period in terms of loss of exclusivity, but the 2030 ambition is not contingent on that. And as we've already alluded to, there's also business development upside beyond our 2030 ambition.

If I sort of come back to a Webcast question which is a little bit more broad, which is looking at capital allocation, maybe, Michael, I can ask you in terms of how do we balance investment at the group level.

And then maybe, Pierluigi, sort of a comment around how you think of capital allocation at a Kabi level.

And then dare I say it, Sang-Jin, maybe just how you think of it from a biosimilars in terms of R&D capacity and how you prioritize those investments at a business unit level to ensure future long-term success.

So maybe, Michael, group perspective first, please?

Michael Sen: Yes, thanks. And I'm grateful for the question because that gives us the opportunity to show what our operating model is. Although we have these different layers, it is not 3× capital allocation decisions with a full degree of freedom.

It is more or less, when we started the journey on #FutureFresenius, that we said capital allocation, as to where the money will flow on the group, is the primary task of the Management Board.

If you look at our financial framework, Fresenius financial framework, there is the growth on revenue and the margin bands for the businesses within that. Obviously, they can allocate what I would rather call resources on a business unit level, and Kabi manages the operations between the businesses, and Pierluigi can allude to that one.

But where the capital goes is clearly the task of the Management Board, and now we have determined the core with the 6 businesses we have. All businesses, all 6 businesses -- and we went into one of them quite deeply today -- are in very attractive positions and have runway for growth.

The second thing, what the group did achieve over the course of the last 3 years, we have the degree of freedom that we delevered without, for example, selling FMC stake.

Now when it comes to capital allocation as is, what Sang-Jin and the team were alluding to, the €300 million capacity expansion, that is obviously baked in to their plans, and now he can decide between R&D and manufacturing, and Pierluigi will manage them together with all the 3 other businesses that we get the highest yield on the assets which are deployed.

But the key thing is it will be key to double down in resources. That's why, in Rejuvenate, we said scale platforms. We need to scale with capital contribution. Capital contribution can be R&D. Capital contribution can be CapEx. Capital contribution can be in-licensing and can be even more.

The good thing is we have the balance sheet today, and we will remain committed to what the financial framework said. That it is the 2.5 to 3 on the net debt to EBITDA, the ROIC, which is there, where we need incremental improvement. It is hardwired with our long-term incentive. And the biggest driver, obviously, is the operational businesses getting progress, and then we can talk about whether the €2 billion and the 20% is conservative or not, but this is the way it works.

Nick Stone: Pierluigi?

Pierluigi Antonelli: I would just integrate what Michael said that we have a pretty robust methodology when it comes to resource allocation within Fresenius Kabi, making sure that we drive allocation to generate sufficient returns, attractive returns for each of the business units based on their potential.

And certainly, for Biopharma, which is why we are here today, we are making sure like the €300 million CapEx that will happen over the next 5 years, that we have what it takes in order to continue to drive this business successfully, competitively, and make sure that we're going to be staying as a long-term successful player beyond 2030.

Nick Stone: Super, thank you. Anything you want to add, Sang-Jin, or you --

Sang-Jin Pak: Actually, I think everything was said already. I think we have the very rigorous metrics and measurements of how to decide strategically and financially which pipeline products we invest in.

But I want to maybe just add that we have those two complementary R&D engines, and we very rigorously look at first-to-market opportunities. We look at the full target product profile, and we look at competitive cost of production, which means a simplified supply chain. And if these are given, then these can be candidates for in-licensing pipeline.

Nick Stone: Just because you mentioned the cost of production, maybe I can come back to you with a question again from the Webcast, which is, looking at the average development costs for small molecules relative to biosimilars today, anything in terms of -- estimation in terms of how much this potentially could fall, given the recent draft guidance from HHS with regards to potential removal for Phase 3 and obviously interchangeability relaxation? So any comment you can make there would be very grateful.

Sang-Jin Pak: So the first comment is, yes, the development costs will decrease by the level of the Phase 3 clinical study, but it's still different molecule by molecule, right? We are seeing, for example, in the oncology space, where you still need to buy -- where you needed to buy the reference product, which is very costly and expensive, there might be a greater cost saving versus, let's say, in immunology in the pharmacy benefit space.

But it's -- molecule by molecule, it's different. And I think the cost savings are one, on the one side, but I think the lead times are very important. And with these cost savings, I think now all of a sudden, we are able to target molecules which are smaller in size of the peak year sales of the originator. And therefore, we can now develop biosimilars for indications where previously there was no other alternative. And I think that's a good thing for patients but also for payers.

Michael Sen: But maybe let me reiterate because we're going to get this question also all over during the roadshows. I think what Sang-Jin mentioned before, it is really important to understand a biosimilars business is not a small molecule business. It's just not. It's a completely different modality.

Through the entire value chain, you need totally different capabilities in development. You need capabilities, and you need the resources. Resources means financial resources. We talked about what kind of efforts. It already starts with patent litigation and so on and so forth. And then I think Fabrice gave you a nice picture of what it takes during the development process.

The manufacturing is a totally different one. This is not process manufacturing like in small molecules. This is bioreactors. This is living organism. This is a different rigor on quality and everything.

And then it comes to the commercialization, which is also different. And by the way, let's say, the deregulation efforts of the administration, which we fully obviously endorse and acknowledge, will not lead to any commoditization of biosimilars but rather will push the diffusion and adoption with everything else, which is being -- needs resources and capabilities being intact. And therefore, we are betting on what Sang-Jin and the team calls a powerhouse of Biopharma.

Nick Stone: I think, can I also just throw on another comment, which I think it's also important? Even though that costs are coming down from a development perspective,

we've also got to recognize, obviously, there is still going to be the IP litigation costs, which will continue to be a barrier or hurdle to entry.

Conscious of time, before we come to you to wrap, Michael, there was a question I just want to pick up on ROIC. And it's a very simple one, which is, we're not going to disclose ROIC at a biosimilar level. But just as a reminder, remember, from a group perspective, we talk about capital efficiency in the range of 6% to 8%.

I think it's also important to acknowledge that very much reflects some of the legacy challenges for the group. And as a consequence, if you adjust for goodwill, we're much closer to sort of the 12% mark. So I just wanted to address that because that was a question on the Webcast.

But maybe, Michael, now that we've concluded the Q&A, if I can come to you for some closing remarks, please.

Michael Sen: Yes, first of all, that we did display the ROIG without the goodwill was a suggestion of you guys from the market saying, why don't you display that? Because I think we can all agree value is only created by incremental value creation going forward.

The goodwill is the goodwill we have to carry. And therefore, if you only look at even with the goodwill, the increment which the company has been delivering the last 3 years -- and Pierluigi just said he's going to be hard-nosed on making sure that the €300 million investment in Biopharma will yield its not only plan but really desired outcome -- that is the way we manage. So future value comes from incremental value going forward with or without the goodwill.

But now let's wrap it up. I think, first of all, thanks a lot -- it's December, I know -- for the questions and the interests, following not only our journey on the company but, today, this what we call very educational session on and biosimilars.

What you have seen -- and that is true for biosimilars, but the good news, it's equally true for all other 5 core businesses we have -- the fundamentals we see in today's world when it comes to asset allocation, the stuff is not economically sensitive.

This is healthcare. So the underlying growth drivers are intact and are very much driving the growth. And we want to get our fair share of the procedure growth. And it's also not in an arena where it's a lot of, let's say, wishful thinking of what can happen or not happen with AI.

This is real. We showed you what is real in there, what is our ambition going forward, derisked with everything we have in the pipeline today. It is an attractive market. It is a vibrant market. Maybe we'll come back in 2 or 3 years and do it again. And I'll bet there will be a lot of change. I will also predict there will be a shakeout of players.

We want to double down and create what they call a Biopharma powerhouse by launching and scaling. We have the R&D machine and told you how capability driven, resource driven that really is and that we have the right pipeline. Good questions, so in-licensing versus own development.

You saw what it takes. If it's price sensitive, price competition is there, then you better have your costs under control when it comes to cost of goods sold. You've got a glimpse. We have a manufacturing platform. We have a manufacturing machine.

By the way -- and this is also what Pierluigi is driving now -- a lot of digitization and AI can help to bring down the costs there in a setting where you still need to be capable of really delivering on that manufacturing platform.

And then the commercial excellence, Pierluigi also highlighted globally. We can even hinge on infrastructure wise on the other businesses, but then very tailored, very tailored individual geographies, even in the US, spreading what Molly said with new innovative kind of access models.

And that's why 2× revenue, EBIT margins, 20%, direction of travel, I still believe it's bold. It's net-net-net positive because it's derisked by what we have. Obviously, we need to deliver on what we have. We need to work on it. We need to deliver in the next couple of years. But it stays that vibrant, and all fundamentals lead to a healthcare system needing to be more efficient. That is a key contributor. Who knows? We can even be in a position to deliver more. We're excited. Watch this space. Merry Christmas, Happy New Year. Over to you, Nick.

Nick Stone: Nothing more to add apart from thank you very much, everyone. As Michael said, enjoy the holidays, and we'll see you all in January.

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