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SASY.PA - Q2 2026 Sanofi SA Earnings Call

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PRESENTATION

Thomas Larsen - *Sanofi SA - Head of Investor Relations*

Hello, everyone. This is Thomas Larsen from the Sanofi IR team. Welcome to the second-quarter 2026 conference call for investors and analysts. Slides can be found on sanofi.com.

Please turn to slide number 3. Here are the forward-looking statements. We would like to remind you that information presented in this call contains forward-looking statements, which are subject to substantial risks and uncertainties that may cause actual results to differ materially. We encourage you to read the disclaimer in the presentation. We also refer you to our Form 20-F on file with the US SEC and our French universal registration document.

We're going to make comments on our performance using constant exchange rates and other non-IFRS measures. Numbers used are in millions of euros and for the second quarter unless we stated otherwise.

Please turn to slide number 4. The agenda for today, we are welcoming Belén for the first quarterly conference call since joining Sanofi. Belén will cover our business and the first reflections as a new CEO. You will also hear from our CFO, François; and our Head of Research, Mike on the pipeline.

We've expanded to 1 hour and 15 minutes to allow for the new CEO update and plenty of Q&A. For the Q&A, we also have the support of Manuela, Olivier, and Thomas to cover our global business, as well as Roy, our General Counsel.

(Event Instructions)

And with this, I now hand over to Belén.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you, Thomas. Welcome, everybody, also from my side. As you can imagine, I'm excited to return to Sanofi ready to drive the necessary improvement and lead the organization in its next phase of growth. I'm also looking forward to reconnecting with all of you on these calls and through our wider Investor Relations engagement with transparency and trust.

Over the past 12 weeks, I have listened, I have learned, and I have completed the critical phase of my diagnosis. We have already started translating those conclusions into decisions and importantly, on near-term priorities. Our teams continue to deliver quarter over quarter, as seen by the results.

At the same time, I have to fully recognize the challenges confronting us and the need to build strategy that delivers on mid and long-term growth. And I can assure you that this is going to be our focus, and we will do it with the right sense of urgency.

At the end of the presentation, I will further share my reflections since rejoining Sanofi. And now I will focus on our Q2 headlines.

Number one, we delivered strong performance with a double-digit sales increase supported by disciplined cost management, leading to double-digit EPS growth. Based on our strong performance in H1 and as we plan further sales and EPS growth in H2, albeit with a lower level of growth, we are upgrading our guidance for full year 2026, and François will provide additional detail around this.

Transitioning to slide number 6 to go through our quarterly results. In Q2, we continued to deliver very strong growth with a double-digit sales increase and this is driven by both pharma launches and the continued strength of Dupixent.

Sales from our pharma launches were up by nearly 50%, led by Ayvakit, ALTUVIIIO, and Sarclisa. Established medicines were stable in the quarter. Dupixent continued its very strong growth at 37% in Q2, and that was driven largely by volume, that means more patients receiving it. Vaccines declined slightly, mainly impacted by a high comparable from last year's influenza sales and that was offset by solid Beyfortus and Heplisav-B performance. Overall, we saw good momentum across our portfolio, and we are confident in our growth trajectory.

Turning to recent launches on slide number 7. Our launch portfolio is a key growth driver. These medicines represent already 13% of our sales and grew over 60% in Q2. Let me walk you through the key contributors. ALTUVIIIO continued its strong momentum in hemophilia A and remains the top choice for patient switches in the US. Ayvakit continues to expand in systemic mastocytosis, driven by continued growth in the number of patients treated and duration of treatment.

Sarclisa is performing well in multiple myeloma, and we are pleased with the recent subcutaneous regulatory approval that is providing greater convenience for patients. We saw a significant contribution from the Heplisav-B vaccine, one of our latest additions and the recently launched rare disease medicines, Wayrilz and Qfitlia are starting to show momentum. What is particularly encouraging is the breadth of this performance coming from multiple disease areas and the continued growth of both early and new launches.

Looking ahead, we have additional launches for these medicines and vaccines in new geographies and thus, we expect this portfolio to continue driving meaningful growth.

Turning to Immunology on slide number 8. Dupixent has more than 1.5 million patients currently under treatment globally and sales exceeded EUR5 billion in the quarter for the first time. Growth was driven by robust demand across indications and geographies. The US also benefited from a favorable adjustment of gross to net deductions in the quarter that François will also detail.

As shared previously, we anticipate the growth rate to moderate in the second half of the year as newly launched indications annualized and comparables become tough.

In the US, Dupixent remains the number one prescribed biologic across important prescriber groups with the recent US approval in chronic spontaneous urticaria for children, we continue to expand the depth of indications. Therefore, we have upgraded our 2030 ambition for Dupixent to around EUR25 billion sales, a reflection of the continued strong momentum.

Turning to Rare Diseases on slide number 9. This is an area where I see potential for greater opportunity in the future. Rare Diseases sit at the heart of the Sanofi's priorities. Sales in rare reached nearly EUR1.9 billion, up by 24%, and this is driven by Ayvakit and ALTUVIIIO. Most medicines across the franchise grew in volume meaning that more patients are being treated for their rare disease conditions.

We recognize that some conditions are more prevalent in specific communities, and this is why we have tailored our portfolio for China and recently launched to innovative medicines there. Myqorzo, a cardiac myosin inhibitor for obstructive hypertrophic cardiomyopathy and rovadicitinib, the first ROCK/JAK dual-active inhibitor for myelofibrosis hydrates.

We will continue to partner with the rare disease communities, communities that we serve, and continue to bring transformative medicines to patients worldwide.

Moving to Vaccines on slide number 10. On vaccine sales reached EUR1.15 billion in the second quarter, 5% lower than last year, and this reflects the high 2025 comparison base in influenza. Influenza vaccine sales declined as anticipated due to the 2025 one-offs and a lower southern hemisphere season.

But this was offset by the solid growth of our launches. First, Beyfortus grew by 50% to EUR108 million, driven by a late US season and continued geographic expansion. Second, Efluelda grew by 43% on a pro forma basis to EUR113 million, offsetting the expected impact of birth cohort dynamics of the pediatric franchise. Overall, the performance of Beyfortus and Heplisav-B shows the resilience of our vaccines franchise.

Moving to slide number 11. Let me speak about our Sanofi Global Health Unit. As you know, around the world, millions of people still lack access to the medicines they need the most and Sanofi's Global Health Unit is changing that. Through impact, our non-for-profit brand of WHO Essential Medicines, our medicines are now available in 30 underserved countries. This is a major milestone on our journey to reach 2 million patients suffering from noncommunicable diseases by 2030.

But access to medicines is only part of the story because the unit is also building a stronger healthcare systems across 40 countries with the highest unmet medical need. Through a strategic partnership, we have reached 6.6 million beneficiaries. 6.5 million people have been screened, 1.1 million diagnosed, and nearly 0.5 million linked to care. And we have trained over 40,000 healthcare professionals and supported more than 1,000 pharmacies and clinics. Stronger systems, sustained care. This is our commitment.

I will now hand over to François, our CFO, for more details on our financials.

Francois-Xavier Roger - *Sanofi SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee*

Thank you, Belén, and hello, everyone. Starting with slide 13, which is illustrating our strong growth. Q2 net sales grew 17.8% to EUR11.6 billion. This growth was primarily volume-driven and included as well a couple of hundred millions of positive adjustments in gross to net. Dupixent strong and continued patient adoptions and our launches continue to experience solid momentum. Restating for Dynavax and Blueprint sales last year, sales growth would have been around 15%.

Our gross margin increased by 3.7 percentage points. This improvement benefited from the reversal of inventory provisions following Sarclisa subcu regulatory approval. Excluding this item, the increase of our underlying gross margin was around 1.7 percentage points, driven by favorable product mix and efficiency.

Operating expenses increased by 13.1%, primarily driven by the Blueprint and Dynavax acquisitions. Excluding the impact of this acquisition and one-off costs, OpEx grew at a moderate single-digit rate. As a percentage of sales, OpEx declined by 1.5 percentage points, demonstrating the strength of our cost discipline.

BOI increased by 35.8% with BOI margin expanding by 3.8 percentage points, driven by gross leverage, cost discipline, and some favorable phasing of capital gains which were roughly EUR80 million higher this quarter compared to last year. Underlying BOI growth was around 20%. Finally, business EPS grew strongly at 33.3%. Excluding share buyback and one-off items, the underlying business EPS growth, which supported by solid operational leverage.

Now turning to H1. Sales growth was 15.7% and business EPS was 22.7%, partly driven by the impact of acquisitions as far as sales growth is concerned and by positive one-offs for EPS. Underlying sales growth was around 13%.

We will face tougher comps in H2, and we anticipate some deceleration of our sales growth. Indeed, we will lap in H2 against a strong sales momentum last year from Dupixent's new indication as well as the consolidation of Ayvakit, which began in July 2025.

Looking further down the P&L. In H2, we expect fewer one-off benefits to gross margin. We don't expect any further Regeneron development balance reimbursement, and we will have reduced benefits from share buyback.

Turning to our 2026 business dynamics on slide 15. We expect vaccine sales growth to be slightly negative in 2026, mainly crystallizing in H2 due to the usual seasonality of this business. For Q3 specifically, we expect a low to mid-teens sales decrease, reflecting a different distribution between Q3 and Q4 of our respiratory vaccine sales compared to last year.

We now anticipate for the full year 2026, a tax rate of around 21%, reflecting the non-deductibility of certain impairment losses on intangible assets linked to recent pipeline decisions.

Q2 marked the end of the Regeneron development balance reimbursement. For the full year 2026, the increase of Amvuttra royalties will fully offset this negative BOI impact. Next year, in '27, we will see a negative EUR200 million BOI gap between these two items. Indeed, we expect a final negative impact from the general reimbursement of about EUR600 million year on year from '26 to '27, while Amvuttra royalties income is expected to increase at the same time by about EUR400 million year on year as well.

We are also introducing on the right side of the slide, the Amvuttra royalty projections until 2030 based on Vara consensus. We take note of recent competitor data, which supports our confidence in the long-term potential of this medicine.

Slide 17. We are upgrading our 2026 guidance to reflect a strong business momentum to date. We now expect sales growth of around 10% at constant exchange rates with business EPS growing slightly faster than sales.

Before concluding, I also want to update our 2020 -- our 2030 ambition originally provided in 2023. Before reviewing the details, a quick word on foreign exchange. When we set this ambition three years ago, we used the euro-dollar rate at that time as a constant currency

base line. Today, we are presenting these updated ambitions still at constant exchange rates, but with today's rate, which is less favorable than it was in 2023.

With that context in mind, I'm pleased to confirm that we are upgrading our sales ambition for the three items combined by almost 10% on a like-for-like basis at constant exchange rates. We raised our Dupixent sales ambition for 2030, which is now expected to reach about EUR25 billion, driven by growth across all indications. Our ambitions for pharmaceutical launches remains unchanged and should generate about EUR10 billion in sales, reflecting the strength and diversity of our launch portfolio.

And finally, our vaccine business is expected to reach about EUR9 billion in sales, thanks to our differentiated portfolio and innovation. The EUR1 billion reduction is split equally between a currency impact and market dynamics. These ambitions reflect our strong commercial capabilities.

Let me now hand over to Mike to cover the pipeline section.

Michael Quigley - *Sanofi SA - Chief Scientific Officer and Global Head of Research*

Thank you, François, and hello, everyone. I'm Mike Quigley, Head of Research, and I'm here today representing the R&D organization. We're thankful for the work Houman has done in the past three years and wish him all the best. We're looking forward to welcoming Paulo in September.

On slide 19, the status of recent pipeline news. Beginning with regulatory approvals, we received a US label expansion for Dupixent in chronic spontaneous urticaria in children. A US label expansion for Tzield and stage 3 type 1 diabetes and Wayrilz in Japan for immune thrombocytopenia.

Sarclisa also became the first anticancer medicine proved in the US, EU, and Japan to be given either subcutaneously or via an on-body injector. In addition, Cenrifki received EU approval in the treatment of secondary progressive multiple sclerosis in patients without relapses, representing an important advancement by addressing disability progression.

Turning to our pipeline. Several Phase 3 studies did not achieve the outcomes we had expected, including two studies of Dupixent in lichen simplex chronicus; second venglustat study in Fabry disease; riliprubart was stopped early in refractory CIDP based on an IDMC recommendation; while the Phase 3 in IVIG treated patients remains on track.

Amlitelimab showed sustained response in the ESTUARY long-term study, although we subsequently decided not to progress to regulatory submission as part of an ongoing strategic assessment of the pipeline. Finally, Nexviazyme met all study endpoints in infantile onset Pompe disease.

In addition, we received four regulatory designations, further reflecting the breadth of our commitment to providing more treatment benefits to patients. With that overview, let's take a closer look at some of those developments over the next few slides.

Now turning to slide 20. I'll highlight the latest updates from our Immunology pipeline. Aligned with Belén's strategic review, which he will discuss in more detail later. In dermatology, the ESTUARY Phase 3 study of amlitelimab in atopic dermatitis, sustained maintenance of clinical response without relapse for up to 72 weeks with no new cases with Kaposi's sarcoma. However, we have decided not to progress to global regulatory submission as part of an ongoing strategic assessment of the pipeline.

Turning now to divakitug. We plan to initiate two Phase 2 studies in hidradenitis suppurativa and fibrostenotic Crohn's disease, complementing our focus in inflammatory bowel disease. We have discontinued itepekimab programs across COPD and chronic rhinosinusitis and balinatunfib programs after Phase 2 studies in Crohn's disease and ulcerative colitis, did not meet our internal efficacy expectations.

Now with Rare Diseases on slide 21. At ATS, we presented new Phase 2 data for efdoralprin alfa in AATD amplezema, demonstrating superiority over standard of care in achieving and maintaining normalized functional AAT levels. Dosed every three weeks, efdoralprin alfa achieved mean functional AAT trough levels, more than 3 times higher than those observed with weekly plasma-derived AAT at week 32. And and was detected in every lung lobe of each participant at week 24. The safety profile was comparable to the current standard of care.

These data will support our discussions with the FDA on a potential regulatory submission already in the second half. We also presented highly encouraging Phase 3 results for Nexviazyme, an infantile onset Pompe disease with 94% of infants alive and free from invasive ventilation at week 52.

Additionally, improvements were observed across all key secondary endpoints with safety consistent with the established profile. These data will support our discussions with the FDA on a potential label expansion, specifically in the US as approvals were already secured elsewhere. And finally, as mentioned earlier, we are pleased that venglustat received US priority review for type 3 Gaucher disease with a target action date of November 25.

Moving to Oncology on slide 22. Sarclisa subcutaneous formulation, including an on-body injector is now approved in major markets across different lines of treatment in multiple myeloma. The Sarclisa CirCLIQ on-body injector, is a compact battery-free device with a hidden needle that automatically delivers the medicine with no manual push and no bioactive excipients. It was designed to enable potential at-home administration, either by a healthcare professional or by the patients themselves were approved and potentially supported by telemedicine. We are pleased with the regulatory approvals in major markets and expect a regulatory decision in China next year.

On slide 23, let me share the status of our key mid and late-stage development portfolio. Despite the prioritizations announced earlier, there is a pipeline of important medicines and vaccines for patients, where we continue to advance our portfolio with several upcoming important data readouts.

Let me now turn to slide 24 and review our expected news flow through the remainder of 2026 and into 2027 and 2028. For the remainder of this year, we expect the final Phase 3 readout for Sarclisa in transplant-eligible multiple myeloma that will result in another US label expansion.

Next year, we expect Phase 2b results for brivekimig and hidradenitis suppurativa, followed by Phase 3 readouts, including frexalimab in relapsing multiple sclerosis, riliprubart, ECITB compared to IVIg and our pneumococcal and yellow fever vaccines. In 2028, we expect multiple Phase 3 readouts for Wayrilz and IgG4-related disease, and warm autoimmune hemolytic anemia as well as frexalimab in secondary progressive multiple sclerosis, and Sarclisa in smoldering multiple myeloma.

Beyond these clinical milestones, we also anticipate multiple regulatory submissions based on data generated over the coming years, together with regulatory decisions for medicines and vaccines already under review.

In representing the research team in Sanofi, we are more focused than ever on starting to deliver meaningful science and patient benefits into the pipeline from our research portfolio. Two external opportunities entered Phase 1 in the second quarter, with internal projects to follow in due force. This year alone, we plan approximately one new Phase 1 start every two months, a meaningful step-up as the changes in research take flight.

Finally, on slide 25, I'd like to highlight our updated epidemiology data book, which provides the latest estimates across many indications represented in Sanofi's portfolio and pipeline. It is now available on our website.

Before I conclude, I'd like to thank all our colleagues in Sanofi R&D with our ongoing commitment in this time of change, and for their unwavering focus on creating new medicines and vaccines for patients.

With that, I'll hand the call back to Belén.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you so much, Mike. So let me briefly -- here are now my first reflection since I joined Sanofi. To start with, let me reiterate my overarching comment that I mentioned at the beginning of the call.

I have to fully acknowledge the challenges confronting us and the need to act with a sense of urgency in order to deliver strategy that improves the perspective of the mid and long-term growth. So I have spent my first 12 weeks on the ground, close to our people, our science, and our stakeholders, the stakeholders will shape some office future.

I am on slide 27. On people, through either town halls or country visits, I engage with company leaders, and I took these opportunities to take the temperature of the organization as well as to share my own expectations. In this chapter, I have seen firsthand the strong commitment of our employees to Sanofi as well as the deep expertise that we have in the company.

Going forward, I plan to build on this commitment to foster a performance-driven culture, greater accountability an ecosystem where people are empowered to make more agile decisions. On science, I also visited R&D sites in France and in the US, interacting with our scientists. And importantly, I also spent time in China, a market that is evolving rapidly into an impressive ecosystem that we must further leverage.

When it comes to R&D and the pipeline, it is very clear to me that we need greater scientific rigor, fact-based decision-making, a stronger, even if linear governance, and more effective operations. We also need to strike the right balance between internal and external innovation in order to improve our productivity. That is why I launched very early a comprehensive outside-in portfolio review, which will inform decisions on our pipeline.

Now focused on the late-stage pipeline, some of which we shared last week and earlier today. And when it comes to business, our ability to deliver commercial results in the US and Europe, as demonstrated by this strong Q2 performance is a key strength.

We can also capitalize on our local footprint in a de-globalizing market, one with greater accountability and empower country leadership, which will contribute to decomplexify the organization and eventually allow us to move with more agility.

Overall, what is clear to me is that Sanofi has core strengths. And it will now be the disciplined choices that we make that will define our next chapter. We are actively developing a comprehensive enterprise strategy versus what has been done before, focus exclusively on the business unit to be able to identify and unlock opportunities.

On slide number 28, I want to highlights some of the early decisions that we have already made as well as some of the key priorities for the months ahead, laying the foundation for our mid and long-term road map.

First of all, on people, we have appointed Paulo Fontoura and accomplished physician scientist and highly respectively to Head of R&D. Paulo is scientifically rigorous and has a proven track record of leading large global organizations and advancing innovative pipeline. Paulo joins a more focused executive committee that was announced last week. Going forward, we will build on Sanofi's employees' commitment to drive the culture of greater accountability high performance and once again, faster, more agile, pack-based decision-making.

On science, we have moved fast making decisions on amlitelimab, as we communicated a few days ago, itekimab and balinatunfib as Mike mentioned, as well as duvakitug where, together with our partners, we have already defined the next two indications. The priority now is to fast-track our wider R&D transformation and Paulo's leadership. We are not going to wait for a minute, and we are already engaging into the early phases of the R&D transformation, starting, as I mentioned, with the R&D with the late-stage pipeline and strategic review. More rigor,more diligence, better returns and always greater patient centricity.

Our portfolio review is ongoing, and we will share our progress in the quarters to come. It is also absolutely imperative that we intensify our business development and M&A activity in a disciplined way, to enhance our mid- and long-term growth prospects, as I already mentioned before.

On the business, we remain committed to Immunology, Rare Diseases, and Vaccines, and we are evaluating as part of the strategic exercise additional growth opportunities. On Rare Diseases, I am convinced there is a greater opportunity for us ahead when our strong capabilities and our leadership position in this attractive market segment. In terms of priorities, we will further build on our strong capabilities in the US and Europe.

We will continue to develop in Japan, and we intend to expand our presence in China. And you may have seen we have nominated Thomas Triomphe, Head of Vaccines to lead China and our expansion there. Given the vibrant ecosystem and rapidly advancing science, combining decision-making with speed and agility, pro-innovation policies and exceptional talent.

Let me talk about something which is very close to my heart. The alliance with Regeneron is of strategic importance for Sanofi. Our discussions to identify opportunities for further collaboration have been productive. These conversations are only and will continue in order to determine the best path forward for both Sanofi and Regeneron.

And finally, on financials. François has presented the upgraded 2026 guidance as well as the 2030 ambition, reflecting our strong business momentum. We will continue to focus on sustainable profitable growth with a strong focus on cash generation. I see also an opportunity to operate with greater financial discipline and to focus our resources on the top growth drivers. Yet, we are confirming our capital allocation principles, and that includes our commitment to the dividend and our dividend policy.

Moving to slide number 29. Last but not least, from September 1, to deliver on the priorities I outlined, we will have a more focused executive team. The members of the ComEx are experienced professionals who will work together will stand behind the strategic decisions of the company in order to shape our future direction. We will have to make disciplined choices and execute those choices with focus in order to create value for our shareholders. Together, we will continue to deliver for our patients, our people, and all our stakeholders.

Let me close with this. I lead Sanofi by delivering concrete actions by delivering complete actions today already after 11 weeks since rejoining while actively working on an enterprise level strategy to strengthen our growth trajectory in the mid and the long term. We aim to engage with you on our strategic direction over the coming months and latest by the end of the year.

In the meantime, you can continue to expect that we will operate in a disciplined, agile manner while being decisive and transparent. Sanofi has strength opportunities and also challenges. What we need is focused decision making, discipline, and executing with a sense of urgency and this is exactly what we aim to deliver. I want to take this opportunity to thank all the Sanofi colleagues I have met today and those who will meet because the openness, genuine feedback, passion, and commitment are absolutely invaluable.

At closing, I want to thank you for your time before we come to the Q&A. And now over to Thomas.

Thomas Larsen - *Sanofi SA - Head of Investor Relations*

Thank you, Belén, and I will now open the call to all of your questions. (Event Instructions)

And then with that, I'll hand over to Marie who'll take the first question.

QUESTIONS AND ANSWERS

Operator

James Quigley, Goldman Sachs.

James Quigley - *Goldman Sachs Group Inc - Analyst*

I've got two, please. So firstly, Belén, on the Regeneron alliance, you've got the benefit of being external to the history of the alliance and a fresh perspective. So can you give us an idea of, from your point of view, what are the key factors that may be blocking faster progress here in terms of adding assets into the collaboration? And you say you're in early stages of the discussions. But what should we think in terms of timelines? Could we see an update here in 2026? Or is that too early?

And then second, on R&D strategy. You highlighted accelerating the R&D transformation is key. What are the key priorities that you have for Paulo as it comes into the seat. And similarly, does -- will we have additional resources here, Sanofi's R&D to sales ratio is still at the bottom end of the sector. So is it a case of how much you spend versus where you spend it? Any thoughts there would be great.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Hi, James. Thank you very much for your question. So look, my impression on the alliance is that, first of all, we have been extremely successful in driving Dupixent and as I mentioned, it is of strategic importance to Sanofi and to Regeneron that we identify the path forward for future collaboration.

To be honest, my fresh impression is that as for any partnership, trust is absolutely essential and for different reasons that I'm not going to judge, I didn't have the feeling that, that was, at this time, one of the environment in which we have been operating.

So my main objective together with Manuela, who is the Head of Specialty Care here with me has been to rebuild fast, to be able to be transparent to one another, to be able to create a path forward for this conversation. I mean, we speak quite often and while I will refrain myself from making any commitment on timing. As I mentioned, the conversations, I feel are productive and we will further disclose to you whenever an agreement is weak in the future.

Manuela, do you want to add anything?

Manuela Buxo - *Sanofi SA - Head of Specialty Care, Member of the Executive Committee*

Perfect. No.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So on the R&D spend and where to spend. Look, as you -- as we have mentioned several times, we are right now in the process of reprioritizing our pipeline in order to focus on the strongest science, the highest unmet medical need and where we can create long-term sustainable value for patients and shareholders.

And in that context, we are going to in coming months. And in the short term, let's put it away. We are expecting to have moderate increases on our R&D spend. And obviously, as we move forward, our R&D spend will move in parallel to any potential BD or M&A that we may that we may add in the future.

So I don't know, François, do you want to add anything to the question?

Francois-Xavier Roger - *Sanofi SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee*

No. I think our investments are driven by contribution to growth and returns over time. So I mean this is what will drive our choices be it in R&D or in the commercial side and the industrial side as well.

Operator

Sachin Jain, BofA.

Sachin Jain - *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Sachin Jain, Bank of America. So just a couple of questions. So first on M&A, you referenced disciplined licensing in BD. So wondering if you could talk about size of deals you're thinking about within your diagnosis is a conclusion of a larger single deal if required on multiple small. Just trying to get a sense of in your early days, how it should change from Sanofi's recent BD strategy. And then areas of initial focus, you called out both rare in China. Is that fair for us to think about as the initial focus? Or could it be broader?

I just had a clarification to the prior answers. So Regeneron, you collapse, which is interesting given the litigation ongoing between the two companies on Dupixent on the rebate, which is in early stages. Does resolution of that influence the timing of any progress? And then on R&D, when you say moderate, can I just clarify, is that in line or could R&D grow faster than sales?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So let me start by your first question, which is size of the deals, and I will put François during one of our conversations today. So traditionally, Sanofi has been on smaller deals, bolt-ons to eventually increase innovation of buildups. I think our appetite for bigger deals is an option.

But obviously, this is something that will be subject to opportunity feasibility and really ticking the boxes of three pillars, our strategic fit, the science and the potential to deliver innovation and of course, our financial guardrails. I guess, today, we are open to eventually consider bigger deals.

Riyadh and China, not exclusively. We are looking at our disease area strategy. So forget about looking at this as immunology and inflammation. We are looking at the disease area level. So where are we strong? We are strong in dermatology, right? And respiratory. So anything that is going to help us -- and in rare, of course. Anything that is going to be helping us move faster and accelerate our mid and long-term growth will be an option that we can consider, right?

China is a priority for us. I mentioned that already. My own impression is that we have lost a bit of momentum in China. And now we have to catch up and benefit from the wave of innovation that is emerging in China, but we will do that in parallel. We will do that in parallel because our strategy in China may not be completely mirroring the strategy that we are going to have globally because the Chinese market can be served in many different ways.

On the Regeneron litigation, let me make only an initial comment. Our current focus is Dupixent, one. Two, Dupixent. Three, Dupixent. And of course, identifying opportunities to work better together, right? This is something that requires is a dynamic conversation. And of course, as being the commercial lead and then being the development need May, after many years, requires some small refinements and this is the focus that we have today. But if you specifically want anything on the litigation, Manuela, please?

Manuela Buxo - *Sanofi SA - Head of Specialty Care, Member of the Executive Committee*

Yeah. So just briefly, first of all, the litigation focuses on a narrow issue concerning information sharing. And as Belén said, the most important thing and the focus of the alliance is maximizing the opportunity with Dupixent, which we're already doing, as you can see in our Q2 results, continuing to do that.

And in the meantime, we're having really productive discussions, frequent discussions, as Belén has shared, and we will continue those discussions. And that's what we are really focusing on delivering on the business collectively as an alliance. I believe it's one of the most

successful alliances in the industry and then really continuing our productive conversations. This is what we're focusing on, and this is where we put our energy.

Olivier Charmeil - *Sanofi SA - Executive Vice President - General Medicines, Member of the Executive Committee*

And Sachin, just to complete -- to complement what Belén said earlier on BD and M&A. We need to address, obviously, the lessons and the learnings from our pipeline lately and the weaknesses that we have.

So we need to make our M&A and BD strategy evolve a little bit. So we talked, as Belén said, a few minutes ago in the part of essentially focusing on early-stage assets. We will continue working on that because we need them as well. But we will probably make it even a little bit more interest for net stage assets and potentially commercial assets.

It's not one single deal you talked about. It could be a different structure and where we need to adapt as well to is available but we are certainly BD and M&A will be a way to address the challenge that we are facing with our pipeline, even that the pipeline will not be able to address it with an immediate impact on our financials in the short term. It's less a matter of -- it's more a matter of relevance, as Belén said earlier, in terms of fit with our strategy in terms of scientific presence and financial returns. So we are not focusing on a given amount, for example, but more on the strategic scientific and financial relevance of what we do.

You asked a question about the R&D as well. Is it going to grow faster or in line with our sales in the short term anyway, given the challenges that we have in decision that we have made lately, it will grow to a moderate level of R&D, which means at a lower level than sales. But as we grow over time and as we gain confidence in our capabilities as well, it will certainly increase.

Operator

Pete Verdult, BNP Paribas. Peter, we don't hear you. Maybe we try the next one for now. (technical difficulty)

Peter Verdult - *Exane Bnp Paribas - Analyst*

Sorry, guys. User error, sorry. Peter Verdult here at BNP Paribas. Belén, welcome back.

Just two questions. Firstly, for you, Belén. Could you remind us how much of the EUR10 billion R&D budget is discovery versus development? And would there be any appetite perhaps from a strategic point of view to become more search and development going forward than research development at Sanofi? And also interested how you're thinking about immunology in light of the numerous pipeline failures and your ability to transact outside of the collaboration?

And then secondly and more quickly, just for François or Manuela, it's very rare that on Dupixent, there's a 10% miss from consensus -- between consensus and reported numbers. You've talked about the true-up. We can see volume growth is robust, but it does seem that the 10% to 15% positive impact from either price or channel mix? So maybe François, Manuela, whether could you just give us a bit more detail about what's going on there to sort of give us the bridge from volumes to the report growth?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Peter, I give you a high-level answer to the R&D budget. So the majority of the R&D budget is clinical development. Mike?

Michael Quigley - *Sanofi SA - Chief Scientific Officer and Global Head of Research*

Correct. Thanks, Pete, for the question. Belén, you're absolutely correct. That being said, I think there's an absolute commitment to research as a long-term pipeline sustainability and cornerstone of that effort that we have that's been relevant to Belén's statement and strategic review.

Another thing I'd add for the benefit is there's not a linear relation between spend and outcome. And so as we think about making the most use of the budget we have to deploy within R&D is critically right decisions go strategically and rigorous, as Bill mentioned earlier, around what we continue to progress versus what we make sure we dynamically allocate away from those medicines that aren't promising. So the key for that is really how we use the capital allocation within the R&D organization.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Pete, on the -- on your second question, my Immunology thoughts related to the pipeline failures. I don't think it has to do with Immunology, right? I mean we have significant capabilities in that area, context, advisers.

I think this goes back to what I said before, we need to be rigorous, right? When you make a decision to go from Phase 2 to Phase 3 and engage a significant and get ready to engage a significant amount of capital, you really need to challenge whether or not your data in Phase 2 are justifying the move to Phase 3, right? And you're going to start by dreaming on a target product profile that is not based on rigorous assumption.

So that's basically where we are going to change. And this is nobody's fault. From time to time, my feeling is that there has been a period in which making decisions on these topics, on these critical topics for the company, we're not very clearly place where those belong, right? So I am expecting the scientists to make scientific decisions. And I am expecting the scientist to make a judgment call whether the data that we have in Phase 2, and I am using this as an example, qualify the asset to go to Phase 3.

So scientific rigor, diligence, focus on fact-based decision-making. I repeat, this is where I believe may have contributed or contributed to some of the studies' setbacks that we have seen lately and we are going to pay a very significant attention to the way we make these decisions and where do we make these decisions.

Olivier Charmeil - *Sanofi SA - Executive Vice President - General Medicines, Member of the Executive Committee*

And Pete, on the question on Dupixent. So first of all, we don't disclose the breakdown between volume and price. But the growth of Dupixent, which is really, really strong in Q2 as it has been in the case since the beginning of the year, by the way, which is remarkable because we are nine years after the launch, is essentially volume led, so this is a very vast majority of the growth.

As we said, there was a little bit of tailwind in the quarter due to some pricing adjustment, the traditional gross to net, which did help a bit in the quarter, which is not something that we will see later in the year. But once again, I mean, the growth was largely volume led, which is reflecting what has been said earlier as well, which is the penetration of biologics across indication is review.

Maybe Manuela, you want to give some additional color on that.

Manuela Buxo - *Sanofi SA - Head of Specialty Care, Member of the Executive Committee*

And just a little bit of a brief add to what François has already said, really driven by underlying demand. And remember, Pete, that when you look at TRx figures from IQVIA, for example, that script data that doesn't fully reflect total demand. The total demand is higher than the script data. And yes, there's fluctuation in the GTA. We have seen -- we have actually focused also on operational effectiveness in the area of GTN to really make sure that -- all of our actions have the right intention get to patients in the right way.

That has also contributed and then the one-off GTN topic that François mentioned. But it was really the vast majority was demand driven, and we expect that demand-driven growth to continue at a more moderate growth rate for the second half of the year.

Operator

Luisa Hector, Berenberg.

Luisa Hector - *Joh Berenberg Gossler & Co KG - Analyst*

Welcome, Belén. I have a couple of questions. Another one on capital allocation. Could you confirm whether the lack of sort of conclusion on the Regeneron collaboration is a barrier to moving forward on any business development and M&A.

And then on the 2030, the various components of guidance there, just your levels of confidence, in particular, the pharma launch is now at EUR10 billion. Could you tell us anything more on the split there? It sounds like that is majority in-market products, but for any pipeline contribution? What is the average risk adjustment applied? And any color on the profitability of that EUR10 billion versus the prior guidance?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you, Luisa, I'm going to take the first question, which is very straightforward to answer. So we have, at this time, no barriers to related to Regeneron to moving forward on M&A. On the pharma launches, François?

Francois-Xavier Roger - *Sanofi SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee*

Yeah. On the pharma launches is the scope that we disclosed does not include vaccines, by the way, but if we look at it because we don't duplicate, we have it as a separate guidance. If we look at it on the scope of the new launches, we will probably reach EUR5.2 billion, EUR5.3 billion already in the full year 2026, you can see it with what we have achieved already in H1.

If you look at the like-for-like growth, which means restating for our products like Ayvakit last year. We were growing in H1 at about 27%. To get to the EUR10 billion by 2030, we need to move to grow on average CAGR by 15%, given that we are on the trend of 27% today.

I'm not worried at all about our capacity to reach the EUR10 billion and we are just talking of -- by the way, the market -- most -- all of these products are already in the market. So it's essentially a commercial risk. So I'm not worried about it.

You asked a question on the profitability of this business. it is already positive in terms of BI, which is quite remarkable due to the fact that we are really in an investment position behind these products to support the growth, but they are already profitable and attractive from a profitability point of view as well.

Operator

Graham Parry, Citi.

Graham Parry - *Citi Infrastructure Investments LLC - Analyst*

So just going back to the Regeneron Alliance and BD. When you're looking to acquire immunology assets, can you just talk us through the decision-making process between putting an asset into the alliance versus going into the loan? And in particular, if you were to go with the

loan, can you talk about the dynamics of sales force allocation between the alliance and Sanofi standalone and would that be a barrier to being able to do Immunology assets alone?

And then secondly, on R&D, Sanofi's been through many iterations of attempting to improve the pipeline. This is, I think, the third CEO sort of my coverage seen come in with a new plan that sounds suspiciously like the old plan. So perhaps could you just talk us through what you think is systemically wrong in the organization and if and how quickly that can change?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So let me reply very briefly to question number one. So yes, when we go for BD, eventually M&A is -- and of course, our internal respective internal pipelines we consider whether the asset can be better performing within the alliance.

Manuela, do you want to add?

Manuela Buxo - *Sanofi SA - Head of Specialty Care, Member of the Executive Committee*

I would just add, Graham, that as Belén said earlier, immunology is a large space. And even dermatology and respiratory, we are looking at opportunities within the alliance. We're looking at opportunities outside of the alliance.

And if we identify an opportunity outside of the alliance, given the commercial capabilities we have, we are confident that we can build the right structure and then launch these products as we are already doing successfully in that context. So both are options that we are currently actively reviewing as part of the strategic review that's ongoing.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So Graham, I am not exactly sure what you mean the pipeline plan sounds old. I mean I assume that you mean that the R&D productivity issues of Sanofi have gone on for quite a while, right? And be totally frank, we are looking at this as if this -- we are looking at this to take potential learnings from the past. But what is driving us is actually to improve our R&D productivity. And I have repeatedly mentioned, what are the focus areas in which we are going to emphasize.

Frequently, as you know, the R&D turning around R&D productivity takes a bit of time. So we are absolutely convinced that while we reignite our R&D engine, we will have to also accelerate our BD plans and M&A, as I mentioned before.

I don't think there is a systemically wrong issue in the organization. I think you have to pull the levers, right, be consistent and never complacent and managing risk and the risk profile of the pipeline is going to be something that will be very much at the top of our priorities. Not always aiming for first-in-class and best-in-class, but rather differentiated innovation that can help us move forward.

Operator

Simon Baker, Redburn.

Simon Baker - *Redburn Partners LLP - Analyst*

Welcome back, Belén. It really follows on from Graham's question, and you alluded to it in your response, that you're targeting a fast-track R&D transformation. And as you said, transforming R&D is not particularly quick. The fastest I can think of in my time is probably AstraZeneca, which was four to five years. So what sort of time frame would you put on this? I'm assuming that Paulo's arrival is not a year zero event. There was a lot of restructuring under Houman's. So where are we in that transformation journey?

And then a second quick question. All of this, of course, is focused around the loss of exclusivity of Dupixent. And one of the simplest ways of dealing with that is to move the LOE out. Now we know you have a lot of IP beyond March '31 out to 2045, I think. I'd be interested to get your early perspectives on what you think as a fresh pair of eyes on this is what you think the strength of the IP beyond '31 is for Dupixent. And therefore, the more realistic possibilities on when we will face biosimilar competition for that asset?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you, Simon. Look, I can only repeat what I have said before. My feeling is that we have a good understanding of the science and some of the setbacks not a significant number of setbacks are operational risk. Fixing operations is a bit faster than cut recruiting capability -- expert capabilities to the organization. So as Mike mentioned, our research efforts are already paying back.

So I am not saying that this is going to be passed, right? But starting by managing operational risk actually would be a variable start. And this is where we are going to do by prioritizing acting and deciding on scientific prefer.

Having the right or the decisions at the right level and managing our clinical operations entirely from an end-to-end perspective, from a study design to conclusion of the trial. And once again, we are not counting that this is going to be fast, so media and M&A together and in parallel to the R&D transformation.

On the LOE of Dupi, I want to hand it over to Roy.

Roy Papatheodorou - *Sanofi SA - Executive Vice President, General Counsel, Member of the Executive Committee*

Thanks, Simon. First of all, you mentioned patents going to '45. Actually, this quarter, we can say it's patent expiration dates going up to 2046. We have a very strong patent portfolio around the many years of R&D, multiple innovations, indications to date. And of course, we intend to be vigorously defending.

You will appreciate, it's too early to speculate on specific dates for biosimilar entry. I think what I can say based on our experience is that we do not expect. We do expect Dupixent to be protected beyond March 2031, how long were which patterns will hold very early days to be able to speculate, even the typical pattern fights comment be able to give you more details of what is being challenged and keep up the speed of us. But rest assured that we have done our best to make sure that the years of innovation are being protected and we intend to really fight it out.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

What I can tell you, Simon, is that we are taking a base case that is associated to the patent to the loss of the product pattern.

Operator

David Risinger, Leerink.

David Risinger - *Leerink Partners LLC - Analyst*

And congratulations, Belén, in on your new role, and thank you for your comments today. So beyond Dupixent target increases longer term, could you please discuss what investors may be underappreciating about Sanofi's future prospects? And then just turning to R&D. There have been a lot of questions. It seems to me that you're simply focused on improving judgments and empowering better decision-making from the ground up. Is that the right way to interpret your comments today?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you, David. So first of all, I believe during my conversation with investors -- what I learned is that perhaps -- we have, for a period of time, over promise and under deliver. That's the bottom line. And this basically keep our credibility tremendously.

And despite the results of today for me as a newcomer is really shocking that the strong performance of this company is really not recognized by investors. And that is the only reason that I can fine and that I have been able to elucidate during my conversations with investors. Any other comments in this respect?

Olivier Charmeil - *Sanofi SA - Executive Vice President - General Medicines, Member of the Executive Committee*

Maybe let me add something then that if you look at value in our industry, it's actually driven by to others. One of them is growth. Belén just said it. I mean, we take the box fully on that because we have one of the highest level of growth in our industry. The other one is pipeline, which, I mean, we know and we met disclosure lately on our pipeline.

We are aware of the challenges there as well. I think that there is an understanding as well that the market is waiting for not only talks and but actions, and this is what we are working upon. And I think that we are all working in this organization in order to not only talk, but execute and act, which we will see certainly in the coming months.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

On the R&D transformation, yes, I think your interpretation is right, David. Amongst other things, improving decision-making. I gave an example to Peter Verdult on transition between Phase 2 and Phase 3, which is a very critical decision. So you are absolutely right that we want to improve decision-making based on facts, scientific rigor and clear accountability at the science level and at the commercial level.

Operator

Seamus Fernandez, Guggenheim.

Seamus Fernandez - *Guggenheim Securities LLC - Equity Analyst*

Congrats, Belén, on the coming-out event here. I guess the two questions from my side. You mentioned -- two areas that haven't quite been a major focus of the prior sort of management, rare disease. And then also, I think your comments on China are interesting. So I just wanted to clarify two things.

First, as it relates to rare disease, is this an area that you see for accelerated business development in the context of Sanofi really leveraging the Genzyme history to a greater degree. We've seen very strong development across the board in rare metabolic disorders across the industry, and it's not an area where Sanofi has really participated in some of those new growth opportunities from our perspective. AAT is a very interesting incremental opportunity, but just interested to understand how you're thinking about staying concentrated in those areas or perhaps broadening?

And then on China, I just wanted to clarify, are you specifically talking about accessing the innovation in China? It is something that the industry is chasing quite aggressively, and we're hearing that the bids have maybe gone beyond what would be characterized as value opportunities in the industry? Or are you talking about the market itself and the opportunity to reinvest in the market to drive growth?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So rare, yes. In rare, I believe we have an opportunity, first because the scope is broad. So we are not going to focus exclusively on rare genetic disorders. We are going to further expand to leverage our capabilities and our podium position because we have a top two or three position in the rare disease market. And I believe this presents an opportunity and is giving us and given our business a significant resilience, I think on China is both.

The market is attractive simply because the population is extremely big. So even if the pricing environment is very different than in other countries, the volumes that you can draw from China specific indications or diseases is attractive, right? So that is one element of it. And obviously, tapping into partnering with companies that are now highly innovative and intend to out license that innovation for global commercialization is also an area which we are going to be doubling down.

Operator

Michael Leuchten, Jefferies.

Michael Leuchten - *Jefferies LLC - Analyst*

Two questions, please, around the ExCom changes, Belén. One obviously, you're kind of an outsider with prior experience, and you've brought in Paulo as an outsider, but the rest of the ExCom change is really internal candidates. Can you talk about sort of pluses and minuses of not having more new blood in that ExCom to really affect the change. You made a very strong point about this being a big drop and requiring really drastic changes?

And then a similar question, not so, but a question to François on your role now also including BD. What changes does that make for you? Does that just increase the speed of action you can perform at? Does it increase flexibility? Just talk about the sort of options you have now that previously were not open to you?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Michael, thank you for your questions. So on the ComEx changes, look, I go externally when I believe that is necessary to search for a more transformative position, right? And this is what we have done in R&D. However, when you look at the ComEx, there are three new members, two -- the three of them from our internal talent pipeline. Manuela, who came a bit earlier than I joined, but she has been in the job for months and came from our internal talent pool.

Jamie, who was groomed by Roy and was absolutely ready to take the job and a leader in vaccines who is now going to take general medicine, and that makes a lot of sense because general medicine is a Sanofi specific business.

So over the years, I have learned that you always take less risk when you go -- when you source from internal talent and going outside, but having the optimal blend between external eye and external expertise and internal talent is a very good option, and this is what I have tried to do with ComEx. I mean there is a significant percentage of the comments. So now we are eight. Three are new ComEx members. So it's a significant percentage with new eyes. And with this, I hand it over of new blood, as you call it.

Francois-Xavier Roger - *Sanofi SA - Chief Financial Officer, Executive Vice President, Member of the Executive Committee*

So on my call, on BD, first and foremost, I'm what the responsibility that comes with it. I think second, we have been very successful in BD and in M&A, just to give you some perspective. Globally, between BD and M&A, we invested EUR47 billion over the last eight years. And we have lost EUR7 billion -- sorry, for the EUR7 billion. But if we have not lost anything, we would not probably have taken the right level of risk.

But we have created the substantial value historically with the remaining EUR40 billion. And I'm sure we'll have the occasion to discuss a little bit more in details what I'm just sharing with you. So we have a good track core both in BD and M&A. I'm honored as well to take over this responsibility because we know that, as we discussed earlier, BDM&A is part of the challenge that we have in order to address some of the weakness that we have within the organization.

So it will allow the fact that we have it under one roof will allow certainly a better coordination, although it existed before. But I insist upon as well that BD is not necessarily naturally within finance in any organization in pharma, but it can be successful only with a very close coordination and very cross proximity to R&D. This will be my main priority is to make sure that even if it sits within my scope of responsibility, and especially for BD, less obviously for M&A, it has to -- it will work only if we are super, super close to the R&D organization.

Operator

Richard Vosser, JPMorgan.

Richard Vosser - *JPMorgan Chase & Co - Analyst*

Just a couple, please. Belén, you've cut a few pipeline programs. Should we think that the review is now complete? Or should we think about further discontinuations when Paulo joins? And on that remaining pipeline, there are a couple of Phase 3 assets that read out in the coming 12 months for riliprubart part, apologies for the pronunciation, never going to get it.

There's some discussion around the chances of success on both. So on frexalimab, there's been discussion on the primary endpoint in Phase 3 and the ability to beat Aubagio. Just interested in your thoughts and Michael's thoughts there? And then on riliprubart part, the MOBILIZE trial failed, obviously. What are the learnings for that for the VITALIZE trial? Are you comfortable that the patient population enrolled will be responsive to the drug?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Thank you, Richard. So the pipeline review is ongoing. So I'm not excluding that we continue some additional assets. But we don't have a target number to discontinue, right? We are going to continue to be operating on the basis of scientific merits and risk, as I mentioned, and potential and some other elements.

So at the end, after a thorough review of our pipeline, we will be once again concentrating our resources, and this is the bottom line. We will be concentrating our resources in those with highest scientific merit, highest unmet medical need and highest potential. On frexa, do you want to comment, Mike?

Michael Quigley - *Sanofi SA - Chief Scientific Officer and Global Head of Research*

Thank you for the question, Richard. On frexa, in the context of the Phase 3, we're on track to read out RMS in 2027 in SPMS in 2028. As you referenced, we've been actively working with global regulators to refine our statistical analysis plan really with an eye to testing realistic endpoints of interest for patients given the recent performance of comparators and RMS studies.

And rest assured that, that will continue to be a focus. The primary doesn't change in the context of anal relapse rates, but we're focused also on key secondary endpoints, including a six-month disability progression in the context of the frexalimab readouts that you'll see.

With respect to mobilize versus VITALIZE, that's a key question. What I'd say and what we put out was that the IDMC recommended not moving forward in the context of mobilize study because you're unlikely to meet the primary endpoint. What I can say is that the two patient

populations between the two studies are very different. So in a refractory patient population in the MOBILIZE study, very hard to treat. These patients don't have, unfortunately, anything available to them.

I contrast that to the VITALIZE study, either patients that are on IVIG but still are progressing despite a treatment paradigm. And so that comparison versus IgG in that kitchen population is where we're looking at it VITALIZE. Importantly, what I'd also add is that the IDMC looked also at VITALIZE and recommended progressing VITALIZE forward. And so we have hope and we're on track to continue to read that out in the latter half of 2026.

Operator

Matthew Weston, UBS.

Matthew Weston - *UBS AG - Analyst*

Belén, a warm welcome back. My first question is for Manuela, and it comes back to Pete's question on DP gross to net. Can I push you on your operational effectiveness comment? Has the alliance changed its policy on 340B claims for to reduce access to heavily discounted drug. And I ask that because that's the only thing I can think of that's the really sign improvement in GTN over the first half of the year.

And I guess if that is the case, why won't that trend continue? And why shouldn't DP be able to deliver stronger than is suggested by the 10% total revenue guide that we've increased to. And then my second question is about the long-term guidance for vaccines. You bought Dynavax, but you cut the 2030 vaccine guide by 10% to EUR9 billion. I know that some of that -- but is it because you're meaningfully more cautious on Beyfortus? Or is it the flu franchise? Or is it something else?

Manuela Buxo - *Sanofi SA - Head of Specialty Care, Member of the Executive Committee*

Yes. So thank you, Matt, for that question. So when we talk about operational improvements, operational effectiveness, fully agree that it is linked to 340B partially. So as I said, is a portion that is recurring. There's a portion that is nonrecurring.

The nonrecurring portion a couple of hundred million. The recurring portion exactly, as you say, is linked to us really looking at how do we ensure patient benefits that reached intended recipients. 340B, enhanced 340B control is a part of that. It's not the only part, but it's a part of that -- a large part of it. And there, we've been thanks to the team successful. And you're right, some of that will continue to occur also in the second half.

The reason why we're talking about a more moderate growth in the second half versus the first half is simply the second half last year was a higher comparison. So we now have a higher base that you're comparing us to. And we are also annualizing some of the indication launches and those two contribute to a slight moderation of that growth versus the first half of this year.

Thomas Triomphe - *Sanofi SA - Executive Vice President - Vaccines, Member of the Executive Committee*

Regarding the second question, Thomas speaking. So thanks for the questions. For the 2030 vaccines ambition, you've noticed the change. Indeed, when you look at the trends between the two numbers, and you remember, first of all, that this ambition was put in 2023, if I recall correctly. So way before the change of administration.

When we look at the drivers of this, this EUR1 billion difference for 2030 is coming on half of it on a US exchange rate, so US to euro, it's pure financial extent rate. The second half is driven mostly by US VC, so US VCI evolution, which has turned out to be weaker than expected following the new US administration. And indeed, it's mostly into the respiratory area.

So classical flu and RSV. But also, you've seen that CDC and other revenues have shown that there has been a decrease on the vaccination coverage rate of US pediatric vaccines. So if you put both together, that explains the difference. It doesn't change anything on our long-term ambition for vaccines.

The fundamentals are very strong. in terms of growing elderly population, our focus on the pipeline on the elderly segment. But indeed, we wanted to recalibrate what has changed with the latest both exchange rate and US overall, I would say, obviously.

Operator

Florent Cespedes, ODDO.

Florent Cespedes - *Oddo BHF SCA - Analyst*

Two quick ones, please. First, for Belén, you announced that you have discontinued some of the projects, some products in the pipeline. I understand that the portfolio reduced ongoing, but do you have some projects remain in the pipeline where you have strong confidence and would be my first question. My second question for Thomas. On China, maybe could you elaborate a bit on your strategy there? And how do you see the dynamic of this market going forward, which is a little bit soft details?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

So listen, of course, as we prioritize our assets, confronting stage of development versus potential, understanding of the biology versus base of development, et cetera, et cetera. You get a picture that classifies those assets into most promising less promising and in the middle of it, right? But I think it's too soon to tell you where are we going to land with a strategic review? I think my -- as highlighted some of the successes on the quarter and also has spoken a bit of the outlook towards next year. So I will remain very prudent until I see data, more data.

And obviously, once we have those solid data that we need to see. We will come back to you to tell you. And as I mentioned during my introductory remarks, we are aiming to give you some kind of perspective in the coming quarters. And obviously, before the year-end, we are expecting to give you a more -- a broader perspective on where we on the strategy and the pipeline. On China, the question for Thomas.

Thomas Triomphe - *Sanofi SA - Executive Vice President - Vaccines, Member of the Executive Committee*

To say a few words. Thanks, Laurent. Don't expect today a big new review of a new strategy for China, as I'm starting September 1. However, I think a couple of things I'd like to highlight. As previously mentioned by Belén.

Obviously, China has revealed to be over the past few years, an extraordinary source of innovation with the speed and the ecosystem associated to it being really, really interesting. We want to double down on our efforts there. We started some and we want to accelerate on this. But indeed, alternatively, if you look also at the China local pharmaceutical marketplace, it's also a very interesting marketplace.

First and foremost, because it's a very competitive one. And I'm pretty sure we can learn a lot of things from China that will also be very important in the long term for this organizer moving forward. So excited by both aspects. What I want to highlight, of course, is that this can only be done in extremely close collaboration first with R&D when it comes to innovation.

So extremely looking forward to work further with Paulo and Mike on this journey. And of course, for the competitiveness of the overall market, it's going to be a transversal effort with all the ExCom to be able in China to be as competitive as we can.

Operator

James Gordon, Barclays.

James Gordon - *Barclays Services Corp - Equity Analyst*

Two questions, please. One was on M&A and BD. When you're thinking about which therapy areas to focus on, do you need to have existing strength in the area? So would you still think about doing a deal that in somewhere like oncology where you don't have a big business on urology or it has to be an area where you've got significant scale? And if you're not going to acquire more in those areas, might you even say, hey, we're not going to do those areas and we'll even divest the assets?

And on M&A, how much urgency is there to complete a meaningful deal this year? Would you like to have a deal that you could talk to us about by the end of the year? Or might we need to be a bit more patient?

The second question was just about spend. So we've heard that you think you might need to do a bit more R&D. But is there any way that you might not need to spend quite so much. So are you looking to reallocate as if you might be able to take some spend, save from SG&A and reallocate it to R&D or not. So is there an opportunity there?

And then just squeezing in the clarification, please. On the Regeneron partnership, is it just about communication and trust or could you -- are you actually looking at the structure of the partnership at all? Is that off the table? Or is that also under consideration?

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Let me start with the Regeneron question. So as I mentioned, it's a combination of looking at options to eventually expand the alliance with assets from both sides, right? And in parallel, looking at potential improvements to the collaboration to be more agile and to bring more transparency to the way we operate.

And of course, as for any other partnership, as I mentioned before, an ongoing development of trust. So this is exactly what I have repeatedly said during the call of today. Regeneron is of state importance to us. And therefore, we will continue the already initiated conversations to be able to land what is best for both companies.

On M&A, to be honest, it's a matter of opportunity, but you can count that we will -- it will be a combination of a strategic fit. So we will likely focus on our pillars on our main pillars on our core pillars. And BD is directly related to our R&D strategy and focus. So we may, after combine M&A with BD. BD to support platforms and research whenever it's more later stage, it will be complementing what we can generate inside.

With those businesses that may not become at the end, a priority growth platform for the company, we will have to evaluate options, and this is not rocket science. It can be partnering. It can be offering those business to other companies. So any potential option that will create value for our shareholders. Reallocation of spend to R&D?

Olivier Charmeil - *Sanofi SA - Executive Vice President - General Medicines, Member of the Executive Committee*

Yes, I can take that one, James. But first, I confirm there is no urgency -- dramatic urgency in terms of the M&A. We are not driven by timing objective were driven by returns and contribution to growth. And the same applies to reallocation of resources and resource allocation.

Obviously, as we said earlier, there might be a little bit of resources available, for example, is a program that we have decided to terminate. We don't need necessarily to the reason rule saying that we have to redistribute that or reallocate it to R&D.

Our choices in terms of spend on -- I would rather talk of investment rather than spend are driven by contribution to growth and contribution to return. So if there is a better return on the commercial side of things, what we will do.

So we don't necessarily -- we don't manage fixed budget within a certain category of investments. And let me just give you an example. A couple of years ago, we were still investing a lot, for example, on the commercial side behind Gen Med, but these products are mature. We have decided to reallocate most of it behind growth assets essentially within spec care and starting with Dupixent, and you saw what it means today. You saw it was impressive, almost 18% growth in Q2.

So once again, this is driven our choices on cost allocation and investment allocation are driven by contribution to growth and returns.

Belen Garijo - *Sanofi SA - Chief Executive Officer, Member of the Executive Committee, Director*

Okay. So this was our last question. I wanted to thank everybody for your interest in Sanofi. And I look forward to continue the very interesting conversation that we have initiated today. Thank you very much.
