LSEG STREETEVENTS

EDITED TRANSCRIPT

SASY.PA - Q3 2026 Sanofi SA Earnings Call

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PRESENTATION

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

Welcome to the third-quarter 2026 results and strategy updates for investors and analysts. Slides can be found on sanofi.com. Please turn to slide number 2.

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'll make comments on our performance using constant exchange rates and other non-IFRS measures. Numbers used are in millions of euros and for the third quarter of 2026 unless stated otherwise.

Turning to our agenda on slide number 3. Our CEO, Belén, will provide an update on third-quarter progress and strategy followed by the business results. Our CFO, François, will review our financials for the quarter, followed by our new Head of R&D, Paulo, who will share his

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first reflections and thoughts over the past two months and also cover the pipeline. For the Q&A, we have the support of Manuela and two times Thomas to cover our global businesses as well as Jamie, our new General Counsel.

(Event Instructions) Now, I hand you over to Belén.

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

Thank you, Thomas. Hello, everyone, and thank you so much for joining us today. First of all, a very warm welcome to Paulo Fontoura, our new Head of R&D, who is eager to share initial reflections and priorities later on this call. I'm now on slide number 5, to start with the progress of our strategy and to signal the progress and execution during the quarter.

When we last connected in July, we set out a number of priorities. Today, I can confirm we have made meaningful progress with the support of our Board. After completing a rigorous diagnosis of our starting point, we are progressing well towards defining our roadmap for the future. We have confirmed our commitment to three focus areas: Immunology, Rare Diseases, and Vaccines, where we are highly competitive, we see robust growth opportunities, as well as the potential for differentiation.

The new leadership team, including R&D, is driving sharper decision-making, including through new governments. Together, we made already our first bold choices regarding pipeline optimization, deciding to discontinue amlitelimab and itepekimab. In parallel, we continue to execute on our simplification agenda. The partnership with the Cheplapharm that we announced last month allow us to exit a growth dilutive business while ensuring these mature medicines will continue to reach patients.

Planning for Dupixent's loss of exclusivity is our top priority, and we have taken the first step in this direction. We expanded our alliance with Regeneron and hence gained access to four new immunology compounds. This is simply the start and we will also turn to BD and M&A to secure growth. More to come on this later.

While we continue to advance our transformation agenda, we stay very focused on maximizing our performance as illustrated by the strong quarter where we deliver both robust commercial and financial results. Moving forward, our journey will be catalyzed by a culture of greater accountability, increasing discipline, and rigorous execution, as I already mentioned during our Q2 call.

On slide number 6 now. As previously said, our top priority is to secure growth through and beyond Dupixent's LOE. We will build on our strengths, notably commercial execution, create value through BD and M&A, leveraging our strong balance sheet and financial resources, and François will share more details on these points later on. Between now and 2013, we expect Dupixent's sustained leadership. The momentum of our recently launched medicines and our resilient Vaccine business to continue to expand our revenue base.

While we reset R&D, external innovation will, in parallel, play a very significant role. We intend to leverage business development and M&A including late stage and commercial medicines with a center and shared focus on our three therapeutic areas. Disciplined bolt-on acquisitions will continue to further support the development of our early-stage pipeline.

And additionally, we plan to source innovation globally, including from China, which, as you know, is a thriving hub for scientific advancement. Beyond 2030, we expect a stronger and more productive R&D engine to become a larger source of innovation than today, and this will complement external opportunities and help propel our growth trajectory.

On slide number 7, I shared with you in Q2 that our alliance with Regeneron was a strategic priority for me and the leadership team. Since then, we have delivered on our objective to define the next chapter of this partnership in a matter of a few weeks. This relationship has already been recognized as one of the strongest collaboration and success stories in the pharma industry with Dupixent. And that is the foundation from which we are building for the future.

Benefits from Sanofi, as you see on the slide, extend well beyond the next three years. This is, no doubt, a win-win where both companies are equally incentivized to succeed with focused investment and payouts linked to milestones driving disciplined value creation. The

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long-acting anti-IL-13 in atopic dermatitis strengthens our leadership in the large and growing aging market, capitalizing on physician and patient preference for sustained efficacy and safety with less frequent dosing.

Importantly, we aim to launch this medicine ahead of Dupixent biosimilars. The ability to leverage our commercial infrastructure grounded on specialty reach, differentiated payer access, and world-class patient services is expected to drive faster uptake. The expanded alliance shows our ability to execute swiftly on our priorities, driven by transparent discussions and building trust, as shown by the settlement of previous litigations.

In summary, this transaction is an important first step to replenishing our early-stage pipeline. But beyond this alliance with Regeneron, we will continue to build on our Immunology leadership, both through external and internal innovation to secure sustainable growth well into the next decade. And this includes other important partnerships, for example, the one with Teva for duvakitug.

Let me now summarize how we are preparing for the next decade on slide number 8. Between 2026 and 2030, our strategy will be focused on disease areas within Immunology, Rare Diseases, and Vaccines. We will continue to drive profitable growth through strong commercial execution and cost discipline, alongside robust cash flow generation to fund business development and M&A transactions in particular, with a focus on later stage and/or commercial opportunities.

In parallel, our R&D transformation is already underway with the aim of enhancing our pipeline and our R&D productivity. Beyond 2030, we aim to further capitalize on internal pipeline contributions to diversify our sources of growth. We expect total revenue at group level to be impacted only moderately by Dupixent's LOE, with our focus being on preserving earnings and cash flow. Once this is achieved, we will focus on accelerating earnings growth.

As our progress in Q2 shows, we are fully committed to executing on our plan and moving with the necessary sense of urgency. We intend to keep moving at the same pace and look forward to providing greater granularity on our priorities and mid- to long-term roadmap during a strategic update before the year end.

Now turning to the Q3 business performance on slide number 10. Q3 was another quarter of strong growth. Our total sales reached EUR14.4 billion, up 14.3% versus last year. Our pharma launches grew over 31%, driven mainly by ALTUVIIIO, Ayvakit, and Rezurock. Vaccine sales were impacted by respiratory vaccines facing this quarter. The increase in other medicines was driven by the diabetes portfolio, partially offset by divestments and legacy medicines.

Dupixent, again, delivered strong performance, surpassing EUR5 billion for the second consecutive quarter with the growth coming primarily from increasing demand. Overall, this quarter reflected the strength of our core growth drivers. Moving on to slide number 11, the momentum of our portfolio of newly launched medicines and Vaccines is providing a meaningful contribution already to our top line.

In Q3, we welcomed a new medicine into this portfolio, Anxu, rovadicitinib, the first ROCK/JAK dual-acting inhibitor for patients with myelofibrosis in China. Sales of new launches reached approximately EUR2.2 billion in Q3, a growth of 19.2%. And this portfolio now accounts for roughly 15% of total company sales, showing the ongoing diversification of our business growth.

Turning to Immunology on slide number 12, Dupixent sales reached EUR5.7 billion in the quarter, and more than 1.5 million patients are currently under treatment globally. US growth was driven by strong demand, as I already mentioned, and by an extended benefit from operational improvement, which resulted in favorable gross-to-net price adjustments. In the US, Dupixent remains the number one prescribed biologic among key prescriber groups.

Outside the US, strong growth was driven primarily by demand from market expansion across major indications in Germany, France, in Japan, Canada, and China. On slide number 13, we see Rare Diseases, and our Rare Disease portfolio reached EUR1.9 billion in sales, up by 12.6%. Mast cell and other performance was driven by Ayvakit, with increasing number of patients starting therapy. This category also includes three new medicines, Myqorzo, Anxu, and Redemplo, now available to Chinese patients.

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Rare blood performance was supported by ALTUVIIIO's continued growth momentum, complemented by recently-launched medicines, Wayrilz, Cablivi, and Qfitlia. Lastly, sales from medicines for lysosomal storage disorders remained resilient despite short-term supply constraints for some of our Pompe medicines. Overall, Rare Diseases delivered another strong quarter of growth.

Moving to Vaccines on slide number 14, remember that at Q2, we have indicated the potential for a low- to mid-teens sales decline in Q3, reflecting the phasing of our respiratory vaccines. While flu was down as expected, the franchise declined by 7% versus Q3 of last year, which is better than indicated in Q2, thanks to more favorable buying patterns than anticipated for Beyfortus late in the quarter.

On PPH, Heplisav-B grew by 60% on a pro forma basis to EUR125 million, well ahead of our initial acquisition plans. Overall, the franchise of Vaccines demonstrated strong resilience in a dynamic market environment. And for the full year, we expect Vaccine sales to be down by a low-single-digit percentage.

And with this, I'm now going to hand it over to François, our CFO, who will take you through our financials in more detail.

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 16, net sales grew strongly again in Q3, up by 14% to EUR14.4 billion. Dupixent continued to see strong growth, driven by demand and by favorable growth to net adjustments. We have also made operational improvements last quarter that have had a positive impact on pricing, for example, controlling the inappropriate use of 340B rebates in the US, and enhancing our gross-to-net provision management with data-driven tools.

Our pharma launches maintained solid momentum and Vaccines were impacted by an unfavorable sales phasing in Q3 versus last year. If you exclude the items that are more one-off in nature, the underlying group sales growth during the quarter is estimated at around 12% in Q3. Gross margin improved by 2.1 percentage points. This was driven by a favorable product mix as well as by the pricing impact highlighted earlier.

Operating expenses were basically stable as OpEx of acquired businesses were almost fully factored into our cost base last year, and more importantly, as we execute very strongly our cost discipline programs, including R&D prioritization. BOI increased by 19.7% in Q3. BOI margin expanded by 1.9 percentage points, driven by operating leverage.

This was partly offset by higher profit sharing with Regeneron, reflecting Dupixent's strong growth and our Q3 BOI was also impacted by the end of the Regeneron development cost reimbursement that took place at the end of Q2. Overall, business EPS grew by 19.6%, delivering profitable growth once again this quarter.

Turning to business dynamics on slide 17, as Belén highlighted, we expect Vaccine sales growth to decrease by low-single digit in 2026. We also expect other operating income and expenses to increase in Q4 versus the prior year, driven by the net impact of two opposite factors. On the one hand, Regeneron profit sharing has steadily increased, reflecting Dupixent's strong growth, and in addition, the reimbursement of the Regeneron development balance ended in Q2, resulting in a BOI headwind of about EUR500 million in H2 2026, evenly distributed between Q3 and Q4.

On the other hand, capital gains for the full-year 2026 are now expected to be lower this year at around EUR250 million, with most of it already booked to date. The end of the R&D reimbursement by Regeneron will be fully offset by the increase of Amvuttra royalties for the full-year 2026.

We are upgrading our 2026 guidance to reflect the full business momentum to date. We now expect sales to grow at a low-teens percentage, which usually means a range of 13% to 15%, and we expect EPS -- business EPS to grow at a mid-teen percentage, which usually means between 15% and 17%. Now, a quick word on 2027. While I do not intend to provide the formal guidance today, it's too early, I would like to flag a few items for early consideration.

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In previous years, our sales growth has been driven by demand with a slightly negative price component. This year, sales growth is also driven mainly by demand, but as highlighted before, we also experienced several positive price effects. Some of these are creating a new price base, while others are one-offs. While we expect our growth to be driven by demand again next year, we also expect pricing to return to its historical pattern in 2027, which means a slightly negative pricing contribution to our global sales growth.

As announced earlier this year, we are continuing to actively manage our legacy portfolio, as evidenced by some business contribution and asset contribution to Cheplapharm, and as evidenced by the sale of Medley, our generic business in Brazil. Both transactions will reduce our sales next year by around EUR1.3 billion, but they allow us to focus on science and to exit margin-dilutive businesses.

Turning to slide 18, which echoes the strategic priorities Belén outlined earlier, we have a very strong cash flow generation, which enables us for disciplined capital allocation, including BD and M&A. We expect industry-leading growth until 2030, driven by continued momentum for Dupixent, new launches in Vaccines alongside our resilient base business. We are accelerating profitable growth with steady gross margin expansion as well as continued operational excellence and strict cost discipline.

Lastly, our strong balance sheet and low leverage allow us to access external financing for BD and M&A, while retaining a strong investment-grade credit rating. We confirm our commitment to our dividend policy, as reflected with 31 consecutive years of dividend increases in absolute value in euro.

I now hand over to Paulo, our new Head of R&D, who will share the latest development of our pipeline.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Thank you, François, and hello, everyone. I am delighted to join Sanofi at this pivotal moment as we tackle the industry-wide challenge of sustaining R&D productivity. Tackling this problem requires addressing multiple interconnected factor, a bit like treating a complex chronic disease. R&D is really no different from that. There's no one simple solution. Success depends not only on strong science and individual capabilities, but on how well we connect them, make sound decisions, and align around shared goals.

We are building on our strengths, deepening collaboration. We can create a more integrated, agile R&D organization that translates scientific innovation into meaningful benefits for patients. On slide 20, let me share some initial reflections from my first eight weeks. In research, we intend to leverage our platforms better, accelerate integration of AI in drug discovery, and expand access to external innovation.

In development, we will put rigorous evaluation of data and science first, continue to expand the use of adaptive study designs and build a balanced risk pipeline with few high-risk, high-return opportunities and a manageable overall risk profile with disciplined execution. Across R&D globally, we intend to sharpen our portfolio focus around our core areas, while pursuing selected moonshots, further strengthening governance through technical reviews, and increased talent density overall. Above all, we will act decisively to build a sustainable pipeline.

Now on slide 21, turning to our pipeline status and key focus areas. Our pipeline comprises 61 development projects across pharma and vaccines, including 36 new molecules. While we lack peers, we have complete actions to close this gap. AI will be a key lever across the R&D value chain. We are going to use it to accelerate discovery through target identification, screening for combinations, and AI design candidates, while enabling faster, data-driven decisions and higher clinical success rates, ultimately shortening development cycles.

Our ambition is to deploy integrated AI agents company-wide and to expand strategic partnerships in this area. China is another important source of innovation, with an ecosystem that reaches translational efficiency faster. We intend to leverage these capabilities to shorten clinical timelines, reduce costs, and accelerate patient access to innovative treatments. We will keep on building strong relationships with the local biotech environment.

On the appendix slide, we highlight some of our China deals, including the commercial agreements for Redemplo and Myqorzo, the clinical development collaboration with Anxu. On slide 22, let me go through some of the Q3 highlights. We received the Ayvakit 50 milligram US label expansion in indolent systemic mastocytosis and MenQuadfi in the EU for meningococcal disease from six weeks of age.

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Teizeild was accepted for review in the EU for stage 2 type 1 diabetes in children aged 1 to 7. We also received two regulatory designations, Beyfortus' priority review in China for the second RSV season, and SP0289 EU PRIME designation for pandemic H5 influenza.

On slide 23, and building on Belén's remarks, we've expanded our alliance with Regeneron to bring four next-generation, long-acting monoclonal antibodies targeting type 2 inflammation from the VelocImmune platform. The first is an anti-IL-13, which is already in Phase 1 for atopic dermatitis, with potential dosing every three to six months. Registrational studies are expected to start in late 2027 or early 2028, positioning it as a potential follow-on to Dupixent as early as the beginning of the next decade.

The other three are set to enter Phase 1 studies in 2027. We have an anti-IL-4 receptor alpha antibody with potential to succeed Dupixent, with improved properties on higher affinity and longer half-life, an anti-IL-4 antibody for combination use, and a bispecific IL-4/IL-13 antibody blocking both pathways in a single molecule. Separately, Sanofi will complete the ongoing lunsekimig COPD program, with readouts expected in 2029. Upon completion of the two Phase 3 studies, there will be the option for Regeneron to bring this nanobody into the alliance portfolio.

On slide 24, let me talk about our research platform, where we are doubling down on replenishing internal innovation. We have approximately 2,000 colleagues across pharma and vaccines research, with main sites in France, Germany, the US, and China, whose role will continue to grow. Our capabilities currently span biologics, synthetics, and genomics, and our priorities are to build a sustainable, high-quality portfolio in our focus areas while selectively exploring wide spaces and moonshots in areas of emerging science.

We aim for a balanced, lower-risk portfolio with a 50/50 internal/external sourcing split, increasing contribution from China and upper quartile speed and cost performance. As the chart shows, we are ramping up output across pharma and vaccines with the ambition to start 12 to 15 first-in-human studies each year, while maintaining the highest quality standards.

Turning to slide 25. Our approach and development is guided by robust, data-driven decisions. When the evidence supports advancing the program, we invest; when it doesn't, we reallocate resources. Following a thorough and ongoing benefit-risk review, we decided not to pursue global regulatory submissions for amlitelimab in atopic dermatitis, and we also discontinued itepekimab development in COPD and chronic rhinosinusitis, reflecting the available data and competitive landscape in these areas.

Lunsekimig continues with Phase 3 studies in COPD and Phase 2 study in high-risk asthma. The Phase 2 results in moderate to severe asthma were encouraging, but differentiation remains to be established. For duvakitug, we are exploring potential additional indications while focusing on execution, differentiation, and generally expanding options for patients with IBD.

In neurology, the frexalimab Phase 3 program across multiple sclerosis is ongoing, with study adjustments for longer observational periods to capture sufficient events and strengthen statistical power. Finally, Cenrifki has had a limited launch in Germany under a strict risk management program with encouraging initial feedback, but we did not plan to expand this development program.

On slide 26, let me share our key mid- and late-stage development portfolio. While the strategic assessment of our pipeline is ongoing, we continue to advance a portfolio of important medicines and vaccines for patients, with several key data readouts expected in the coming months that I will highlight on the next slide. Let me now turn to slide 27 and our expected news flow.

Next year, we expect Phase 2 data for lunsekimig in high-risk asthma and brivekimig in hidradenitis suppurativa, followed by multiple Phase 3 readouts, including riliprubart in CIDP versus IVIg in our pneumococcal and yellow fever vaccines. In 2028, we expect Phase 3 readouts for duvakitug in ulcerative colitis, Wayrilz life cycle indications, and frexalimab in multiple sclerosis.

Beyond these clinical milestones, we also anticipate multiple regulatory submissions and decisions for medicines and vaccines already under review. Before I conclude, I want to thank all our colleagues across Sanofi R&D for the continued commitment throughout this period of change, and for their unwavering focus on bringing new medicines and vaccines to patients.

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QUESTIONS AND ANSWERS

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

We'll now open the call to your questions. (Event Instructions)

Operator

Matthew Weston, UBS.

Matthew Weston - *UBS AG - Analyst*

Thank you very much. Two questions, please. The first, I think, probably for Manuela. Looking into 2027, your Dupixent competitor is getting much more vocal on EBGLYSS and stepping up DTC. Given we're solidly in PBM negotiating season, can you let us know whether you think there's any risk of major formulary changes next year or net price movements, or are payers prepared to support all of the products like they did this year?

And just quickly following up on the comment around more normal trends for Dupi in 2027, should we expect the normal step-down in gross-to-net price in Q1 that is just the traditional seasonality? And then a second quick one for Paulo. You used the term registrational enabling studies for the long-acting anti-IL-13. Is that Phase 3? And I ask because it triggers a milestone.

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

Very good. Thank you, Matthew. First of all, about your question on EBGLYSS DTC, I think the first thing that I will say across all indications, and the same is true for atopic dermatitis, we're very pleased with Dupixent's performance in Q3, but also throughout the year. The vast majority of that performance is driven by demand, and that is true also for atopic dermatitis.

What you will remember is that advanced therapy penetration in atopic dermatitis and almost all the other indications is still very low. We're talking about 20% advanced therapy penetration in AD, and by EBGLYSS and other competitors, but also ourselves, educating patients through DTC and other means, you're actually helping create more awareness for all products in this space, and that's what we need.

We need more patients to come into advanced therapies, including Dupixent, and with us having the majority of the market share in this space, we will also have the majority of the benefit. But again, more players in this space is going to help actually create more awareness, more market growth, and that's ultimately what we want to see, more benefits for patients.

On your second question, for 2027, we've had an amazing year this year. We obviously create a larger base then for comparison for next year, so we expect year-to-year growth to moderate, but we also expect that demand growth will continue. You will likely see the same Q1 adjustment that we see in the US every single year, but again, demand growth will continue to stay strong also in 2027.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Thank you, Matt. Just to clarify, currently, the status is that we've started the Phase 1 studies in the Q2 of this year, and the studies are ongoing right now. We are looking forward to seeing the full Phase 1 data, which includes PK and safety. So far, the data looks good. And, of course, we will, if those data continue to be positive, accelerate towards Phase 3 studies.

Operator

Luisa Hector, Berenberg.

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

Thank you very much. A couple from me, please. So maybe just to remind us on M&A business development, your capacity for deals now that you've struck the Regeneron with the payments there. So just capacity for deals and perhaps a little bit more color on how this is different from before, because M&A was a strategy previously, so how you think about it differently to before.

And then on the comment, the slide that mentions frexalimab and the optimization of those Phase 3 trials, can you explain anything in -- what was that optimization, and are there other trials which have been similarly optimized? I'm thinking, for example, in lunsekimig, COPD, maybe some of the HS trials. So just keen to get any color there from Paulo. Thank you.

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

Thank you, Luisa. Let me start with what is different from before, and then I will ask François to speak about the capacity for deals. So as I mentioned, we are laser-focused on ensuring growth beyond Dupixent LOE, ensuring that we mitigate our BOI impact. We know that the pipeline and the R&D reset will take a bit of time to materialize and bear fruits. So the reason why we are moving to later-stage commercial assets will allow us to derisk scientifically and clinically, but also leverage our commercial capabilities much better.

A priori, I have to once again emphasize that we will stay extremely disciplined to ensure that any deal, regardless of the size, fits our strategic, scientific, and financial criteria. With this, François, perhaps you can comment on capacity.

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

Thank you, Belén. Good afternoon, Luisa. I know that everybody is looking at an amount, so I'm not in a position to give you an amount. I wish I could, first of all, because we are looking at a different set of options in terms of BD and M&A. It's not necessarily one asset. It could be one asset, could be different deals and several deals and transactions as well.

It's less a matter of value. It's exactly what Belén just said. First and foremost, it's about strategic intent and scientific relevance. And then, obviously, from a financial point of view, first of all, we are conservative people, so we have a conservative financial policy. So it's driven by returns, obviously, and it's driven by outcome. And by outcome, what I mean is that we want to retain strong rating anyway, so that puts a limit to a certain extent to what we can, because we do intend to retain a strong rating.

And as you heard me saying earlier, we are totally committed as well to our dividend practice where we have increased our dividend for 31 consecutive years.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Now turning to your question, Luisa. So first of all, thank you. I would say this is very much one of my areas of focus in my first eight weeks here, and will continue. We've gone through, and I'm going through the whole pipeline and speaking with the teams, looking at the ongoing studies and what else we can do or should be doing to increase probability of success.

So very specifically on the frexalimab program, this is a Phase 3 program that, as you know, is being studied both across relapsing and secondary progressive multiple sclerosis patients. The trials are fully enrolled right now, and these are superiority studies looking at annualized relapse rate and confirmed disability worsening at six months as the key endpoint. And the trials were designed as event-driven trials.

So as part of what we have started since I came in, which is very thorough technical review process of all of these studies, we continuously monitor how the trials are performing. And in this case, we feel that prolonging the observational period for those studies actually allows

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us to collect sufficient events that will sufficiently power the studies for the intended statistical analysis plan. I would say that's one of the, let us say, more impactful decisions in the short term, but this is certainly an ongoing process.

Operator

Sachin Jain, BofA.

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

Hi there. Sachin Jain, Bank of America. Two questions, please. Firstly, for Belén, I think in your intro commentary, you mentioned the potential for a strategy event by year end. You had previously indicated you would do that when you had enough to say. So should we be hopeful of M&A by year end, or what would you think you could discuss over and above what you have talked about today?

The second question is for François on margins. Obviously, the quarter is evidenced by very strong cost control. So if you could just update us on your thoughts on margin development into '27. Prior comments have been, I think, flattish, so where do you sit now? And then if I can add an addendum to that, I know you used consensus for Amvuttra, but there is substantial debate overnight on the Alnylam call regarding 2027 Amvuttra outlook, so just any thoughts there. Thank you.

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

Thank you, Sachin. Look, our strategic event is aimed to bring additional clarity to you and your investors, and our investors, on the disease areas where we intend to play and not to play, how we aim to mitigate the Dupixent LOE and long-term ambitions, including how are we going to deal with the R&D turnarounds. So Paulo shares some impressions, but I think it merits a bit more color, so that you understand what we are going to be doing in coming months.

And of course, showing to you our capital allocation strategy and framework, including the role of BD and M&A in our long-term trajectory. Of course, this is regardless of any potential event that can be communicated at any time before the end. I think that covers your question.

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

There's a question on cost control. So Sachin, on cost control, indeed, we are very pleased by what we have seen in Q3, and you will see the same in Q4, which is strong growth, and alongside basically flat OpEx, which means that we get the full throw into the bottom line, and we get the benefit of the gross leverage.

It's too early to give some guidance on '27, and this is not the right time to do it. But that being said, do expect probably something similar, which means profitable growth, which means that we will have certain level of growth, which I don't want to comment at this stage, but our cost base will grow at a lower level than our sales. So we do confirm what we have confirmed anyway for what we have said for some time already, which is we will increase our BOI in absolute value next year, as well as in BOI margin.

By the way, it's not only for '27. We expect to do that each and every single year between now and 2030, so profitable growth each and every single year. And that in spite of two things. In spite of -- for '27, the impact in H1 '27 of the end of the R&D reimbursement, because we get the impact in H2 '26, but we will get the impact as well in H1 '27. But in spite of that, we expect to grow our BOI in absolute value and in BOI margin.

As far as Amvuttra is concerned, we took note of what they announced yesterday. We don't see any impact for 2026.We're already well advanced. You can see anyway that we will get probably EUR1 billion of royalties from Amvuttra this year in 2026. I don't see any change

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versus what we had in our plan. As far as '27 and the following years is concerned, I need a little bit of time to update our model because we are not speculating to a certain extent on the level of royalties going forward.

We are taking the consensus from the market, extracted from sales as provided by analysts. So I wait a few days to see a little bit what that means for the medium term. It may have some moderate impact going forward for us from '27 to 2030, but it's still early for me to comment. I'm not necessarily worried. I don't think that this will be that material for us.

Operator

Michael Leuchten, Jefferies.

Michael Leuchten - *Jefferies LLC - Analyst*

Thank you. Two questions, please. One, François, just going back to your comment just now when you talk about the OpEx growth below sales for 2027 and 2028, is that purely organic or are you already leaving some wiggle room here for M&A/BD that may come into the equation? So if you did something that came with R&D, can that be tucked into your outlook or would that be incremental to what you just said?

And then a question for Paulo, my understanding is you've joined with one remit to really focus a little bit more on research as opposed to development, which I think is what your slide was all about. Now managing for speed of execution is all well and good, but can you talk a little bit about how you're going to think about getting assets into the organization that allow you to be quick with or is there enough there that you can go through.

So like getting the stuff to work on that you then can speed up and deploy the stuff that you outlined too. Like how do you think about that? Thank you.

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

Michael, I would say difficult to answer your question. My comment, obviously, for '27 is based on an organic growth next year, plus we always factor some bolt-on in terms of acquisition. After that, as long as we have not announced anything or done anything in terms of BD and M&A, if there was anything more significant than bolt-on, difficult for me to reflect and to comment on that because we have not announced anything. So let's see what the future will be made of.

But once again, it's based on organic growth plus the traditional bolt-on that we have done traditionally over the last couple of years.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Yeah. Thank you, Michael. Maybe one point before the full answer. My focus is not only on research. My focus is across the whole R&D value chain, and research is definitely very much a part of that. But we're looking at development deeply as well as we speak even right now. You saw the comments I made about the review of the pipeline and increasing the probability of success for our ongoing study. So again, the focus is very, very end to end.

Regarding your question specifically, we do have some very good internal assets, both in research as well as in development, and we are going to maximize their use. We have the ongoing review for all of them, but again, if there is an opportunity to either increase their PTS, increase their speed, expand their use across more line extensions, et cetera, we're looking at all of those things as we speak. Internally, we have a number of partnerships that I am particularly excited about.

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I don't need to go into all those details, but it's also clear from my comments that this is not going to be enough for us. So we are doing -- as we review the ongoing internal pipeline, we are looking at many opportunities to either strike collaborations. Belén and François already mentioned the opportunities for BD and for M&A.

Obviously, the expansion of the alliance with Regeneron is something I am very excited about. This is a great company with amazing scientists, and the assets we are getting in from that collaboration are going to be really key for us in one of our core areas of strength. And then just to finalize, what I want to make sure as well is that we are expanding not just in traditional biopharma, if you want.

We're also incorporating AI technology very much into research, but across research and development, with two different intentions, if you want. On the research side, to increase the research funnel, to have more targets, more drugs, more diversity of chemical space, and in development, to do there to focus on speed, efficiency, delivery. But I would say this is a very encompassing end-to-end strategy right now.

Operator

Richard Vosser, JPMorgan.

Richard Vosser - *JPMorgan Chase & Co. - Analyst*

Hi. Thanks for taking my questions. Two, please. Just on the back of Paulo's comments there, how should we think about the R&D spend going forward? There's not a lot of late-stage development at the moment, so should we anticipate even spend being slightly down in '27 before increasing again, or a flat budget? Just thoughts on that.

And then secondly, just going back to Dupixent, it sounded from the comments that we should anticipate volume growth with a little bit of price decline next year. I mean, that sort of pushes towards almost the EUR25 billion level even next year. So just wanted your thoughts on that sort of thinking. Thanks very much.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Maybe I'll take that first part. So it's a great question. Sanofi already has a very significant investment in R&D. We don't expect it to really change much in the next year. The focus will change, though, because as you say, of course, the late-stage pipeline is now shorter. We are looking at existing molecules to see what else we can do with them, so you might see some additional trials, indications, et cetera.

But where we're actually pivoting towards is the earlier stage in research. So we will increase definitely investment there, including in AI, as I mentioned. And of course, as we bring in these new molecules, including the Regeneron molecules, we may increase investment there. But overall, our commitment to investing in R&D is the same as it was.

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

And on the Dupixent question, Richard, as I said earlier, we definitely expect that the strong demand growth will continue. But when you look at it on a comparable base, the base, of course, increases, and therefore, the growth will moderate. But having said that, when we look at the EUR25 billion, and that was a number that we gave at constant exchange rate, we're very confident that we can confirm that by 2030.

At this point, we're not prepared to talk about an acceleration here. But definitely, strong growth, we're very happy with the growth, and we're definitely confident that we will get there.

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Operator

Peter Verdult, BNP Exane.

Peter Verdult - *Exane Bnp Paribas - Analyst*

Peter Verdult, BNP. Two questions on R&D and Dupixent, please. Paulo, I realize this is unfair given you're only two months in, but just a bit more on how you are trying to improve R&D culture and scientific rigor at Sanofi, given over and above what you laid out in your prepared remarks. I'm asking that question given that I think 60% or over 60% of your -- the majority of your headcount is based in Europe.

So is this about just upgrading talent? Is it bringing clinical trial operations more in-house? Is there a significant R&D reorg coming? And how do you keep your scientists at neurology and oncology motivated, given that the focus is clearly going forward going to be Rare Disease and Immunology?

And then for Belén or François, if I could just build on the prior question around Dupixent. You've got five years of growth left -- at least five years of growth left. You're analyzing at EUR25 billion. What stops this franchise from topping EUR30 billion, EUR35 billion at peak? And just shorter term, anything around this 340B litigation? The industry, and Sanofi is an example, but across the industry, we're seeing better policing of these 340B discounts, but states are starting to push back with litigations.

Just want to make -- just checking on.

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

Peter, your line is breaking up, so let me, can you repeat the questions? So just to confirm, R&D culture and scientific rigor, geographical location, and the second one is what stops Dupi from EUR30 billion to EUR35 billion, and the 340B litigation.

Peter Verdult - *Exane Bnp Paribas - Analyst*

Yeah. Correct. Thank you, Belén.

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

Okay, thank you.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

All right, Peter. I'll take the first one. So what I mean by changing the culture in R&D to have more scientific rigor, part of it is obviously, let's say, intangible. It has to do with having the right conversations, truth-seeking behaviors, pushing on the data, the review of these programs. Part of it is actually now entrenched in our new governance.

So we have now established a thorough scientific review process, a technical review governance that will act in parallel to the normal governance of all of our portfolio. This starts in the preclinical stage, continues in development all the way through, and it's an ongoing dialogue. So that is clearly a change for something which we didn't really have, or didn't have institutionalized. As I was saying, now it's very much core to our new ways of working.

Regarding the organization, I think it's a bit premature now. One thing is clear, we want to have more of an end-to-end integrated therapeutic area focus to also be able to be deep in those areas where we are working to attract the right talent and also to ensure the right ownership

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of that pipeline. So that's already ongoing now. And in terms of location, et cetera, I think we're fortunate to have great talent in Germany, in France, in the US, in China.

We don't really envision, or I don't look at talent in a geopolitical lens. I know we have strong capabilities. I want to make sure that we create a system in which those people can thrive and do their best job. And then maybe finally, on one aspect that I know I keep coming back to, but it is the integration of new types of talent as well, including if we want to be players in AI, we have to be open to new sorts of talent and where those talents are. It's a very competitive area, and we want to be leaders in it as well.

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

Peter, on Dupixent, we just upgraded our guidance to EUR25 billion. As Manuela just said, we are very confident about it, especially so that the latest news on the foreign exchange seems to support anyway the EUR25 billion. Be assured that if we can go beyond that, we are working on it on a daily basis, but I don't think this is a time to do it anyway.

As I said earlier, we are conservative. When we give a guidance, it's with the idea to meet or exceed this guidance. For the time being, we stick to the EUR25 billion, but be assured that we are working towards -- I mean, to get even more if we can. But this is not the right time to do it now. We talk every three months, so let's see how it goes in the next couple of quarters.

Jamie Haney - *Sanofi SA - Executive Vice President, General Counsel, Member of the Executive Committee*

And Peter, on your question on 340B litigation, I wish we had a crystal ball as to what will happen in both the state and federal litigation that's been ongoing in 340B. I think what you see there is, given the dollars at stake, it is very dynamic. It continues to be. I think the best we can say is we continue to have a really robust program that's aimed, as François said in his opening comments, at ensuring the appropriate utilization of 340B. And beyond that, we can't speculate as to what the outcome of litigations will be.

Operator

David Risinger, Leerink.

David Risinger - *Leerink Partners LLC - Analyst*

Great. Thanks very much, and congrats on the exceptional performance. So I have two questions, please. First, for Dupixent in 2027 in the US, could you talk about the volume growth pushes and pulls? And then second, with respect to 340B scrubbing activities, could you just talk about what has been accomplished to date in 2026, and opportunities for additional scrubbing benefits in future quarters. Thanks very much.

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

Thank you, David. I'll take both of those questions. So on the first one, pushes and pulls when it comes to volume. As I said earlier, Dupixent being the leader across all the specialties that Belén had outlined earlier in her presentation, we really are very confident in continued volume growth. Of course, when you're thinking about the base that we now have, more than 1.5 million patients on treatment, the growth as a percentage of that base is going to slightly moderate, and that's what we're highlighting.

Of course, when you also have more players coming into the space, that will impact growth as well, even though there is a lot of opportunity to still grow the market. Let's not forget that. So I think those are the main elements. We are really looking at growth from a cross-indication perspective. We're currently growing across all of the indications that Dupixent has, all nine, across all geographies, and that's our continued focus also in the future.

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On 340B scrubbing, to your point, we've had operational improvements. 340B is one of those examples. But once you have done the work, and we will continue to do work to see how do we optimize gross to net. That's part of operational excellence. But eventually, you get to a point where you don't grow on that base, right?

So I think that needs to be the expectation here. We will continue to do an excellent job on operational improvements and gross-to-net management, but don't expect that to continue to grow, is my point.

Operator

James Quigley, Goldman Sachs.

James Quigley - *Goldman Sachs International - Analyst*

Great. Thank you for taking my questions. I have two, please. So both for Paulo. Firstly, you mentioned that Sanofi lags competitors in terms of pipeline size and maybe productivity. What are the most important factors of the ones you highlighted today that help you to close the gap? And you mentioned AI as one of the important factors earlier, but why is Sanofi going to be better or potentially more successful than others in integrating AI into the R&D processes?

And then secondly, on China and the innovation expansion here, as you said earlier, China only makes up around 1% of R&D colleagues. How easy is it to hire in China, given that there's a lot of demand, a lot of activity in the region, 7,000 biotechs, I think there is? You've just opened a new R&D site there, but how are you thinking about the speed of build-up of this facility? What are you planning to do in China that maybe you can do faster or can't do in the US or Europe? And how does that then feed into your R&D productivity goals? Thank you.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Thank you. It's a pretty complex question. So starting with the productivity, as I mentioned, there are many, many factors here. Volume is clearly something that we need to increase. We don't have a large pipeline right now, and of course, we need more options, okay? As I said, I'm happy with the pipeline we have internally. They're good molecules. We need more of those good molecules.

The fact that we're going to start focusing more on certain key areas allows us to go deeper and broader in those areas as well, instead of dispersing our efforts much more broadly, okay? The second thing really is around the speed of decision-making and the speed of execution. Decision-making, as I mentioned, we've revamped our whole governance. We have very strong technical reviews that allow us to move faster, and we are using AI-assisted tools to help us make stronger decisions based on data.

We will expand and continue to do that. On the execution side, I think we've shown that we have global capabilities to execute. We will continue to try and improve those to deliver faster at lower cost. Everyone benefits from those measures. Your question on AI, why are we going to be better? I think different companies do it different ways. Sanofi has been a pioneer, actually, in adopting a lot of AI technology.

I was pleasantly surprised when I came here to find how much we are already doing, and also the openness, the willingness for us to do a lot more. Different companies, as I said, have different strategies. We're elaborating ours. One thing is clear to me, this is a very fast-moving field with a lot of external partners we can collaborate with and want to work with us. We already have some strong partnerships with Recursion, with Owkin. We'll continue to do more of those.

On China, it's pretty early days. Our intent right now is to access the local ecosystem. We've had some earlier starts there with Tigermed and with Intrépide. I think we want to build on those. We certainly feel we need to have a strong presence on the ground to be able to access that environment. But again, it's pretty early days to give you more details.

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LSEG DATA & ANALYTICS

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

Maybe just to complement on China, what's very interesting is that, and it will, of course, remain a competitive place to hire, which was the heart of your question. But what's interesting to highlight is that we have a strong commercial presence today, with more than EUR2.5 billion sales in China. We have also a strong manufacturing presence. As you know very well, we are building an insulin facility in China.

In addition to the capabilities we are expanding, as just laid out by Paulo, in terms of R&D. And of course, there are multiple ways to expand our R&D capabilities, ourselves, but also in partnership, and we're looking at all these opportunities altogether.

Operator

Florent Cespedes, ODDO.

Florent Cespedes - *Oddo BHF SCA - Analyst*

Good afternoon. Florent Cespedes from Oddo BHF. Thank you very much for taking my questions. Two quick ones, please. First for Belén, on the collaboration with Regeneron. As you announced that you could acquire late-stage products or eventually products already on the market, so could you consider at some point if you acquire a company with a product already inflammation on the market to ask Regeneron if they are interested to add this product into the JV? That's my first question.

And I have a very quick follow-up question for Paulo regarding China and the Chinese ecosystem. Maybe, Paulo, could you share with us if you see areas in China where the local companies have a stronger, let's say, are doing things better, and which are those areas where you could be interested in? Thank you.

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

Hi, Florent. On the Regeneron collaboration, first of all, let me tell you that, as I mentioned already, this is a very, very important alliance for us. Right now, we have the four compounds within, and Regeneron took an option on lunsekimig. Then, yes, we have all flexibility to do -- to pursue later-stage deals, earlier-stage deals inside and outside of the alliance, and we can do it on our own, which is giving both partners tremendous flexibility, or we can do it together if this is something that would be of interest to both partners.

So the current approach, as I mentioned, is a win-win, is giving us either Regeneron or Sanofi tremendous flexibility to opt in to the alliance or to go independently if we believe this is better for the individual partners.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

Thank you. Just to follow up on your question regarding China. I have been going to China now for over a decade, and I think there are two areas where they make enormous progress. One is in access to different technologies for drug discovery and essentially chemical matter creation. Right now, their speed of generating new binders, new molecules, whatever technology you want, is just really much higher than we can do in many other areas.

And that obviously gives us a lot of optionality, so we are very interested in that. The second one is around translational speed, so the speed at which they can generate quickly proof-of-concept data in the relevant disease states we want. So if you want, those two things combined could actually be really interesting for a company like ours, because we have more chemical matter, more shots on goal, quicker to find out if they work or not. So I'm very interested in leveraging that.

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Operator

Graham Parry, Citi.

Graham Parry - *Citi Infrastructure Investments LLC - Analyst*

Great. Thanks for taking the question. Just going back to Dupixent, could you just quantify in euro terms the gross-to-net benefits that you saw across Dupixent, Lantus, Toujeo, and then across the group? And then if you look at the Dupixent growth of 40% year on year, that was 23 points higher than the prescription growth.

So how much of that is a one-off benefit from rightsizing the gross to net versus the ongoing productivity improvements on gross to net that would carry forward into 2027? So in essence, how much of a headwind is there of one-off gross to net in the base for Dupixent as we go into next year?

And then on slide 5, Belén, you say that there are other focus areas under review. Just wondering if you could elaborate on that, given most of the focus here has been on the core therapeutic areas. And when you're looking at M&A, is there a preference across Rare Disease, Immunology, or Vaccines at the moment? When you're looking at Immunology transactions, it sounds like Regeneron is not that interested in putting any new mechanisms of action into the alliance for atopic dermatitis.

So if you were looking for a different mechanism of action in that space, is it safe to say that would be something you would be doing on your own and would have to negotiate sales force allocation over time for? Thank you.

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

Graham, let me maybe take the first question. I will not answer specifically for Dupixent, but be aware of the fact that we grew 14% in Q3. The underlying growth, if we exclude the one-offs, is 12%, which means that between 85% and 90% of our growth is recurring, demand-driven, sustainable growth, and is not linked to one-off. So the impact of one-off is relatively minimal. But we just wanted to flag it.

So this is the same conclusion for Dupixent, and this is the same conclusion for insulins, by the way. But once again, more than 85% of our growth is sustainable and demand-driven, and there is only a small portion of it which is linked this quarter to exceptional items.

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

And building on the second part of that question, Graham, on the net sales growth versus script data growth, remember that script data does not always reflect total demand, because you also have to account for patient mix. So that is a piece to remember. And then, as I said earlier, we have also continued to make operational improvements across various programs.

Jamie mentioned making sure that patient benefits reach the intended recipients, and that has also contributed to year-over-year gross-to-net improvement. So as François was saying, the part of one-offs is a smaller part of that equation. And to your question on other mechanisms of action in atopic dermatitis, for example, do we have flexibility outside of the alliance? Yes.

First, as we always do, and Belén has reiterated that before, we always look at, does it make scientific sense? Is it strategically compelling? And then the question whether it goes in the alliance or not is a subsequent question. And we do have flexibility, absolutely, in AD, and other indications as well. I&I is a broad space to do things on our own, and Immunology outside of the alliance remains a strategic pillar for us.

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

So Graham, part of your third point has been addressed already by Manuela. Back to the therapeutic area in focus for M&A, as I mentioned, our three pillars, Immunology, Rare Diseases, and Vaccines are in focus, right? And we are looking at different options within. But keep in mind that within those therapeutic areas, there are several disease areas.

For example, if I take Immunology, we have an undisputable leadership in dermatology. We have a leading position in respiratory, and we are emerging in gastrointestinal, for example, right? So that is the distinction that we need to make, because the choices are broader, right, when you look at what is within the therapeutic area, right? Same for rare. Right now, we play mostly on hematology and genetic diseases.

There are multiple other Rare Diseases which we may look at if this brings opportunity, scientific robustness, and are within our financial guardrails. So this is exactly the clarity that I want to bring to you, that we want to bring to you mid-December, so that you understand what is going to be the focus that we will place beyond the broad therapeutic area, Immunology, for example, or Rare, or Vaccines.

Operator

(Operator Instructions) Thibault Boutherin, Morgan Stanley.

Thibault Boutherin - *Morgan Stanley - Analyst*

Yes, thank you very much. I just want to touch on the comment you make on your slides on the moderate impact on sales, Dupixent loss of exclusivity. Just to understand what gives you confidence here, is it the transition of the franchise to the new asset in the collaboration with Regeneron, or is it execution on pipeline, on business development, M&A, to sort of compensate for the revenues? So the building blocks to basically get confidence that the top line will only see a moderate impact.

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

So once again, our priority is to generate revenue growth post-2031, and we expect the total revenue at group level to be impacted moderately by the Dupixent loss of exclusivity. The point that I want to make is that our current focus is going to be really preserving the earnings. Due to the alliance with Regeneron and the profit split, you can imagine that the impact on earnings is lower than on revenue.

And of course above all, we aim to preserve our cash flow. Once we get there, we will also focus on accelerating earnings growth. And once again, I would like to point at the December timeframe to give you a bit more granularity of the roadmap.

Operator

James Gordon, Barclays.

James Gordon - *Barclays Services Corp - Analyst*

Hello. James Gordon from Barclays. Thanks for taking the question. One was for Paulo, and thoughts on the existing pipeline. So looking at slide 25, lunsekimig differentiation unclear, and 26, riliprubart and in brivekimig, there's not a lot of mention there. So are there assets, though, that beyond the recently partnered Regeneron assets that you are more excited about? Because you talked about good molecules, so what makes you excited, even if it's something earlier, maybe the STAT6, or anything else that the market is overlooking that is more exciting?

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And if I could just squeeze in a clarification, there was a talk about therapeutic focus, like I&I, Rare, and Vaccines, but what does that mean for other areas? Are you just talking about M&A focus where you buy more, or are you considering more base business divestments like the Chepla deal? Could we see you become a more sharply focused company because you're going to make significant divestments?

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

You want to start with the first?

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

Yes, please.

Paulo Fontoura - *Sanofi SA - Executive Vice President, Global Head - Research & Development Pharma, Member of the Executive Committee*

So, thank you. This is the type of question that gets me into trouble, because all the teams are looking to see which molecules I like or don't like. So I'll restrict my comments maybe to the ones that are most visible or that have recent news flow. As you know, efdoralprin alfa is something we haven't really mentioned today.

This is a very exciting program. It addresses a real medical need in the population that up until now has really poor standard of care, and it could be both best in disease in terms of convenience, but also in terms of efficacy. And actually, in our ongoing conversations with the health authorities, it's clear they share the excitement, but also the data standards they hope us to fulfill, which is why we're making sure to take enough time to collect all the data to support a good application.

For frexalimab, we spoke about this. I mean, it's a very exciting new mode of action for MS, an area in which I've worked for many years. We are also exploring it in type 1 diabetes, in transplant. So again, this is one of those broad immunological mechanisms that can stand to do a lot of good things across a range of conditions, and we are taking that exploratory approach as well.

For the lunsekimig, I want to clarify maybe. This is clearly a drug that works in moderate to severe asthma. The question is around differentiation, and this is a highly competitive space where Dupixent certainly is a very good drug. There are other very good drugs. We're looking to see what is the advantage in that specific population for this dual mode of action. But I personally am very excited about the COPD potential for this drug, so we're focusing on execution on that.

Again, within the scope of this partnership, we have the opportunity to come back with good data and have that conversation. And of course, we can spend a lot of time here. I'll finish maybe on duvakitug. This is a very exciting new mode of action for IBD. Our earlier data in Phase 2 actually shows very strong efficacy, both in terms of induction and potential in terms of maintenance.

So this could actually be a best-in-disease drug as well, which including has a subcu development, which means it would actually be the only subcu launched from the start like that. So again, I'm just really excited about what we have. I just think we need more, and that's what the focus is on now, which is actually reviewing the ongoing to maximize their chances and increasing the size of our pipeline, both through internal and from BD and from M&A.

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

Let me now address the last question on your therapeutic area focus. I will start by saying, what does it mean for the therapeutic areas in focus, right? So what it means is that the majority of our capital, both R&D as well as external innovation, will be allocated to those therapeutic areas in focus. For example, our R&D spending over the last few years have been extremely fragmented and focused on many disease areas. And of course, when you do that, the risk is increased exponentially.

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So it is important that we link disease area strategy and capital allocation. What does it mean for the areas that are not going to be in focus? Depends. We will have to look for strategic options, and it could come as an out-license eventually. It could be that we decide to partner or eventually to close, depending on where is the contribution. But the majority of the capital and resources of the company will go behind the therapeutic areas and the disease areas that we will put in focus.

Operator

Simon Baker, Redburn.

Simon Baker - *Redburn Partners LLP - Analyst*

Thank you very much for squeezing me in. I'll save the R&D question for (inaudible) and one for François. On -- I just wonder if you could give us a little bit more detail on the data-driven gross-to-net management that you've introduced. Have we effectively seen the main impact, and going forward, the impact will simply be a smaller gap between volume and sales, or is there more to come there? Any insights there would be really helpful. Thank you.

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

Simon, it's a good question. I don't expect much more to come beyond what Manuela mentioned earlier anyway. Traditionally, in Q1, maybe a bit in Q2, we have some reversal of provisions. I mean, once we have closed a few weeks or months after we have closed the year. So this will come anyway, the traditional one.

This year, we have a little bit more because indeed, we made some good progress, which is data-driven, partly linked to AI as well, where we have a much better control of gross to net, which is a super complex issue, as you know, in the industry. But data management and AI can help. With these tools, we have improved tremendously our knowledge, and that allows us to improve the accrual level and the provision level that we do for gross to net.

And as a consequence of that, we had some kind of one-off exceptional in Q3 that we talked about earlier, and I don't expect that to replicate, so -- or not to the extent that we saw in Q3. So this is the reason why we see that more as a one-off, which is explaining these 2 percentage points of exceptional growth that we had in Q3. I don't expect that to be big again and happen in the other quarters.

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

Very good. Thanks for this last question. With this, I would like to thank you for the interest in Sanofi. I will now close the call.

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