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EDITED TRANSCRIPT

SASY.PA - Sanofi SA to Acquire Insmed

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PRESENTATION

Operator

(audio in progress) strategic acquisition that strengthen Sanofi's long-term future. Slides can be found on sanofi.com.

Let me briefly cover our forward-looking statement on slide 2. We would like to remind you that information presented on this call contains forward-looking statements which are subject to substantial risks and uncertainties. We encourage you to read the disclaimer in the presentation and in our press release regarding the acquisition.

We also refer you to our Form 20-F on file with the US SEC and our French Universal Registration Document, document d'enregistrement universel. On slide 3, here are our presenters for today: our CEO, Belén Garijo; our Head of R&D, Paulo Fontoura; and our CFO, François Roger. Manuela Buxo, our Head of Specialty Care, will join us for the Q&A.

With that, I will turn the call over to Belén. Belén?

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

Thank you very much and good day, everyone. Welcome to our call. I'm very pleased to announce the acquisition of Insmed, which is another critical strategic step further shaping Sanofi's success for the mid- and long-term future.

Insmed doesn't come in isolation or as a standalone move. It is a critical step forward in our strategy that is already in motion and we are executing with discipline and rigor across several dimensions. I'm on slide number 4, by the way.

First, our performance continues to be strong, with our revenue growing by 15% in the first nine months of the year with disciplined control of our operating expenses driving profitable growth. As a result, as you know, we upgraded our 2026 guidance during our Q3 call. While we continue to deliver on our financials, we have also advanced the transformation of the organization, as illustrated by initiating the R&D reset and the simplification of our business, including the recent Cheplapharm transaction.

We have made strong and decisive moves on the portfolio to ensure focus and the ability to stay competitive in areas where we already have a leading presence. We recently expanded our alliance with Regeneron, which was another important first step in rebuilding our early stage pipeline. Today, we are announcing a major strategic step forward with the acquisition of Insmed, which will expand our portfolio within our core therapeutic areas.

Turning to slide number 5, the decision to acquire Insmed was made after a rigorous analysis of multiple targets that you can imagine, a process that was initiated soon after my arrival in May. Insmed stood up as the company that addresses all of our key value creation drivers. And let me explain why we see Insmed as a strong strategic fit.

First of all, it broadens our position in respiratory diseases. Sanofi is not a stranger to respiratory diseases, and we already have a presence in respiratory across vaccine and immunology. Insmed builds on this strong position and expands it by adding commercialized medicine and a pipeline in immunology and rare diseases.

Importantly, Insmed strengthens our mid- and long-term growth outlook. We expect peak sales of the acquired medicines and pipeline to exceed $10 billion in the next decade.

Third, it brings two promising commercialized medicines, Brinsupri and Arikayce; and a differentiated later stage pipeline molecule with TPIP. And we are acquiring an established business with significant growth potential and not simply investing in future scientific promise.

Fourth, it reinforces our own immunology capabilities in a complementary way to the Regeneron alliance and leverages our commercial strengths. We have the commercial know-how and the scale to help these medicines reach more patients around the world.

And importantly, this is a value-creating deal for our shareholders. The transaction is expected to be business operating income positive while delivering fast EPS accretion, and François will be giving more details of this later on the call.

On slide number 6, let me give you a bit more color on Brinsupri, a transformational first-in-disease medicine. Brinsupri is the first and the only approved treatment for patients with non-cystic fibrosis bronchiectasis or NCFB. It is an oral DPP1 inhibitor that targets neutrophilic inflammation. That complements our own deep expertise in type 2 inflammation, which is one of the reasons why these fit is so natural for us.

The commercial performance of Insmed has been remarkable, as seen by the outperformance when comparing with strong launch analogs. The chart on the left shows quarterly net sales since launch, which was in August of last year. With the product only launching in August of last year, in the first four full quarters, Brinsupri has already generated more than $1 billion in net sales in the US, and the launch in Japan is now underway.

The opportunity ahead is still large. Around 500,000 adults in the US are on label or candidates to be treated for NCFB, and only about 32,000 out of those 500,000 are currently treated as of October 2026. Therefore, this is a large and untapped market.

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There is also potential beyond the current indication, and we have identified potential opportunity in patients with respiratory comorbidities. For example, the ASPEN study showed benefit in patients with comorbid NCFB and other severe respiratory conditions. We are confident that Brinsupri's growth will benefit from Sanofi's robust commercial capabilities, as I mentioned before.

Turning to Arikayce on slide number 7. Arikayce is the only approved inhaled antibiotic for refractory Mycobacterium avium complex lung disease, and it has shown consistent and steady growth since launch. Today, Arikayce is approved in second-line refractory setting.

The next growth opportunity is in treatment naive MAC lung disease which currently has a PDUFA date set by the FDA on January 28, 2027, based on the positive Phase 3B ENCORE study. If approved, that would meaningfully expand the patient population that can benefit from Arikayce. Sanofi's experience in patient identification, patient support, and specialist engagement would help us reach more of these patients faster.

And with this, let me hand it over to Paulo for him to review our late-stage pipeline opportunity, TPIP.

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

Thank you, Belén. Moving to slide 8. Good day, everyone. Let me walk you through why we're so excited about treprostinil palmitil inhalation powder or TPIP.

Today's inhaled prostanoid therapies have a proven mechanism of action and provide clear benefits for patients. However, they come with a real burden for patients because the drugs need to be inhaled four times a day, which has a negative impact on tolerability and long-term adherence.

Therefore, the full benefits of prostanoid therapy are not translated into real-world health outcomes. TPIP is designed to address this treatment burden by offering a potentially more convenient treatment option with just one daily inhalation.

There are several reasons to be excited about this molecule. Firstly, this potential once-daily option could be a meaningful quality of life improvement for patients managing a chronic condition. Secondly, there is potentially better safety profile because TPIP avoids the sharp peaks and troughs associated with frequent dosing, which is translated into lower discontinuation rates.

Thirdly, potential better efficacy, as the Phase 2 signals have been strong and consistent with what we have seen in the pharmacokinetic data where treprostinil levels were sustained over 24 hours. Furthermore, in the real-world setting, improved adherence driven by once-daily dosing should translate into better and more sustained long-term health outcomes for these patients who rely on these medicines for months and years of treatment.

The unmet need here is considerable. We're looking at roughly 450,000 diagnosed prevalent patients across four indications in the US, EU5, and Japan, with about 125,000 in PAH, around 85,000 (sic - see slide 8, "86,000") in PH-ILD, and roughly 254,000 across both PPF and IPF combined.

As I mentioned, the core issue with existing therapy is adherence, as four inhalations a day is hard to sustain and underdosing at night is a well-recognized problem in these conditions. A single dosing option is the opportunity TPIP is built to address.

Additionally, this mode of action could be beneficial across a range of pulmonary conditions that (technical difficulty) similar pathophysiology related to both vascular reactivity and fibrosis. And that's why there are currently four Phase 3 studies underway as part of the PALM program, enrolling more than 2,000 patients.

Sanofi brings deep, established experience in respiratory disease, and our strength in this area gives us a real opportunity to accelerate clinical development, raise disease awareness, and bring this medical innovation for more patients faster.

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Now moving to slide 9. Beyond our near-term drivers, Brinsupri, Arikayce, and TPIP, we have a promising early stage pipeline across multiple areas of focus. In respiratory diseases, INS1148, an SCF monoclonal antibody, is Phase 2 ready for idiopathic pulmonary fibrosis.

INS01033 (sic - see slide 9, "INS1033") is a next-generation oral DPP1 inhibitor explored in Phase 1 in COPD, rheumatoid arthritis, and finally, in ulcerative colitis. We have also selected two gene therapies which are currently in Phase 1, INS1201 for Duchenne muscular dystrophy and INS1202 for ALS or motor neurone disease. Together, this portfolio complements Sanofi's pipeline and feeds future IND flow, supporting our confidence in innovation beyond our current lead medicines.

Now let me hand over to François to discuss the financial terms.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

Thank you, Paulo. Moving to slide 10, it is my pleasure to share with you the financial terms of this strategic transaction which is expected to create value for Sanofi and its shareholders.

Starting with the terms of the transaction, Insmed shareholders will receive $175 per share in cash, which values Insmed at about $41 billion or around EUR37.6 billion on a fully diluted basis. We see this as a financially compelling and strategic acquisition. We expect business operating income to be positive in 2027, and we expect the transaction to be EPS accretive by the end of 2028, with estimated annual cost synergies of more than $500 million.

This transaction will be funded through a combination of debt financing and cash. Debt financing is fully secured as we speak. We expect to maintain a strong credit rating after closing with the ability to retain appropriate capacity to continue investing in early stage business development and M&A opportunities.

We will remain very disciplined in terms of financial policy. We maintain this flexibility while remaining fully committed to our progressive dividend policy. On timing, we expect the transaction to close in the first half of 2027, subject to customary regulatory approvals.

I'm very pleased to see that we were able to find a complementary fit to our portfolio and look forward to showing how we can create added value for Insmed differentiated portfolio under the Sanofi umbrella.

And let me now turn back to Belén for some closing remarks before going to Q&A.

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

Thank you, François. Thank you, Paulo. Let me close by summarizing what this transaction means for Sanofi on slide number 11 and how it fits into the strategy we are executing at pace.

We have been clear about our priorities: number one, delivering sustainable and profitable growth; number two, strengthening our portfolio; number three, improving the productivity of our R&D engine. Our guiding principle is to concentrate capital, talent, and innovation where we can be the most competitive.

First, Insmed accelerates our growth beyond DUPIXENT. It is an anchor acquisition that spans our leadership in immunology and rare diseases while strengthening our respiratory franchise. We will combine our strong US payer relationship and our patient support expertise with Insmed differentiated portfolio to bring these medicines to more patients.

Second, this acquisition supports profitable growth, led by rigorous execution on the top-line, coupled with cost discipline as our new medicines scale.

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Third, Insmed complements our efforts to rebuild a productive innovation engine. While we transform our R&D organization to improve productivity, we intend to use early-stage bolt-ons to complement our pipeline and strengthen our innovation capabilities for the longer-term.

And importantly, it is a value-creating deal for our shareholders. As François articulated, the transaction is expected to be business operating income positive already in 2027 while delivering fast EPS accretion by the end of the year 2028.

We are planning to share further updates on our strategy update on December 9, next month. Please stay tuned to learn more on how we are shaping the future for Sanofi.

And before we go to the Q&A, I want to take this opportunity to sincerely thank both the Insmed and Sanofi teams for their remarkable collaboration, which is always a good indicator of how a future collaboration can become. Also, I want to thank the Sanofi Board and its Chairman for their invaluable support to make this transaction happen. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Luisa Hector, Berenberg.

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

So I guess I'm just curious. How long were the companies speaking? It's a little bit why now. And was this something where the board needed convincing? How long has there been a dialogue going? And did Regeneron look at the deal with you? Is that something that could yet happen in the future?

And then perhaps François could expand a little bit on the cost synergies, the $500 million, and where that comes from and how quickly.

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

We are not going to disclose confidential information on timing of this discussion, but you know that for every M&A, it takes two to tango, as you have heard me saying before. And the Board obviously challenged and supported us, and it was on our side to make and to build a very solid case to justify this strategic transaction.

Regeneron didn't need to look at any deal that we do that is not competing with our alliance. That is the way it was. Of course, as a courtesy and when it was possible without breaking the rules, I called Len to inform him that we were going to announce the deal.

I think on the cost synergies and how is the $500 million spread, François, do you want to comment on that?

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

I can. Yes, Belén. So the cost synergies, we confirm an amount in excess of $500 million of synergy. This is mainly going to be in G&A, which means, to be a bit more specific, in real estate, IT support functions.

We will try at the same time to ring fence commercial infrastructure, obviously. And to a large extent, the same applies as well for this ring fencing for R&D.

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In terms of timetable, we'll move fast. So for most of the cost, we should be able to move really fast. I don't want to give an exact deadline now, but we will move very fast.

Operator

I think Sachin dropped off the line, so I'm going to go with Peter Verdult from BNP Paribas. Peter?

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

Hello. Sachin here, if that works. I didn't drop off. I'm live and kicking. So two or three questions, if I may.

So firstly, if you could comment on your confidence or your due diligence in the Insmed $14 billion peak sales that they provided in the middle of the year and the $7 billion for Brinsupri.

And then the second question, I'll keep this to just high level, obviously, you've been talking to Len about solving the DUPI cliff. So when you're modeling assumptions with DUPI in '31, how much does Insmed go to filling that midterm path -- sorry, midterm gap and giving you a path to now stable levers?

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

So let me start with the confidence in the diligence because we had a very sizable team behind, looking deeply at each and every angle that was absolutely key to making a decision, particularly the commercial assumptions and the peak sales.

So we have already mentioned that we are expecting peak sales above $10 billion. And the difference between our view and the one of Insmed has to do simply with the way we have risk adjusted our own revenue forecast. So this is one thing.

This transaction -- if you remember our Q3 discussions, we said we were committed to compensate the impact of DUPIXENT LOE on our BOI, right? And for this, we need around EUR8 billion, François? So perhaps you can speak a bit more on the model and DUPI.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

No. So I mean, Belén said it. we knew that the impact of the DUPIXENT LOE, we could manage it only as far as the bottom line is concerned. Because as we have already shared, we will reach probably EUR25 billion of sales in 2030 and we will lose, at the time when the LOE comes in 2031, '32, '33 -- whenever it comes -- probably a very significant proportion of these EUR25 billion.

We won't be able to compensate for sales, but we were always confident on the fact that we will be able to compensate one way or the other as a combination of our pipeline plus BD M&A. And this is what we are discussing today.

The loss of the LOE, as far as the bottom line is concerned, we estimated that this gap that we had as we talked was about EUR8 billion by 2035, and Insmed actually does it basically. So even if this is not -- we don't do it only for that because we do it because of the growth opportunity as well, but it does a job to a certain extent.

Just be aware of one thing as well. It may not be exactly the case year by year, but I mean, directionally, for 2035, we are getting there.

Operator

Peter Verdult, BNP Exane. Sorry for the miss earlier.

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Peter Verdult - *Exane Bnp Paribas - Analyst*

No problem. Peter Verdult, BNP. Can you hear me?

Operator

Yes.

Peter Verdult - *Exane Bnp Paribas - Analyst*

Look, I'm going to be a bit more blunt and just repeat and re-ask Sachin's question. Belén, given the commercial prowess of Sanofi globally, that $7 billion peak sales number, do you think that you can push that upwards? And François, just quickly, am I right in thinking the IP on this is late '30s?

And if I could squeeze one in just from Paulo on TPIP, where are the risks here? Because you've got the LPA1 antagonist. You've got the active INS doing very well. I don't think we're going to see any Phase 3 readouts in those big indications until later in the decade.

So just how have you thought about TPIP in terms of what's currently in consensus, what you've assumed? So just a little bit more information there would be helpful.

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

Yeah. So let me start by the -- perhaps, we can give the word to Manuela, who is in the US, to speak about the commercial forecasting. But it's not a matter of being conservative or not, it's delivering, right? We have to deliver on our business case, which is not that far from what we have seen in the seller side and is actually quite close to consensus, right?

So we see opportunity mostly on the comorbidities that I mentioned during the prepared remarks, but perhaps Manuela can add a bit more color on this front.

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

And fully aligned with what you said, we're really excited about the assets. And in particular, on Brinsupri, we believe that there is opportunity within bronchiectasis to treat more patients, as Belén said earlier. There is definitely an opportunity also in comorbid patients with COPD or asthma.

But we wanted to be disciplined in our forecasts. We are broadly aligned with the Brinsupri forecast that Insmed had put out there. And as Belén said, there might be additional opportunities in the comorbid space, but it's too premature. And we really want to make sure that the business case we put out there, we can deliver, and that's how we have looked at forecasting.

And for pipeline assets, as Belén mentioned earlier as well, like the TPIP, we have appropriately risk adjusted those. Because as you rightly said, some of those readouts won't happen before the end of the decade, and we just want to make sure we are conscious about that as well.

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

Peter, was there a second question or was your second question on TPIP?

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Operator

Peter, can you repeat the second question, please? He's back.

Peter Verdult - *Exane Bnp Paribas - Analyst*

Yeah. My second question was to Paolo -- I'm sorry about that. Second question was to Paolo on TPIP. And then if I can --

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

On TPIP? Yeah, exactly. Okay. Paulo, please.

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

Yeah, happy to take that. So first of all, we're very excited about this molecule. This is a well-validated mode of action. Actually, there's an approved similar molecule here. This is the prodrug, essentially.

So what that allows us to do -- first of all, it addresses one of the major flaws, if you want, with the molecule that's already commercialized, which is the need for very frequent administration to sustain sufficient levels of drug at target, essentially.

Now this, for these patients, is a big liability because we're talking about taking this inhaled drug four times a day. There's significant cough associated with that, so that leads to problems with compliance, adherence. And therefore, we're first of all excited about that, that validated mode of action.

And the early data we have on the pharmacokinetics and distribution of the drug is that actually, you achieve very high levels of drug in the lungs consistently over 24 hours. So scientific risk in my perspective is really not high.

Again, we're being very disciplined, as Manuela said, meaning that when we look at the execution of these ongoing Phase 3 trials, that's really where we're going to be focused in the years to come, to make sure that they are robustly executed and the data comes in as soon as possible.

Now, within all those indications, probably PPF is the one where we have the least data, even though there's some translatability from IPF to PPF -- they're both fibrotic diseases. And we already know that personalized work in the IPF. TPF is still not approving. Therefore, if you want, that's the higher risk spectrum for the PALM program. But again, we feel very confident that this is a validated mode of action.

Operator

Graham Parry, Citi.

Graham Parry - *Citi Infrastructure Investments LLC - Analyst*

Yes, it's a similar vein to the greater than $10 billion versus $14 billion. I mean, the price you're paying here is actually $175 per share. It's below the average sell-side target price for Street analysts. So I'm just wondering why you would -- I guess, more to the point, the company would be happy to sell for less than the Street thinks the stock is worth?

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Then secondly, if you could just talk to what early platforms that Insmed has you think could leverage your early R&D, particularly discovery and pre-clinical. Is there anything here which you feel could improve the product flow into the clinic as well as the late stage assets that you focused on?

And then the final question is just on sales force engagement. So -- and just, can you talk to see the mechanics of how the sales forces can engage on these products across DUPIXENT, given the alliance? So how would that work in terms of -- do they have to be completely ring fenced and separated or can there be any sort of crossover or cross-sell?

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

Well, let me start by your last question on the -- it's beyond the sales forces, all the commercial capabilities that we have. Keep in mind that one of the strategic consequences of this acquisition is that we are going to be able to build our own Sanofi immunology capabilities outside of the alliance. At the same time, we are going to rely on our expertise and on our own capabilities to be able to further boost the potential of Insmed medicines.

Having said this, as you know, DUPIXENT remains a major growth driver for Sanofi, and we will also focus on maximizing the potential, right? That goes for the sales force.

Clearly, we are very well placed. We are already in the respiratory field, and we have capability beyond the capabilities beyond the alliance to develop and accelerate these medicines so they can reach more patients.

On the platform for R&D, Paulo?

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

Yes. It's a great question, it is. Actually another reason to be excited about this deal is that there's very strong strategic alignment with our own areas of interest, not just in respiratory diseases with the more advanced compounds. But if you look at the earlier stage pipeline, the two gene therapies which I mentioned for Duchenne's and for motor neurone disease, very much on target for our rare disease focus.

And thinking even about the research pipeline, there's at least two platforms that we're looking at, including one which allows for split AAV for large cardinal gene therapy that's a very good fit with our existing platforms for gene therapy. We'll expand our capabilities there. And there's also a CRISPR-based synthetic rescue screen based on human genetics that allows us to identify potentially therapeutic targets for disease modification across a range of rare diseases, including the ones that we've spoken about.

So we're all -- obviously, in the weeks and months to come, we're going to look more closely at those and see how best to synergize that with our own research capabilities. But at this time, we're very excited about that.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

Graham, let me answer your question on the price of the transaction. So we offered $175 per share, which is a 46% premium over the unaffected share price, which is the price before the leak. If you look at it, 46% premium is very much in line with similar transaction of that score because, I mean, it's a big transaction. I'm referring there to the premium paid by CGEN, Horizon -- for CGEN, Horizon, and Alexion, which are exactly in the same ballpark.

That price corresponds to a 17% lower level than the peak price and at $211, just for your information. So we made an offer and we paid a premium based on an unaffected share price at $120, which was 44% below the peak. So I think that we can --

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

(inaudible) there anyway.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

Yes, exactly. So, we came in at the right time, I would say, I mean, making a market-related premium share price at the time we offer for the unaffected share price that was 44% below its peak a year ago.

And just -- I want to confirm as well just to avoid any misunderstanding. We are actually, in our model, close to both the consensus by product and globally and close as well to the Insmed sales plan. While I reiterate it as well, there are $14 billion, the figure, that is mentioned which is not risk-adjusted, which is not -- when we do evaluation anyway, we need to do some risk adjustments obviously.

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

Manuela, anything you want to add to the sales force question?

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

No, I think you described it very nicely, Belén. This is not an either/or. Like DUPIXENT remains highly valued and important part of our immunology strategy, and that won't change. That continues. It's a key priority for us as a company.

And this is really a complementary strategic fit to the existing alliance. It allows us to serve more respiratory patients, other respiratory patients out there with high unmet needs. And as you said, Belén, we're building on strong capabilities that we have as a company in the area of diagnosing patients and the areas of serving patients -- patient services, market access, and other things that we do as a company at large. So really excited about that.

Operator

James Quigley, Goldman Sachs.

James Quigley - *The Goldman Sachs Group, Inc. - Analyst*

I've got one on Brinsupri, one on TPIP, and a very quick financial one. So for the ex-US opportunity for Brinsupri, consensus seems to only really be modeling US and Japan, France, while you just said you're quite close to consensus. So how are you thinking about the ex-US, ex-Japan opportunity? How much investment could be needed here for Sanofi?

And again, just to confirm, is that included in the peak sales expectations? And then maybe another quick one there, I don't think there is, but are there any MFN considerations there as we think about that ex-US launch?

And then on TPIP, on the intellectual property -- again, Paulo, as you said, it's a prodrug. There has been some litigation in this space previously. The FDA treats prodrugs as different molecules. But how confident are you in the strength of the IP around TPIP across the indication and under investigation, and what are the risks there?

And then very quickly, financial one, what is the range of the cost of debt we should assume for the deal?

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

Very good questions, James. Manuela, want to start with the ex-US?

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

Yes, I can maybe address ex-US and also the IP question. So ex-US, as you said, is definitely -- there is an opportunity. It's early today, right, when we think about it, but there's absolutely an opportunity for geographic diversification.

When it comes to Brinsupri in particular, as part of our modeling, we have obviously considered MFN implications. And we're going to look at that in more detail, what more can be done in terms of geographic expansion. Because given our global scope as a company, it's definitely one of the opportunities we see, which has been partially included in the business case, but with discipline, again, given MFN considerations.

And then on the patent question, IP for TPIP, as you said, we currently expect that the patent estate that we have for TPIP goes well into the 2040s. So we feel confident about that, but it's too early to speculate around these things as well. And of course, as we will do for other assets that we also have in our portfolio, we will make sure that we complement the patent estate with additional innovation as we go along.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

James, on the model that we built, it's essentially in line with the consensus, which is predominantly US and Japan. There is very little outside of that, which we are on the conservative side there.

And as far as the cost of debt is concerned, you can make an assumption of 5.5% of interest rate, which is pretty much in line with what the market is today -- where the market is. As I said earlier, we have already secured the financing, at least for a bridge financing, and we'll refinance it publicly very soon.

Operator

Alyna Shamsi, Jefferies.

Alyna Shamsi - *Jefferies - Analyst*

I was just wondering if you could give some color on how quickly Sanofi expect net debt to EBITDA to come back to below 2 times. And then perhaps, could you give us a sense of how competitive the bidding process was here, too?

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

We don't comment on the competitive process. Anyway, it's not worth to comment.

Just on the net debt to EBITDA ratio, I just want to clarify because I saw some papers indicating that we could be above 3 in terms of net debt to EBITDA. We will not be. We will be far below 3 to start with, I mean, at the end of '27, and then we will deleverage very quickly.

So this will be a key priority for us. And we will go down very fast in terms of deleveraging. Once again, starting significantly below 3 at the end of '27.

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Operator

Thibault Boutherin, Morgan Stanley.

Thibault Boutherin - *Morgan Stanley - Analyst*

Just a question on the comment on EPS accretion by the end of '28. Should we understand this as not necessarily accretive at '28, but turning accretive potentially later, maybe Q328, Q428? Is that what this comment means?

And then just if you could tell us what you factor in terms of competition for Brinsupri, given the sync Phase 3 data next year for verducatib, which could be on the market relatively fast? And there's also a follow-on drugs from a Chinese company. So if you could give us a little bit of detail on how you see the competitive landscape for Brinsupri going forward?

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

Thibault, on the EPS question, you're right. When we said EPS accretive by the end of '28, it means rather maybe not necessarily for the full year of '28, but certainly at the end of '28. I'm not eliminating the fact that we could get to an EPS accretion in '28, but as you know, we want to underpromise and overdeliver, which is the reason why we give an indication which is rather conservative. But anyway, by the end of '28, we'll get there, which means Q4, maybe before.

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

Manuela, you want to comment on the competitive environment that we factor in the business case?

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

Absolutely. I think, first of all, as Belén outlined earlier in her opening remarks, NCFB is an area of high unmet need with quite a sizable patient population. So there's definitely an opportunity for more than one player. We have factored in additional competition in our models in line with expected readouts and expected approvals. So that has been all modeled in.

And the only thing I would say is, of course, those still need to materialize. They're still all in development, so we will see what that looks like. But yes, we have factored in competition into our modeling.

But given the strength of Brinsupri and the opportunity to really establish that asset in that time frame before competition launches, we also see a real opportunity to continue to grow beyond that. And there's a lot of opportunity to grow through that market and create awareness.

Operator

Richard Vosser, JPMorgan.

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

A couple, please. Just going back to the synergies and thinking about the R&D comments, how are you thinking about that integration of the Insmed budget into Sanofi's budget? Would you make room within your budget? So could your budget go down to accommodate that spending? Just thoughts there.

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And then secondly, thinking about future BD&L moves, how are you thinking about that early stage? Are we thinking Phase 1, Phase 2? What sort of thoughts do you have for the next moves that could be added on?

And aligned to that, you sold half or just over half of the Opella stake a number of years ago. That -- the rest of the stake is sitting there, not doing a lot. So how are you thinking about timing mechanism for potentially monetizing that to unlock further firepower?

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

Okay. So Richard, on the R&D, we will probably take from Insmed about EUR1 billion -- $1 billion of cost coming from R&D next year in our P&L coming from Insmed. We need to figure out exactly the way -- the exact number, but directionally, that gives you an idea. It's too early to tell you what that means for our total budget, '27; and we'll come back to you at the end of Jan.

Anyway, as we have indicated earlier, we are not in a position today, given the setback that we had last year, to significantly increase or to increase our budget for R&D. So we'll be able probably to accommodate part of this $1 billion within our own budget. But I can't tell you for the time being, and I don't think the public can either, to what extent. But we'll come back to you, maybe providing a little bit more color, on December 9, certainly at the end of January.

On Opella, first and foremost, Opella does very well. So you may have seen it because they are raising public debt. So there is some available information. They are growing nicely, which is very great. They are increasing their margins. We are very happy with it.

We put EUR11.5 billion when we sold the first 51.5%. We still have 48.5%. We don't think that this is the time now to exit. We plan that probably an exit should probably happen at the -- around probably 2030, depending on market conditions and so forth at that time.

We don't need it, by the way. In order to deleverage our balance sheet, what I mentioned earlier, we did not assume that this deleveraging will come from Opella. So we keep that as another opportunity probably to be actioned and activated maybe at the end of the decade or early in the next decade.

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

Let me address the business development question, Richard, because I defined Insmed as an anchor acquisition, as the one that is going to give us the traction to secure long-term growth and contribute a differentiated pipeline. So once we have landed this acquisition and for the coming months, even if we deleverage fast, as François mentioned, we are going to go for smaller either bolt-ons or a specific earlier stage pipeline, probably post-POC.

So Phase 1, Phase 2 would be definitely part of the options as well as preclinical assets if we believe that this is going to be of interest to us. But at the end, we are running in parallel to our external innovation moves. We will continue to groom our internal innovation engine and investing in our R&D in order to deliver more shots on goal and eventually bring more products to human, ultimately, to the market.

Operator

Seamus Fernandez, Guggenheim. Are you there?

Seamus Fernandez - *Guggenheim Securities LLC - Equity Analyst*

Yeah, I'm here. So just a couple of quick questions, and congrats on executing the deal.

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First question is on TPIP. Can you help us understand the realities, as you see it, for the opportunity in PH-ILD? In particular, there are some claims and potential issues that this could fall a foul of FDA's rules around orphan drug exclusivity. So just interested to know if you see any issues there.

I think our internal assumptions are that small differences can actually result in success for a second product. But just wanted to get your assumptions on the PH-ILD opportunity in the context of that potential challenge from the existing competitor.

And then separately, as we think about just the overall IP position, can you just remind us what percentage of patients could potentially fall under IRA? Or do you believe that Brinsupri would fall outside of IRA issues? I believe this is not an orphan indication, so just interested to understand that a little bit better.

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

So Paulo, can you please start with the PH-ILD question?

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

Yeah, of course, happy to. It is, of course, a great question. And we are going to continue the dialogue with the FDA that our colleagues at Insmed have already started.

As you mentioned, there's usually a bit of flexibility here, and this is considered as a new molecular entity. I don't think -- we don't expect that there's a need to generate superiority evidence. In this particular case, given the mode of action, I think it is going to be based on, let's say, the type of different administration profile, pharmacokinetics, potentially safety, et cetera.

But it is obviously an ongoing dialogue that we're going to keep having. I don't want to say too much before actually having that dialogue with the agency. But I think internally, we feel confident that that's possible.

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

Manuela, do you want to take the assumptions we have made for IRA?

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

Yes, happy to. So on -- first of all, on the Medicare population, given the elderly population that you tend to treat with NCFB, there's definitely a sizable expectation of Medicare patients here. And we have made assumptions that there will be an IRA impact in our modeling, yes.

Operator

Justin Smith, Bernstein HE.

Justin Smith - *Sanford C Bernstein & Co LLC - Equity Analyst*

It's Justin Smith, Bernstein. Just a quick one with regards to Belén's comment about using the transaction to build immunology capabilities ex-alliance. So I recall that that was part of the rationale at Blueprint. So Blueprint plus Insmed, does that give you the scale you should need, or should we be thinking that actually, more transactions would be needed to maximize the scale of that platform?

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

Well, Blueprint is closer to rare diseases than it is to immunology, and we are now leveraging our rare disease team to support and to further develop revenues in acceleration of that business in the future. Definitely, Insmed is complementary to anything that we have built before, right, and it's complementary also to Regeneron, which we have insisted several times during the call, but we haven't said why.

So mostly, the efforts that we have around the Regeneron alliance goes to dermatology and allergy, right, while, you are right, Blueprint is contributing to respiratory. However, additional scale will be brought by the acquisition of Insmed, giving us a more competitive footprint in the US. Manuela, anything you want to add?

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

Yeah, just to go a little bit deeper there. Because you're right that initially, we looked at immunology. However, as we dug into it further, we really felt, as Belén was saying, that [Avocate] and Blueprint were better suited in the rare disease portfolio, given the prescriber base of heme-oncs and allergies, but in particular, heme-oncs for systemic mastocytosis. So that's why that remains fully dedicated within rare.

And then we see great value, as Belén said, in the Insmed sales force that will complement everything that we have both on rare with Blueprint, but also on the alliance with DUPIXENT. And we're excited to actually welcome the Insmed talents to really help us create this additional team.

Operator

Steve Scala, TD Cowen.

Steve Scala - *Cowen and Company LLC - Analyst*

I have two questions. The first question is similar to other questions that have been asked, but I just wish to clarify. Can the Insmed assets be added to the Regeneron alliance at some point in the future, or is that unlikely or not possible and that is why Sanofi plans to build an independent immunology capability?

The second question is, I am curious, what should be our expectation for the meeting on December 9, particularly given that the company has said quite a bit in recent months? Is this a review of what has already been said or an opportunity for new news and new perspectives on the future?

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

So can this be added to the Regeneron alliance? This is not the plan today, right, but we have no limitation to do it if the partners would decide to do so. There are no limitations. We are building our own footprint in immunology with this acquisition. And as said, everything that we -- the value that we can bring through Insmed is very complementary to what we are doing with Regeneron.

For December 9, what we will do is to show you additional strategic insights around the exercise that we have been conducting during the last three months and what is going to be the disease areas in which we plan to focus with more details that we have done during the quarterly calls and today, right, and what are the consequences for Sanofi coming from that updated strategy.

We are going to give you more detail on what the R&D transformation will bring and what can you expect the consequences will also be. And last but not least, we are going to give you an updated financial outlook with a bit more perspective on what the new decisions that

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we have made and implemented at this time will be on the financial outlook. So ultimately, you see the implications of all the decisions that we have been making in the last few months in this context for the financials.

Operator

Emmanuel Papadakis, Deutsche Bank.

Emmanuel Papadakis - *Deutsche Bank AG - Analyst*

Just a follow-up really on the IP for Brinsupri, because -- apologies if I missed it, but I'm not sure if it was answered earlier. Can you just confirm your assumptions for composition and map expiry in the US and Japan, indeed? And would also be helpful to hear if your diligence led you to make any assumptions around either lifecycle management or follow-on programs on that product.

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

Manuela?

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

Yes. So on Brinsupri, the assumption is that the patent life goes until the end of the next decade. And as I mentioned earlier on the TPIP patent estate, we will also look to complement that patent estate with additional innovation, as we would usually do.

It's too early to speculate on what LOE dates, et cetera, look like, but definitely end of the next decade for the patent expiration in the US and a little bit later for Japan. I think Europe is the beginning of the subsequent decade, but we can confirm Japan specifically as well.

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

It's also related to Brinsupri. Emmanuel, can you confirm that the diligence for LCM on follow-ons is related to what products?

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

He's back.

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

Emmanuel?

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

Yeah. Sorry, I was muted. Yeah, exactly. My question was relating to lifecycle management or follow-on programs for Brinsupri. But any other comments you have would also be welcome.

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

Yeah. Manuela?

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

So follow-on pipeline assets, you mean, for Brinsupri?

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

And lifecycle management.

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

Lifecycle management, okay. So for Brinsupri, there's several opportunities. There's definitely the opportunity -- because the label for Brinsupri is quite a broad label. So as we said earlier, the current treatment is predominantly after [to access] the patients even though the label in the US, in particular, is broader than that. So definitely, that is an opportunity for life cycle management and generating more data accordingly.

And then the second one is really NCFB with comorbid, either COPD or asthma. That is also an opportunity that we're looking at. So those are specifically the things that we have outlined. Especially, the comorbid opportunity can be quite a sizable opportunity, but we will definitely learn more about that as we go along.

Operator

Dominic Lunn, UBS.

Dominic Lunn - *UBS - Analyst*

So oncology is looking increasingly isolated as a business. So is there any opportunity to make divestments here and double down on your core areas of immunology and rare? And then just a quick one on the modeling. Can you keep the benefits from the tax loss carried forward upon integration of Insmed?

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

I think on the disease area strategy, this is exactly what we are going to discuss with all of you on December 9. But at this time, we are not planning any divestment of any business. We are looking at the strategic options. And once again, on the basis of the decisions we have made, we will communicate to you what are the strategic options that we are looking at for those areas in which we are superscaled.

Francois Roger - *Sanofi SA - Executive Vice President, Chief Financial Officer*

On the tax, I'm not sure exactly of which benefit you are talking specifically about. But anyway, we are trying always to reap any benefit that we can take from that is -- that we find in the company that we acquire. But I think that if I understand properly what you say, the answer is yes for some specific tax benefit that we found in the company.

Operator

Naresh Chouhan, Intron.

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Naresh Chouhan - *Intron - Analyst*

Can I also ask just a more specific question on Brinsupri sales in Europe, please? Obviously, there are some MFN constraints, and consensus -- Insmed consensus has very little ex-US. Can you help us understand where you think you can or can't launch? And should we assume material sales in Europe by 2031?

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

Manuela?

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

Yes. So as we said earlier, we have looked at Europe and other geographies as well, ex-US and Japan where the product is launched. As you probably know, Insmed has received EMA approval, so there's definitely an opportunity there.

We have specifically looked at a couple of geographies. I'm not going to go into details in Europe, but there are geographies like Germany where we believe there might be an opportunity. And we will more broadly think about geographic diversification, as I said earlier, to see which other markets could play a role within the MFN guidelines, as we said earlier, because that is important.

But we have the aspiration to make Brinsupri available to as many patients and as many countries as possible within MFN considerations, yes.

Operator

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

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