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EDITED TRANSCRIPT

MRK.N - Merck & Co Inc to Acquire Verona Pharma PLC

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OVERVIEW:

Company Summary

REFINITIV

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PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Company Incorporated, Rahway, New Jersey, USA Investor Event announcing the acquisition of Verona Pharma Public Limited Company.

(Operator Instructions) This call is being recorded. If you have any objections, you may disconnect at this time.

I would now like to turn the call over to Mr. Peter Dannenbaum, Senior Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum *- Merck & Co Inc - Senior Vice President - Investor Relations*

Thank you, Ivy. Good morning, everyone. Welcome to Merck's investor call highlighting the announced acquisition of Verona Pharma.

Our agenda this morning includes Rob Davis, Merck's Chairman and Chief Executive Officer, who will lead off our presentation. Rob will be followed by Dr. Dean Li, President of Merck Research Laboratories; Jannie Oosthuizen, President, Human Health US; and Caroline Litchfield, Chief Financial Officer. Q&A will follow the presentation.

Before we get started, I'd like to remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the safe harbor provision of the US Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of our company's management and are subject to significant risks and uncertainties. If our underlying assumptions prove inaccurate or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Our SEC filings, including Item 1A in the 2024 10-K, identify certain risk factors and cautionary statements that could cause the company's actual results to differ materially from those projected in any of our forward-looking statements made this morning. Merck & Company Incorporated, Rahway, New Jersey, USA undertakes no obligation to publicly update any forward-looking statements.

During today's call, a slide presentation will accompany our speakers' prepared remarks. These slides and our SEC filings are posted to the Investor Relations section of our company's website.

With that, I will turn the call over to Rob.

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Thanks, Peter, and good morning, everyone. Merck is entering a period of rapid transformation. Our pipeline has expanded dramatically and continues to advance successfully. In recent weeks, we've announced a significant number of important data readouts and approvals, which reinforce our confidence in the strong progress we're making.

We're building on past commercial successes and are now launching important new medicines and vaccines. In fact, we expect to benefit from approximately 20 additional new growth drivers in the coming years, almost all of which have blockbuster potential.

In short, our science-led strategy is working, and we are confident in our future. But as we've said before, our work is not finished, and we continue to assess science and value-driven business development opportunities with urgency and an eye toward driving near- and long-term growth and value creation.

So today, I'm very pleased to speak to you about the acquisition of Verona Pharma. We've tracked Verona's progress for a number of years, including the success they've had both clinically and now commercially, and we're impressed by what they've achieved to date, and are very happy to bring this team to Merck and to help enable the realization of their vision. This transaction is another example of our company acting decisively when compelling science and value align, and we're confident in the benefits it will provide Merck and our shareholders.

Verona brings us Ohtuvayre, the first novel mechanism for inhaled maintenance treatment of chronic obstructive pulmonary disease, or COPD, for adults in over 20 years. Ohtuvayre was successfully launched by Verona in 2024 and is experiencing very rapid uptake due to the substantial clinical benefit it provides patients suffering from COPD, a very large disease area.

The acquisition of Verona is consistent with the business development strategy we've communicated and is based on the compelling science behind Ohtuvayre. The addition of Ohtuvayre strengthens and complements our cardiopulmonary portfolio and addresses an area of significant unmet medical need.

Ohtuvayre also provides us with another important building block as we transition to a more diversified future. We're very confident in its sustained growth trajectory and expect to achieve multibillion-dollar peak commercial potential, and it will add to our revenue growth in both the short and long term. We're excited to welcome the strong science and talented people of Verona to Merck and look forward to benefiting from their complementary skills and further contributions.

Importantly, we're well positioned financially to complete this transaction while maintaining our ability to pursue additional business development opportunities. And we remain energized and highly focused on delivering innovative medicines and vaccines that address important unmet needs and sustaining our success over the long term.

We're now well on our way toward transitioning to a portfolio with a far more diversified set of future growth drivers. And the addition of Ohtuvayre is another step in positioning us to successfully navigate the KEYTRUDA LOE over time. We recognize there is more to do and remain committed to advancing our internal pipeline and supplementing it with additional science-led external innovation.

With that, I'd like to turn the call over to Dean, who will speak more about the strength of the science and clinical data underpinning Ohtuvayre's profile.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Thank you, Rob. Good morning, everyone. It's great to be here with you this morning to speak about this announcement.

Ohtuvayre represents a compelling scientific opportunity with the potential to address significant unmet need in COPD. It aligns well with our strategy of finding the best external science to complement our internal innovation and enhances our presence and expertise in cardiopulmonology.

Chronic obstructive pulmonary disease is a broad term used to describe a progressive respiratory condition characterized by restricted airflow and difficulty breathing. Emphysema and chronic bronchitis are the two most common types of COPD. Common symptoms of COPD include dyspnea, and ongoing cough or a cough that produces significant mucus wheezing, chest tightness, and fatigue. It is the fourth leading cause of mortality globally.

COPD remains a disease with significant unmet need. Despite a number of treatment options, many patients are persistently symptomatic, severely impacting their ability to accomplish regular daily tasks. In particular, patients with exacerbations are more likely to experience even worse outcomes, with about half of these patients dying within four years of their first hospitalization for severe COPD exacerbations.

Ohtuvayre is the first inhaled therapy for the maintenance treatment of adults with COPD that combines bronchodilator and nonsteroidal anti-inflammatory activities in one molecule, and the first novel inhaled mechanism for the maintenance treatment of COPD in over 20 years.

Ohtuvayre is a selective dual inhibitor of phosphodiesterase 3 and 4, which results in increased levels of intracellular second messenger molecules, cyclic AMP and cyclic GMP, responsible for relaying signals from the outside to the inside of the cell. This mechanism of action leads to changes that relieve the symptom of COPD, including bronchodilation, reduced inflammation, and enhanced ciliary function.

Ohtuvayre was evaluated in multiple Phase 3 studies as monotherapy or in addition to background therapies in patients with moderate-to-severe symptomatic COPD. Background therapies included concurrent LAMA, LABA -- or LABA and inhaled corticosteroid combinations.

The primary endpoint was met in both the ENHANCE-1 and 2 trials, where Ohtuvayre led to an 87-milliliter and 94-milliliter change in baseline of forced expiratory volume in 1 second area under the curve over 12 hours, or FEV1. Consistent benefits were also demonstrated for peak FEV1 and morning trough FEV1 as well as across all subgroups. These results provide strong clinical validation for Ohtuvayre as a highly effective treatment for patients with moderate-to-severe symptomatic COPD.

In addition to improvements in lung function, a reduction in moderate or severe COPD exacerbations was demonstrated with Ohtuvayre versus placebo in both trials and confirmed in the prespecified pool analysis of the two trials. Importantly, the consistent benefit was shown across all examined subgroups.

Ohtuvayre demonstrated a positive safety profile in clinical trials with low rates of adverse events versus placebo. AEs greater than 1% reported with Ohtuvayre and higher than placebo included back pain, hypertension, urinary tract infection, and diarrhea. Importantly, the 48-week safety profile was similar to the 24-week profile. Overall, discontinuation rates due to adverse events were low.

Several initiatives are underway to leverage Ohtuvayre's novel mechanism of action and expand its utility through additional indications, combination therapies, and alternative formulations. Today, we will speak to two promising opportunities in more detail: the potential expansion in non-cystic fibrosis bronchiectasis, and the nebulized fixed-dose combination of Ohtuvayre plus glycopyrrolate, a muscarinic antagonist.

A Phase 2 study is ongoing in patients with non-cystic fibrosis bronchiectasis, a chronic disease marked by recurrent infection and progressive lung damage. Currently, there are no FDA-approved therapies specifically indicated for this condition. If successful, we believe this could represent an attractive indication expansion opportunity and support continued development.

In parallel, the development strategy includes investigating Ohtuvayre in a nebulized fixed-dose combination with glycopyrrolate, a LAMA therapy for the maintenance treatment of COPD. Ohtuvayre was used on top of LAMA therapy in the ENHANCE clinical trials. And in vitro data support a strong synergistic effect in bronchial smooth muscle and isolated bronchi by combining these two mechanisms. Additionally, a fixed-dose combination would enable a more streamlined option for patients and for providers.

Finally, I'd also like to echo Rob's comment and highlight Verona's strong clinical achievements and the success they've had in advancing the science in this important disease area.

With that, I will turn the call over to Jannie, who will highlight Ohtuvayre's commercial opportunity in more detail.

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Thank you, Dean, and good morning, everyone. As Dean noted, there remains a significant unmet need for patients with COPD. COPD is the fourth leading cause of global mortality, with an estimated 3 million people dying each year due to the disease and significant costs to healthcare systems.

Given the progressive nature of the disease, patients often need additional treatment to manage their condition. Over half of patients with COPD are symptomatic, with persistent symptoms like dyspnea or shortness of breath, decreased activities and potentially exacerbations, which typically require intervention or hospitalization, and often take over a month to recover from.

Common background therapies include three major classes of maintenance treatment: LAMA, LABA, and inhaled corticosteroids, and goals for COPD treatment are to manage symptoms and reduce the risk of exacerbations.

Ohtuvayre is the only product to combine bronchodilatory and nonsteroidal anti-inflammatory properties in a single molecule, and has the potential to redefine the maintenance treatment paradigm for patients with COPD. This is aligned with the medical community's goal to reduce steroid use.

Ohtuvayre was included in the 2025 Global Initiative for Chronic Obstructive Lung Disease, or GOLD treatment guidelines. Since inclusion in the GOLD guidelines, Ohtuvayre has been prescribed across a wide range of patients for the maintenance of COPD. We see ample opportunity to expand use within this indicated population over time, continuing our track record of delivering novel science-driven solutions to patients.

The patient opportunity for Ohtuvayre is significant. In the US alone, there are approximately 15 million people diagnosed with COPD, of which approximately 8.6 million are receiving some form of maintenance therapy. About 50% of those receiving maintenance treatment are persistently symptomatic, highlighting the need for additional treatment options. The US launch is just beginning. Only a small fraction of these adult COPD patients are being treated with Ohtuvayre, which underscores the tremendous opportunity to positively impact more patients and drive growth for our company.

The Verona team is already making a meaningful impact by bringing this important medicine to patients, and the launch is off to a great start. In its first eight months on the market, Ohtuvayre has generated approximately $114 million in sales, with the first quarter nearly doubling from the fourth quarter of 2024 to $71 million.

All the underlying key launch metrics have been performing very well. New patient starts grew more than 25% in the first quarter compared to the fourth quarter of 2024, and total prescriptions increased to approximately 25,000. About 60% of dispensed prescriptions were refills, which will become increasingly important, given the chronic nature of the disease.

Approximately 50% of Ohtuvayre use to date has been in patients on triple background therapy, including those on inhaled corticosteroids. Over time, we believe there's an opportunity for Ohtuvayre to be used earlier in the maintenance treatment paradigm, given its benefit-risk profile.

There has also been a strong growth in the depth and breadth of physician prescribers, reaching approximately 5,300 since launch, with steady increases in the number of prescriptions written per prescriber. We believe the strength of our capabilities and scale will lead to further increases in all of these key metrics over time.

Now let me walk through the longer-term opportunity for Ohtuvayre. We are highly motivated and well positioned to maximize the potential of this first-in-class medicine. With Ohtuvayre's broad label for the maintenance treatment of adults with COPD and favorable benefit-risk profile, we believe it has the potential to become the preferred maintenance therapy for patients who are persistently symptomatic despite being on background therapy. We will work to accelerate the launch through increased promotional resources to expand customer reach. We expect continued strong uptake of Ohtuvayre by physicians and patients, thanks to its differentiated mechanism of action and clinical benefits. And this will be enabled by the favorable payer coverage that has been established.

The COPD therapy market is large and growing. In the US, it currently represents approximately $17 billion annually and is projected to reach approximately $27 billion by 2032. We believe that with increased promotional support and education of physicians and patients, Ohtuvayre has the potential to become a multibillion-dollar therapy into the mid-2030s. We are pleased to add this important therapy to complement our growing cardiopulmonary commercial footprint.

I will now turn the call over to Caroline.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

Thank you, Jannie. Merck is in a strong financial position, allowing us to announce the acquisition of Verona, while retaining significant capacity to pursue our capital allocation priorities, including future business development, should additional attractive opportunities arise.

As Jannie highlighted, given the substantial unmet need in a large patient population and the significant benefit Ohtuvayre provides for patients, we believe there is a multibillion-dollar peak revenue potential and that it can be a meaningful driver of growth for Merck in the near term and into the mid-2030s. We are confident that this transaction has the potential to create value for patients and shareholders.

Turning to the financial details of the transaction. Merck has agreed to acquire all outstanding shares of Verona Pharma for $107 per ADS, a premium of 23% versus yesterday's closing share price, and 39% versus the 60-day volume-weighted average price. This results in a total transaction value of approximately $10 billion, or $9.8 billion net of approximately $200 million of cash and investments and debt. We have the flexibility to finance the transaction through a combination of cash on hand, commercial paper, and new debt issuance, and we expect no impact to our credit rating.

We anticipate the transaction will close in the fourth quarter of this year, subject to Verona shareholder approval and regulatory approvals, and as sanctioned by the High Court of England and Wales.

We believe this transaction will be dilutive to non-GAAP EPS by approximately $0.16 in the first 12 months, representing costs associated with financing the transaction, partially offset by Ohtuvayre's performance. We expect the transaction will result in the capitalization of most of the purchase price as an intangible asset for Ohtuvayre and amortized in our GAAP results over time.

Our balanced approach to capital allocation remains unchanged. We will use our strong balance sheet and growing cash flow to continue prioritizing investment in our rich portfolio and pipeline. We remain committed to funding and growing our dividend over time, and we preserve the ability within our strong investment-grade credit rating to pursue additional value-enhancing and innovation-driven business development transactions, which remains an important priority.

Finally, we intend to continue share repurchases this year at the same pace that we've previously communicated.

Thank you for your interest. I'll now turn the call back to Peter.

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President - Investor Relations*

Thank you, Caroline. Ivy, if you could please start the Q&A session.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Mohit Bansal, Wells Fargo.

Mohit Bansal - *Wells Fargo Securities LLC - Analyst*

Congratulations on the deal. My question is related to the expansion opportunities you talked about with the combination of LAMA as well as the bronchitis opportunity. One, how much value you are assigning to those opportunities?

And number two, since COPD is also a disease in a little bit older individuals and Medicare could come in, could this fixed dose combination be an opportunity to actually have some sort of life cycle management as well for the product in normal term?

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

So Dean, why don't you maybe just speak to some of these areas he's mentioning, then we'll speak to the valuation.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. I mean, what I would just say is it's -- we're interested in first steps next, and you're talking about what could be next. One is these combo nebulizers, you laid that out. Yes, that could be very important, not so much as a life cycle management, which is what I would leave Jannie to speak to, but it's actually I think what patients would need and want moving forward.

There's also opportunities in relationship to indication expansion. And you've mentioned one of those indication expansion. And Verona had done other clinical signal finding in other indications, so we'll just have to see what those data look like.

And clearly, there is a possibility of thinking about changes in mode of delivery, not so much in nebulizers, but in others. And those are all things that are being considered by Verona and all things that we would need to learn from Verona as we proceed with this merger and acquisition.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then in terms of the valuation, the valuation is really driven by COPD. That said, we have incorporated the potential for some of the new indications using standard POS adjustments.

Operator

Carter Gould, Cantor.

Carter Gould - *Cantor Fitzgerald Investment Advisors LP - Analyst*

Great. Congrats on the deal. Rob, you talked about desire to continue to use BD, but I guess specifically wanted to get your desire to do -- and appetite to do deals as big or bigger than Verona? It seems historically, you guys haven't really gone beyond this $10 billion to $12 billion range when we think about Acceleron, Prometheus, et cetera. The challenges post 2028 are pretty well appreciated. Is there a reluctance or sort of built-in governor that keeps you from looking at potentially larger deals?

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Yes. No, Carter, I appreciate the question. As we've said in the past, our strategy is aimed at looking at where we see a great science opportunity, like we have here, bringing in a first-in-class new mechanism of action and where we see good science, strong science, and it fits within our strategy and portfolio. If we can see value, we move.

And as we've talked about in the past, the sweet spot we see is that $1 billion to $15 billion range. But as we've also consistently indicated, we're willing to go beyond that for the right opportunity. And we continue to be interested in looking at a range of opportunities from what are early stage assets, Phase 1, Phase 2, as well as all the way up to commercialized assets like what we've done here. It always starts with the question of science, portfolio value, but we are not foreclosing any opportunities, and we are very interested in continuing to do further BD to augment what we have, which is a very strong internal pipeline we're going to accelerate.

Operator

Courtney Breen, Bernstein.

Courtney Breen - *Sanford C. Bernstein & Co LLC - Analyst*

This one might be for Jannie, specifically really thinking about the scaling capability. I'm interested in what parameters that you expect that will be able to really help with scaling and how much overlap there is with the current commercial business and the capabilities you're deploying for other assets? And should we be expecting that relative to consensus expectations for Verona's revenue trajectory right now, that the scanning capability could accelerate those expectations or increase the peak expectations? So hopefully, you can give us some details there.

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. Thank you, Courtney. Yes, good question. So I think that is really something that we as Merck bring to this product in terms of adding our scale and commercial excellence behind Ohtuvayre. Obviously, we have an anchor product with WINREVAIR in this cardiopulmonology space. And it's not an exact overlap, but it's an area from which we can operate with strength, both with commercial as well as with clinical capabilities moving forward.

In terms of where will we take this, I think as you've all seen, Verona has done a good job in terms of the launch trajectory in the first year, and we are certainly determined to continue with this momentum. So we will work hard to pick up on that momentum and continue to take it forward and then really expand our commercial footprint in terms of reaching more prescribers.

We've seen an inflection every time there's additional sales reps coming in, that sales go up. Obviously, as you reach a broader prescriber base, there's about 14,500 physicians prescribing in this space. So I think our scale brings a good ability to expand fairly rapidly into that broader prescriber base, educate, and get Ohtuvayre to be added to existing background therapies, especially in those patients with persistent symptoms.

As I said earlier, this area is going to expand from about $17 billion today to $27 billion by 2032, so there's ample growth opportunity. Dean spoke to the unmet need that we can continue to address with this asset, as well as further life cycle development. So I think there's an ample opportunity to build this out into a significant business and a huge impact for patients over time.

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Maybe I just could add a little bit to that. Obviously, I also appreciate your question about consensus. And I would just say, obviously, we share the analysts' excitement about the opportunity, given the significant unmet need that remains for patients with COPD. And while there are other products that treat in the space that have meaningful market shares, this is the only one with a differentiated mechanism, the dual mechanism that Dean spoke of, bringing nonsteroidal relief on both the dilatory and anti-inflammatory spectrum, so that's very important. As such, we continue to -- we're going to really do everything, as Jannie says, to maximize the penetration of this.

I don't want to speak specifically to consensus, but I would just say, as Jannie has said and I said earlier, we are very confident in the opportunity of this being at least a multibillion-dollar product. And as we move forward, we'll determine what data best to share to give you a sense of our progress. But I just would leave you with, we really believe this has the potential of being the preferred drug for maintenance therapy for COPD patients based on that unique combination of bronchodilatory and non-steroidal anti-inflammatory effects I mentioned. So we're excited about this, and I think we're going to really be able to do good things.

Operator

Evan Seigerman, BMO Capital Markets.

Evan Seigerman - *BMO Capital Markets (US) - Analyst*

Maybe walk me through some more details kind of on the potential commercial synergies you might have with your current respiratory franchise. Can you leverage the folks that you have marketing and helping with WINREVAIR? Do you really need any more primary care-focused buildout here?

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. No, good question. So I think that definitely is an anchor position to start from. That obviously is across pulmonology as well as cardiology. Most of the high prescribers are more focused on PAH specifically, but no doubt, there's a lot of commercial synergy.

And even if you look at how WINREVAIR is positioned, the positioning of WINREVAIR as a treatment is -- there's a lot of similarities with how we're bringing Ohtuvayre or how Ohtuvayre is coming to this market with a broad label that can be used across numerous -- different patient segments as they progress in their disease journey. So I think there's a lot of similar approaches in terms of positioning and commercially how we will go after the education and the adoption of this treatment.

You're right, I mean it will go beyond. The WINREVAIR PAH community is a much smaller, much more concentrated rare disease base of prescribers, whereas with COPD, we're looking more at 14,000, 14,500 prescribers in total that really makes up the bulk of prescriptions. So we believe as Merck, we can truly expand into that prescriber population. And we will continue to look at -- Dean can maybe speak to some of the pipeline opportunities as we look at other assets coming into this space that we will continue to be able to leverage forward both from a clinical as well as from a commercial perspective.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. I'll just say we're focused on Ohtuvayre in COPD. We're talking about WINREVAIR in PAH, but we had MK-5475 that we're exploring in this space, we're exploring tulisokibart in this space, and MK-2225 in this general space. So we believe that there will be ample possibilities of synergy, not just on the commercial side, but the clinical side, the medical affair side, and in some sense, for many of these pulmonary more focused diseases from the research side.

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

And you asked about primary care. Like I wouldn't say this is exactly primary care, like I think this is going to be a very efficient buildout in this space in terms of how we commercialize. So again, if you look at that 14,500, those are really pulmonologists as well as high respiratory condition treaters, and it's not really a true primary care place. So it's going to be, we believe, a very efficient buildout to commercialize this product.

Operator

Luisa Hector, Berenberg.

Luisa Hector - *Berenberg Capital Markets LLC - Analyst*

I wonder if you could say something more on timing. Why now?

And then just perhaps some color on the ease of use of the nebulizer. It looks pretty straightforward, but it's twice a day. So what are you assuming for treatment persistency and perhaps compliance? Should we model to 12 months' use twice a day?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes. So I'll just state, when one looks at the data, and then I'll turn it to Jannie, what is really interesting to me is -- I spoke about the sort of improvement in FEV1, but what's really interesting is that peak. That peak FEV1, when you look at it for that two, three hours, I mean, that's substantial for our patient. And it's twice -- it's essentially twice a day that they feel, like, really differently. And that's the objective, but I believe that all the patient reported sort of feedback has justified that. And so I believe that if you look at the FEV1 curve, it might suggest, to me, that a patient who really wants to breathe and have more O2 in their air will want to use this. But in terms of the commercial persistence in this, I'll turn it to Jannie.

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. No, that's a good question. I mean, this is a medicine that is delivered through a jet nebulizer, and patients take about five to seven minutes twice a day to deliver the drug. That is the only way to deliver this treatment mechanism right to patients.

So -- and to Dean's point, patients really feel good. So -- and if you take into account that this is really a population with persistent symptoms, I think it's going to be that need to feel better that drives patients coming back to the nebulizing in the morning and potentially in the evening.

Having said that, we obviously take this in as one of the set of assumptions in terms of how we look at compliance in terms of our projections and forecasts, so it does feature. It could, by patient, vary from time to time, depending on where they are in terms of their symptomatology. Some weeks, they might nebulize twice a day, and maybe at times, just once a day. So these are obviously -- this is a factor that we do take into our set of assumptions of how we look at our projections overall.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then in terms of why now, first, I'd start with our company has business development as a top priority. So we continue to assess a number of different assets, companies, and where value and the science aligns, we will act. Verona is one such company we have been following for some time. We're very excited about the science, the unmet medical need, and the opportunity to add value for patients and shareholders with this transaction, so that's why now.

Operator

Trung Huynh, UBS.

Trung Huynh - *UBS Limited - Analyst*

Congratulations on the deal. So just a couple here. First on positioning. Do you see a shift to the use in potentially more moderate patients using this? So the patients with single bronchodilators, dual bronchodilators. Are you just -- could there be a guideline in the future where they try to avoid using steroids?

And then just on EU, how you're thinking about the regulatory path forward there, given the ENHANCE trials were done against placebo, and EMA typically requires an active comparator? Does your multibillion target include ex-US?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So let me take one part of that question, which is the question about steroids. So steroids are really important drugs in this space, but they have a number of adverse effects that is well accustomed to and know. And there has been a trend to see, is there a different way to produce anti-inflammation without all the risks associated with corticosteroids? So there is a possibility that this could create that opportunity.

The other point that I would just emphasize is we can talk about FEV1, but I would point to the exacerbation data. And I think the exacerbation data is not head-to-head, and so one has to be a little bit careful of how I say what I'm about to say, but if you look at the point estimates of 36% and 43% reduction of chronic -- in terms of COPD exacerbation, and you compare that to steroids or biologics or any other thing, you would sit there and go, that point estimate of 36%, 43% is quite a stark number in terms of what it can do to reduce chronic exacerbation. It's not head-to-head, but that -- those numbers are one that catch my eye.

Jannie?

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. And then, Trung, in terms of your question, could this product be used earlier? Absolutely. I mean, the label is very broad. This can be added to any background therapy for maintenance patients with uncontrolled disease or persistent symptoms. In fact, Verona has said that their current sales is coming about 50% from patients on triple therapy, which would be your more severe patients, so the other half is coming from patients earlier, right? So you could add this. Even in mild disease, there's still a number of patients with uncontrolled symptoms, so it could be added earlier on.

And again, when you add Ohtuvayre, you really add two, three effects. You add the bronchodilation as well as the anti-inflammatory activity, which has never been an option before in one product. So I think that's a powerful additional treatment for patients that are uncontrolled.

And the guidelines, the GOLD guidelines already support this, right? So those guidelines are really in place, they are widely followed. So we believe as we move forward and specifically as physicians gain more experience, we see them starting to use it early and earlier for patients. So we are very confident that we're going to see an expansion into earlier use for Ohtuvayre.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And then in terms of the global opportunity, we will assess the potential filing and launch in the ex-US market, and our valuation is largely driven by the United States.

Operator

Umer Raffat, Evercore ISI.

Umer Raffat - *Evercore ISI Institutional Equities - Analyst*

I feel like a lot of the questions on the commercial side have been asked, so I want to focus on the duration of this asset for a second. Specifically, it looks like there's very clearly a legal bet being made here on the thermodynamically stable polymorph, and my question has two parts.

One, I'm curious, as part of the diligence process, did Merck go through all the iterations of the polymorphs that were generated as part of this existing composition, which is technically off patent already? I'm curious if you looked at those data sets on individual polymorphs, which presumably any generic would want to work around?

And secondly, will your NPV math for $10 billion still work if the duration of IP is six to seven years?

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Yes, Umer, thanks for the question. Maybe I would just start by saying as you think about the patent, and as you point out, this is -- the key patent is the polymorph patent, which is around the -- really the suspension formulation of this molecule. I can tell you that we spent significant time and diligence understanding all of the different approaches to how you could produce the polymorph, whether or not there would be workarounds around the patents, and the technical challenges that it would require. And given Merck's history in this space, if you go back even to some of the assets we had at Schering, we have a lot of people in-house who actually understand the inhaled space quite well. And we are quite confident that the technical challenges of producing around the polymorph patent is -- are very high. And so our belief that we have protection out to the mid-2030s, both in terms of the patents themselves and the risk of a workaround, regardless, we are very confident in our ability to protect out to the mid-2030s. And that was very important in the decision to move forward.

As it relates to the value, we have -- obviously, as we do in every deal, we look at a range of scenarios, we do a probabilized -- look at what we see as the probabilized value of the deal. And across all of those scenarios, we think at this price point, we are very well covered.

Operator

Chris Schott, J.P. Morgan.

Chris Schott - *J.P. Morgan Securities LLC - Analyst*

Just wanted to come back to the line extension opportunities from here, so just maybe a two-parter. First, on the non-CF indication, can you just talk about your confidence that you can see efficacy in the setting?

And then my second question is just around an inhaler for the drug. I guess how difficult and how important is that in terms of the commercial profile of this versus the nebulizer?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Let me take the inhaler sort of thing. We think the inhaler may be a very important -- something that the field will really want as Ohtuvayre itself advances at the nebulized form. So that's a place that I know Verona was interested in, and that's a place that we would be interested in. And as Rob has said, we have in-house expertise along that, given the history of Merck and Schering-Plough.

In terms of other indications, other indications that Verona has explored is, as we've said, COPD, it has been asthma, and they also have a Phase 2 with bronchiectasis, and we'll be eager to see the results on bronchiectasis as that come up -- comes out. And if that comes out as positive, it could be an important contribution to the field.

Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

And the only thing I'd add to that is the value that we've ascribed is really based on the current treatment of the nebulizer, and so moving forward with new formulations would be upside.

Operator

Steve Scala, Cowen.

Steve Scala - *TD Cowen (Research) - Analyst*

I'd like to also ask about the patents. So I'm wondering if you can identify products protected by polymorph patents that survived over the long term. It would seem to me that at best, Merck now has a 10-year patent overhang, on which we probably will never get clarity, or might there be such an event that could provide that clarity. And at worst, a franchise that doesn't last as long as it's needed. I appreciate that the Schering people have great expertise, but the competition is gaining ground as well. So how could we become more comfortable with this topic?

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Well, it starts with -- I just would reiterate our confidence in this topic and the fact that we think the patent estate is strong around the polymorph. And the workarounds, everything we see would point to you have to go back to the Form 1, which is the polymorph that is patented that we have covered.

And so I wouldn't say there's a specific clearing event I can point to, but there is ample examples of where products in this space -- in inhaled spaces have had long lives, even post the period of expiration of their own IP protections, just given the fact that the complexity of making these forms of inhaled molecules is very, very complicated. This is not something easy to do, and so that's why as we assessed it, we move forward very confident on that, and so I'd just reiterate that confidence.

I don't know, Dean, if you'd add anything, but we'll have to continue to watch it and educate all of you on this, but I can tell you, this is not something that is a strong concern to us.

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

Yes, I would just add, if we're talking about a polymorph in an oral medicine, that's one thing. But a polymorph with characteristics required for inhalation that would require you to create the same pharmacokinetics, pharmacodynamics of what the lead molecule is, is not a simple task, especially if you're looking for a stable polymorph that can do that. And so yes, polymorphs are different than composition of matter, but this space of inhalation medicine is also different than other parts of medicine.

Operator

Akash Tewari, Jefferies.

Akash Tewari - *Jefferies LLC - Analyst*

So it looks like the deal premium for Verona is more modest than what I think we've seen historically. How much of that has been biotech CEOs kind of pragmatically recognizing the takeout multiple for a small molecule (technical difficulty)? And how do you think about modeling the Verona portfolio post the IRA negotiation period?

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Yes. You broke in and out a little bit, but I think I caught the question, which is, how do we think about the premium we're paying and the fact that it could be that you have seen their stock run quite a bit over the last couple of months, and how much of that has had takeout premium in it?

But just to give you kind of the facts of where we are, if you look at where we were versus yesterday's close, it was about a 23% premium. If you look at it -- and this is important, if you look at over the 60-day VWAP, it's about a 39% premium. So in our sense, we feel like we are definitely paying a full and fair priced Verona, which will enable a good return for the Verona shareholders, but also allows us to be able to have a reasonable return as well. And so I feel very good about where we are, both in terms of the discipline this shows from our perspective, but the fact that there is a good return on the other side. I think it's a win-win for both sides as far as that relates. And then as it relates to the IRA --

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Caroline Litchfield - *Merck & Co Inc - Chief Financial Officer, Executive Vice President*

We've modeled the impact starting 2034.

Operator

James Shin, Deutsche Bank.

James Shin - *Deutsche Bank Securities Inc. - Analyst*

I have one for Dean and one for Jannie. Dean, I appreciate Ohtuvayre's dual mechanism, the FEV1 improvement, steroid reduction. But DPP1s, IL-5s, they've also shown similar effects, so is there anything else aside from maybe the exacerbations that you pointed out that sets Ohtuvayre apart?

And then Jannie, is it just a market that's so big that they can accommodate all these different mechanisms?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

So you broke up a little bit. So I would just emphasize, the mechanism of action of PD-3/4 is novel. It does that dual. I think the nonsteroidal anti-inflammatory part will become increasingly important in the field. It's already been important for the last 5, 10 years as people have gone from systemic steroids to inhaled steroids, and now trying to be more steroid-sparing, so I do believe that will be important.

There is a broad label. When I -- when you gave some of the other examples, one of the things I would just highlight is this is a broad label. It is for all patients in relationship to subset analysis of COPD, not simply those who have high eosinophils. Some of the examples that I think I heard you say is in a subset of the COPD population. And if you look at the point estimate of this drug in a broad COPD, not just in a high eosinophil, that percentage competes extremely well, and from a point estimate, is actually higher than some of the other examples that you've given.

Jannie?

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. And I would just say, to the question about penetration in the space, there's a lot of treatment options. I would say this is probably one of the most differentiated treatments that could be added to these patients. Rob spoke about it earlier that there are other treatments with far less differentiation that has captured significant share, so we believe this product with its dual mechanism could be added to any of the existing treatments.

And it brings an additional component, right, whether it's bronchodilation to the biologics, or whether it's going after inflammation for any of the other bronchodilators, I think Ohtuvayre is uniquely positioned to add a significant benefit to any of the products that is being used. And it could replace some of the early inhaled corticosteroid use, where we know there's some attempt to reduce that use, so I think this provides a different angle. Even in combination with biologics, this provides another angle of going after the inflammation, right? So I think Ohtuvayre is well positioned to be used broadly across the range of patients and treatment option combinations.

Operator

Tim Anderson, Bank of America.

Richard Wagner - *BofA Securities, Inc. - Analyst*

It's Richard Wagner on for Tim Anderson. I wanted to return to the opportunity before inhaled steroids. Jannie had noted that Verona themselves have said that half of the use is in this segment. What has been initial feedback, either within your due diligence or communicated to you from Verona, from physicians in this segment?

And in terms of the implied sales acceleration, is this going to be the near-term push by Merck, or rather, would it focus on the more severe COPD patients, who might overlap more with the WINREVAIR prescribers?

Jannie Oosthuizen - *Merck & Co Inc - President - Merck Human Health US*

Yes. That's a good question, and I'll answer it both in terms of what we've learned in diligence and also, I think what Verona has mentioned before is that when you look at it very early on the Tier 1 prescribers have adopted within the first 60 days very strongly in terms of adopting Ohtuvayre. And we've seen that once physicians start to use it in the more severe patients, which I think with any new medicine, is a logical place to start to figure out the risk-benefit ratio. But we've seen that once they start in the more severe patients, they quickly move to less severe and added to dual therapy as well.

So that gives us great confidence that there's going to be a strong position within the triple or the more severe population. But definitely, I think based on patient feedback, and I think Dean mentioned some of these patients really feel good after the nebulization for this treatment to be increasingly adopted in the earlier patients and alongside dual and maybe even single therapy for patients that still have persistent symptoms.

Operator

Asad Haider, Goldman Sachs.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Congrats on the deal. A two-parter from me. First, for Dean or Jannie, maybe just double-click a little bit further on how you're thinking about positioning in the non-CF indications, specifically with respect to Insmed's brensocatib, which could get approved there next month? And how should we be thinking about timing of that indication to reach the market?

And then with -- for Rob, just with respect to further BD, with this deal now in the bag, where else across the Merck portfolio do you now see opportunity to scale up or lean in?

Dean Li - *Merck & Co Inc - Executive Vice President, President - Merck Research Laboratories*

I'll just take the first question. It's hard to talk about positioning until we have data, and we don't have data right now. So I don't want to speculate on that until we actually see clean data that we can present and review with the Verona team and with us and with the broader community.

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Yes. And maybe just to add to that, I think Caroline said it earlier, but I'll just reinforce it. The valuation that drove this deal is COPD. We do have some assumptions of value associated with the bronchiectasis in the non-CF population, but by the time you add the probability of technical success or probability of success, so risk adjust those numbers, it's small to the total deal. So -- but it doesn't mean we're not excited about it, but I don't want that to be thought that that is the driver of the deal, it was COPD.

And then as it relates to further BD, to your point, we are going to continue to look with focus to continue to add to our portfolio, consistent with what we've been doing. The areas of focus, I would come back to what we always say, which is we first start with where do we see interesting science? So we never start with the therapeutic area, we start with where there's interesting science.

And then we look at the strategy and the portfolio overlap, which takes into account the therapeutic areas. If you look at where there continues to be a compelling science, obviously, oncology, we intend to continue to be a leader in oncology, as we've said, with a broader and more diverse portfolio there well into the next decade. We see opportunities to continue to look there. Immunology continues to be a space as well. So it's pretty broad. Cardiometabolic. It's all the areas where we play today would be things we'd look at, but it's going to start with, do we see the compelling science?

Peter Dannenbaum - *Merck & Co Inc - Senior Vice President - Investor Relations*

Great. Thanks, Asad, and thank you all for your time and interest today. As a reminder, we'll be hosting a call next Thursday, July 17, to highlight our HIV pipeline and opportunities, so hoping many of you will be on that call, and we look forward to talking to you then. Thank you very much.

Robert Davis - *Merck & Co Inc - Chairman of the Board, Chief Executive Officer*

Thank you all.
