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SCHEDULE 14A
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PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934
(AMENDMENT NO.)

Filed by the Registrant ☐

Filed by a Party other than the Registrant ☒

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule14a-6(e)(2))**

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☒ Soliciting Material Pursuant to Rule 14a-12

VERONA PHARMA PLC
(Name of Registrant as Specified in its Charter)

MERCK SHARP & DOHME LLC
(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check all boxes that apply):

☒ No fee required

☐ Fee paid previously with preliminary materials

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Filed by Merck Sharp & Dohme LLC
Pursuant to Rule 14a-12 under the
Securities Exchange Act of 1934, as amended
Subject Company: Verona Pharma plc.

This filing contains a transcript of the investor call that Merck & Co., Inc. held on July 9, 2025 related to the potential acquisition of Verona Pharma plc ("Verona Pharma") by Merck Sharp & Dohme LLC.

Additional Information and Where to Find it

In connection with the proposed transaction between Verona Pharma and Merck, Verona Pharma will file with the Securities and Exchange Commission ("SEC") a proxy statement on Schedule 14A. Additionally, Verona Pharma may file other relevant materials with the SEC in connection with the proposed transaction. Investors and securityholders of Verona Pharma are urged to read the proxy statement (which will include an explanatory statement in respect of the Scheme of Arrangement of Verona Pharma, in accordance with the requirements of the U.K. Companies Act 2006) and any other relevant materials filed or that will be filed with the SEC, as well as any amendments or supplements to these materials and documents incorporated by reference therein, carefully and in their entirety when they become available because they contain or will contain important information about the proposed transaction and related matters. The definitive version of the proxy statement will be mailed or otherwise made available to Verona Pharma's securityholders. Investors and securityholders will be able to obtain a copy of the proxy statement (when it is available) as well as other filings containing information about the proposed transaction that are filed by Verona Pharma or Merck with the SEC, free of charge on EDGAR at www.sec.gov, on the investor relations page of Verona Pharma's website at https://www.veronapharma.com/investors/, by contacting Verona Pharma's investor relations department at IR@veronapharma.com, or on Merck's website at www.merck.com.

Participants in the Solicitation

Verona Pharma, Merck and certain of their directors and executive officers may be deemed to be participants in the solicitation of proxies from the shareholders of Verona Pharma in connection with the proposed transaction. Information about Verona Pharma's directors and executive officers, including a description of their direct interests, by security holdings or otherwise, will be included in the proxy statement (when available). You may also find additional information about Verona Pharma's directors and executive officers in Verona Pharma's proxy statement for its 2025 Annual General Meeting filed on March 18, 2025 and Verona Pharma's other filings with the SEC available at the SEC's Internet site (www.sec.gov), including any statements of beneficial ownership on Form 3 or Form 4 filed with the SEC after such proxy statement. Information about Merck and its directors and executive officers can be found in Merck's proxy statement filed on April 9, 2025 and Merck's other filings with the SEC available at the SEC's Internet site (www.sec.gov), including any statements of beneficial ownership on Form 3 or Form 4 filed with the SEC after such proxy statement. Verona Pharma shareholders may obtain additional information regarding the direct and indirect interests of the participants in the solicitation of proxies in connection with the proposed transaction, including the interests of Verona Pharma directors and executive officers in the proposed transaction, which may be different than those of Verona Pharma shareholders generally, by reading the proxy statement and any other relevant documents that are filed or will be filed with the SEC relating to the proposed transaction. You may obtain free copies of these document using the sources indicated above.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This communication of Merck & Co., Inc., Rahway, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including with respect to the company's proposed acquisition of Verona Pharma, and readers are cautioned not to place undue reliance on such statements. Such forward-looking statements include, but are not limited to, the ability of the company and Verona Pharma to complete the transactions contemplated by the transaction agreement, including the parties' ability to satisfy the conditions to the consummation of the transaction contemplated thereby, statements about the expected timetable for completing the transaction, the company's and Verona Pharma's beliefs and expectations and statements about the benefits sought to be achieved in the company's proposed acquisition of Verona Pharma, the potential effects of the acquisition on both the company and Verona Pharma, the possibility of any termination of the transaction agreement, as well as the expected benefits and success of Verona Pharma's products

and product candidates. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees that the conditions to the closing of the proposed transaction will be satisfied on the expected timetable or at all, or that any pipeline candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, uncertainties as to the timing of the proposed transaction; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the proposed transaction contained in the transaction agreement may not be satisfied or waived (including, but not limited to, the failure to obtain the approval of the proposed transaction by Verona Pharma shareholders and the failure to obtain the sanction of the High Court of Justice of England and Wales); the effects of disruption from the transactions contemplated by the transaction agreement and the impact of the announcement and pendency of the transactions on Verona Pharma's business; the risk that shareholder litigation in connection with the transaction may result in significant costs of defense, indemnification and liability; general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2024 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

Acquisition of Verona Pharma plc by Merck & Co Inc Call *(Corrected version)*

Event Details

Date: 2025-07-09
Company: Merck & Co., Inc.
Ticker: MRK-US

Company Participants

Peter Dannenbaum - Merck & Co., Inc., Senior Vice President, Investor Relations
Robert M. Davis - Merck & Co., Inc., Chairman & Chief Executive Officer
Dean Y. Li - Merck & Co., Inc., Executive Vice President & President, Merck Research Laboratories
Jannie Oosthuizen - Merck & Co., Inc., President, Merck Human Health US
Caroline A. Litchfield - Merck & Co., Inc., Chief Financial Officer & Executive Vice President

Other Participants

Mohit Bansal - Analyst
Carter Gould - Analyst
Courtney Breen - Analyst
Evan David Seigerman - Analyst
Luisa Hector - Analyst
Trung Huynh - Analyst
Umer Raffat - Analyst
Chris Schott - Analyst
Steve Scala - Analyst
Akash Tewari - Analyst
James Shin - Analyst
Tim Anderson - Analyst
Asad Haider - Analyst

MANAGEMENT DISCUSSION SECTION

Operator

Thank you for standing by. Welcome to the Merck & Company., Inc. Rahway, New Jersey, USA Investor Event, announcing the Acquisition of Verona Pharma Public Limited Company. At this time, all participants are in a listen-only mode until the question-and-answer session of today's conference. 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

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 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., Inc. 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 M. Davis

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 multi-billion-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 Y. Li

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 and 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 in breathing. Emphysema and chronic bronchitis are the two most common types of COPD. Common symptoms of COPD include dyspnea and ongoing cough or 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 the 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 phosphodiesterase 4, which results in increased levels of intracellular second messenger molecule 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 symptoms 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 combination. The primary endpoint was met in both the ENHANCE-1 and ENHANCE-2 trials, where Ohtuvayre led to an 87-milliliter and 94-milliliter change in baseline of forced expiratory volume in one 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 a pre-specified pooled analysis of the two trials. Importantly, a 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. AE is 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 indication, 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.

The 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 enhanced 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

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 because of 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 includes three major classes of maintenance treatment: LAMA, LABA and inhaled corticosteroids, and goals for COPD treatment are to manage symptoms and to 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 is being 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 for 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's 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 A. Litchfield

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 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's shareholder approval and regulatory approvals and the sanction 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

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

QUESTION AND ANSWER SECTION

Operator

Absolutely. Our first question comes from Mohit Bansal from Wells Fargo. Please go ahead.

Analyst: Mohit Bansal

Question – Mohit Bansal: Great. Thank you very much for taking my question and 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 aspiring to in (00:21:22) those opportunities? And number two, since COPD is also a disease in little bit older individuals and Medicare could come in, could this fixed dose combination be an opportunity to actually have some sort of lifecycle management as well for the product in longer term? Thank you.

Answer – Robert M. Davis: So, Dean, why don't you maybe just speak to some of these areas he's mentioning and then we'll speak to the valuation?

Answer – Dean Y. Li: Yeah. I mean, what I'll just say is that 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 lifecycle 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.

Answer – Caroline A. Litchfield: 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 (00:23:06) adjustments.

Answer – Peter Dannenbaum: Great. Thank you, Mohit. Next question, please, Ivy

Operator

Next, we'll go to Carter Gould from Cantor. Please go ahead.

Analyst: Carter Gould

Question – Carter Gould: Great. Congrats on the deal. Rob, you talked about a desire to continue to use BD, but I guess, specifically want to get your desire to do – an 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. 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? Thank you.

Answer – Peter Dannenbaum: Yeah. 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 our 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.

Answer – Peter Dannenbaum: Great. Thanks, Carter. Next question, please, Ivy.

Operator

Next, we'll go to Courtney Breen from Bernstein. Please go ahead.

Analyst: Courtney Breen

Question – Courtney Breen: Fantastic. Hi, all. Thanks so much for taking the question. 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 this scaling capability could accelerate those expectations, or increase the peak expectations? So hopefully, you can give us some details there. Thank you.

Answer – Jannie Oosthuizen: Yeah, thank you, Courtney. Yeah, 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 the 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 being 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 ample opportunity to build this out into a significant business and a huge impact for patients over time.

Answer – Robert M. Davis: Maybe I just – if I 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 non-steroidal 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 multi-billion-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 think we're going to really be able to do good things.

Answer – Peter Dannenbaum: Great. Thank you, Courtney. Next question, please, Ivy.

Operator

Next, we'll go to Evan Seigerman from BMO Capital Markets. Please go ahead.

Analyst: Evan David Seigerman

Question – Evan David Seigerman: Hi, guys. Thank you so much for taking my question. Maybe walk me through some more details 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 build-out here?

Answer – Jannie Oosthuizen: Yeah, no, good question. So, I think that this is an anchor position to start from that obviously – it's 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 bring Ohtuvayre or how Ohtuvayre is coming to this market with a broad label that can be used across numerous space – 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 14,500 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 the space that we will continue to be able to leverage forward both from a clinical as well as from a commercial perspective.

Answer – Dean Y. Li: Yeah, I'll just say we're focused on Ohtuvayre in COPD, we're talking about WINREVAIR in PAH. But we have 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 and medical care side. And in some sense, for many of these pulmonary, more focused diseases from a research side.

Answer – Jannie Oosthuizen: 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 the 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 build-out to commercialize this product.

Answer – Peter Dannenbaum: Thank you, Evan. Next question, please, Ivy.

Operator

Next, we'll go to Luisa Hector from Berenberg. Please go ahead.

Analyst: Luisa Hector

Question – Luisa Hector: Hello. Thank you for taking my questions. 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 up to 12 months use twice a day? Thank you.

Answer – Dean Y. Li: Yeah. 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, 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.

Answer – Jannie Oosthuizen: Yeah, no, that's a good question. I mean, this is a medicine that is delivered through (00:33:28) nebulizer and patients take about 5 to 7 minutes, twice a day to deliver the drug. This is the only way to deliver this treatment mechanism, right, to patients. And to Dean's point, patients really feel good. And if you take into account that this is really a population with persistent symptoms, I think there'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 forecast. So, it does feature – it could, by patients, 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 obviously – this is a factor that we do take into our set of assumptions of how we look at our projections overall.

Answer – Caroline A. Litchfield: 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 values 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.

Answer – Peter Dannenbaum: Great. Thanks, Luisa. Next question, please, Ivy.

Operator

Next, we'll go to Trung Huynh from UBS. Please go ahead.

Analyst: Trung Huynh

Question – Trung Huynh: Hi, guys. Thanks for the questions. 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 guidelines in the future where they try to avoid using steroids? And then, just on EU, how are you thinking about the regulatory path forward there, given the enhanced trials were done against placebo and EMA typically requires an active comparator? Does your multi-billion target include ex-US? Thanks.

Answer – Dean Y. Li: 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 field 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 that possibility that this could create that opportunity.

The other point that I would just emphasize is we cannot buff FEV1, but I would point to that 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 those numbers are one that catch my eye. Jannie?

Answer – Jannie Oosthuizen: Yeah. 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 persistence 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 early on. And again, when you add Ohtuvayre, you really add two 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 earlier and earlier for patients. So, we are very confident that we're going to see an expansion into earlier use for Ohtuvayre.

Answer – Caroline A. Litchfield: And then, in terms of the global opportunity, we will assess the potential filing and launch in the ex-US markets and our valuation is largely driven by the United States.

Answer – Peter Dannenbaum: Right. Thank you, Trung. Next question, please, Ivy.

Operator

Next, we'll go to Umer Raffat from Evercore ISI. Please go ahead.

Analyst: Umer Raffat

Question – Umer Raffat: Hi, guys. Thanks for taking my question. 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 least 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 datasets 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? Thank you very much.

Answer – Robert M. Davis: Yeah, 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 a cheering, 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 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.

Answer – Peter Dannenbaum: Great. Anything else, Dean? Okay. Thanks, Umer. Next question, please, Ivy.

Operator

Next, we'll go to Chris Schott from JPMorgan. Please go ahead.

Analyst: Chris Schott

Question – Chris Schott: Hi. Great. Thanks so much. Just wanted to come back to the lung extension opportunities from here. So, just maybe two-parter. First, on the non-CF indication, can you talk about your confidence that you can see efficacy in the setting?

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

Answer – Dean Y. Li: 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 as a nebulized form (00:42:05). 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 then (00:42:31) asthma, and they also have a Phase 2 in bronchiectasis. And we'll be eager to see the results on bronchiectasis as that comes out. And if that comes out as positive, it could be an important contribution to the field.

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

Answer – Peter Dannenbaum: Great. Thanks, Chris. Next question, please, Ivy.

Operator

Next, we'll go to Steve Scala from Cowen. Please go ahead.

Analyst: Steve Scala

Question – Steve Scala: Thank you very much. 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 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? Thank you.

Answer – Robert M. Davis: 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 the 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 of that. And so I 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 of strong concern to us.

Answer – Dean Y. Li: Yeah. I would just add, if we're talking about a polymorph in an oral medicine, that's one thing. But a polymorph with the characteristics required for inhalation that would require you to create the same pharmacokinetics/pharmacodynamics to what the lead molecule is, it's 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.

Answer – Peter Dannenbaum: Great. Thanks, Steve. Next question, please, Ivy.

Operator

Next, we'll go to Akash Tewari from Jefferies. Please go ahead.

Analyst: Akash Tewari

Question – Akash Tewari: Hey, thanks so much. So, it looks like the deal payment 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 take-out multiple for a small molecule [Technical Difficulty] (00:46:02) and how do you think about modeling the Verona portfolio post the IRA negotiation period? Thank you.

Answer – Robert M. Davis: Yeah, 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 take-out 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 – 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 price for 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 that it 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 ROICs.

And then, as it relates to the IRA...

(00:47:19)

Answer – Caroline A. Litchfield: We've modeled the impact starting 2034.

Answer – Peter Dannenbaum: Great. Thanks, Akash. Next question, please, Ivy.

Operator

Next, we'll go to James Shin from Deutsche Bank. Please go ahead.

Analyst: James Shin

Question – James Shin: Hey, morning, team. Thank you for the question. I have one for Dean and one for Jannie. Dean, I appreciate Ohtuvayre's dual mechanism, FEV1 improvement, steroid reduction, (00:47:44) also show similar effects. So, is there anything else aside from maybe the exacerbations that you pointed that sets Ohtuvayre apart? And then, Jannie, is it just the market's that so big that it can accommodate all these different mechanisms? Thank you.

Answer – Dean Y. Li: So, you broke up a little bit. So I would just emphasize the mechanism of action of PDE3/ PDE4 is novel. It does that in dual. I think the non-steroidal 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 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 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?

Answer – Jannie Oosthuizen: Yeah. And I would just say to the question about penetration in the space, there is 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 off to inflammation for any of the other bronchodilators, I think Ohtuvayre is uniquely positioned to add a significant benefit to the product that is being used.

And it could replace some of the early inhaled corticosteroids 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.

Answer – Peter Dannenbaum: Great. Thanks, James. Ivy, we have time for maybe a couple more questions.

Operator

It looks like we have two left. Our next question comes from Tim Anderson from Bank of America. Please go ahead.

Analyst: Tim Anderson

Question – Tim Anderson: Hello, can you hear me?

Answer – Unidentified speaker: Yeah. Good morning. Thank you.

Unidentified speaker

Question – Unidentified speaker: It's Richard Wagner (00:50:41) 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?

Answer – Jannie Oosthuizen: Yes. Yeah, 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 add it 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 basically, 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.

Answer – Peter Dannenbaum: Great. Thanks, Richard (00:52:41). Final question, please, Ivy.

Operator

And our final question comes from Asad Haider from Goldman Sachs. Please go ahead.

Analyst: Asad Haider

Question – Asad Haider: Great. Thanks for taking the question and congrats on the deal. 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 indication, specifically with respect to Insmed's brensocatib, which could get approved then next month? And how should we be thinking about timing of that indication to reach the market?

And then, 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? Thank you.

Answer – Dean Y. Li: 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.

Answer – Robert M. Davis: Yeah. And maybe just to add then I think Jannie (00:53:41) 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, that 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 work 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 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 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 look at, but it's going to start with that we see the compelling science.

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 opportunity. So, hoping many of you will be on that call and we look forward to talking to you then. Thank you very much.

Thank you all.

Operator

Thank you all for joining today's conference. You may disconnect your line and have a great rest of your day.