LSEG STREETEVENTS

EDITED TRANSCRIPT

MRK.N - Q1 2026 Merck & Co Inc Earnings Call

EVENT DATE/TIME: APRIL 30, 2026 / 1:00PM GMT

OVERVIEW:

Company Summary

LSEG DATA & ANALYTICS

CORPORATE PARTICIPANTS

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

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

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

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

CONFERENCE CALL PARTICIPANTS

Carter Gould *Cantor Fitzgerald LP - Analyst*

Jason Gerberry *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Michael Yee *UBS AG - Analyst*

Asad Haider *Goldman Sachs Group Inc - Analyst*

Vamil Divan *Guggenheim Securities LLC - Equity Analyst*

Daina Graybosch *Leerink Partners LLC - Analyst*

Steve Scala *Cowen and Company LLC - Analyst*

Christopher Schott *JPMorgan Chase & Co - Analyst*

Louise Chen *Scotiabank GBM - Analyst*

Umer Raffat *Evercore Inc - Equity Analyst*

James Shin *Deutsche Bank AG - Research Analyst*

Geoffrey Meacham *Citibank - Analyst*

PRESENTATION

Operator

Thank you for standing by. Welcome to the Merck & Co., Inc. Rahway, New Jersey, USA, first-quarter sales, and earnings conference call. (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, Julie, and good morning, everyone. Welcome to the first-quarter 2026 conference call for Merck & Co, inc. Rahway, New Jersey, USA. Speaking on today's call will be Rob Davis, Chairman and Chief Executive Officer; Caroline Litchfield, Chief Financial Officer; and Dr. Dean Li, President of Research Labs.

Before we get started, I'd like to point out that we have items in our GAAP results such as acquisition-related charges, restructuring costs and certain other items that we have excluded from our non-GAAP results. There is a reconciliation in our press release.

I will also 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 2025 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 & Co., 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, along with the earnings release, today's prepared remarks and our SEC filings are all posted to the Investor Relations section of our company's website.

With that, I'd like to turn the call over to Rob.

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

Thank you, Peter. Good morning and thank you for joining today's call. Advancing and delivering breakthrough science to address unmet medical needs remains the foundation of our strategy to create sustainable value for patients and shareholders. We continue to make tangible progress in accelerating and augmenting our pipeline. And with the recent new product launches, the transformation of our portfolio to a far more diversified set of commercial drivers is now well underway.

Turning to our first-quarter results. We delivered year-over-year growth with revenue of $16.3 billion, driven by continued strength in oncology, animal health, and growing contributions from new products. We remain confident in our outlook for 2026, which Caroline will speak to in a moment.

We also achieved several important pipeline milestones, the FDA approved IDVYNSO as a new treatment option for adults with virologically suppressed HIV-1, reflecting our ongoing commitment to innovation to address the evolving needs of people living with HIV. Additionally, the FDA granted priority review for I-DXd, our antibody drug conjugate being developed in collaboration with Daiichi Sankyo for adult patients with previously treated extensive stage small cell lung cancer.

In ophthalmology, we initiated Phase 2b/3 studies in neovascular age-related macular degeneration for MK-8748, our TIE-2/VEGF bispecific antibody. The second candidate from our acquisition of EyeBio. We also presented important Phase 3 results across multiple other therapeutic areas.

Finally, in our Animal Health business, we have high expectations for long-term growth, driven by new and ongoing product launches. We're pleased to have introduced NUMELVI to the US market, the first and only second-generation JAK inhibitor for allergic dermatitis in dogs. Our planned acquisition of Terns Pharmaceuticals with its promising candidate for certain patients with chronic myeloid leukemia is another example of our science-led business development strategy in action.

TERN-701 has the potential to be a best-in-class therapy in a disease where there is an opportunity to further improve depth and duration of response for patients. Given the substantial unmet need for additional options, we believe TERN-701 has multibillion-dollar commercial potential and will be a significant driver of growth in the next decade. This transaction demonstrates our disciplined approach to pursuing business development when compelling science and value align. And we are confident in our belief that TERN-701 can benefit patients while generating value for our shareholders.

Looking ahead, we continue to expect a particularly robust period of Phase 3 data readouts from novel candidates over the next 18 months. Our portfolio is undergoing a meaningful transformation to one with a rapidly expanding and diversified set of growth drivers. We're in the midst of initial launches of over 20 new products, almost all of which have blockbuster potential across a broad set of therapeutic areas. To move with the speed and precision this opportunity demands, we announced an evolution of our commercial operating structure.

Our new business unit model, organized around products in therapeutic areas is built to drive accountability, sharpen focus and increase agility, ensuring that every part of our commercial organization delivers on the promise of our pipeline for patients. We're pleased to welcome Brian Foard to our executive team to lead our new specialty, pharma, and infectious diseases business unit.

While Jannie Oosthuizen has been appointed to lead our new global oncology and MSD International business unit. Chirfi Guindo has taken leadership of a newly formed strategic access policy and communications unit. Each of these individuals brings deep experience to these important roles.

Together, this leadership team and structure will enable strong execution of our strategy, which includes extending our leadership in oncology while building a powerful, diversified portfolio across a range of therapeutic areas. We're confident that this change will best position us to deliver on a potential commercial opportunity of over $70 billion by the mid-2030s from these 20-plus anticipated new growth drivers alone.

We're also taking important additional steps to accelerate our ongoing transformation as it relates to artificial intelligence. Last week, we announced a multiyear partnership with Google Cloud to scale advanced AI, data, and agentic capabilities across our company. This complements our recently expanded collaboration with Tempus AI designed to advance our precision oncology strategy as well as a recent agreement with the Mayo Clinic that will allow us to leverage Mayo's clinical insights and genomic data sets at scale.

Together, these efforts support improved productivity across our organization and create a real opportunity to advance the innovation in our pipeline with greater speed and with a higher likelihood of ultimately reaching patients. As we look forward, we continue to see robust demand for our innovative medicines and vaccines around the world. We're investing behind our pipeline, optimizing our operating structure and are fully committed to our purpose of using leading-edge science to save and improve lives. We're encouraged by the progress we're making and look forward to the many significant milestones coming in the months ahead.

In summary, we remain confident in our strategy and in our ability to deliver sustained growth and value for our shareholders. Before I turn the call over to Caroline, I want to recognize Sanat Chattopadhyay and Joe Romanelli, both of whom have announced the retirements from Merck. Sanat and Joe have made lasting contributions to our company and to the patients we serve, and I want to thank them for their many years of impact. And now to Caroline.

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

Thank you, Rob. Good morning. As Rob noted, we delivered growth in the quarter driven by continued strength in Oncology and Animal Health as well as increasing contributions from our many compelling product launches. Our commercial and operational execution continues to enable us to generate strong results in the short term while we advance our broad and deep pipeline and invest in innovation to deliver long-term value for patients, customers, and shareholders.

Now turning to our first-quarter results. Total company revenues were $16.3 billion, an increase of 5% or 3% excluding the impact of foreign exchange. The following revenue comments will be on an ex exchange basis.

In Oncology, sales of the KEYTRUDA family of products which includes KEYTRUDA and KEYTRUDA QLEX, increased 8% to $8 billion, with global growth driven by continued strong demand from metastatic indications and robust uptake in earlier-stage cancers. Strong utilization in tumors that primarily affect women, including breast and cervical cancer, continues to be a key contributor to growth.

In addition, we saw increased use of KEYTRUDA in combination with Padcev in locally advanced or metastatic urothelial cancer. In the US growth benefited by approximately $250 million from the timing of purchases. We are pleased with the positive feedback following the recent launch of KEYTRUDA QLEX, Sales in the quarter were $128 million. On April the 1st, we received the permanent J code, and we look forward to having an even greater impact on patients and health care systems.

Our broader oncology portfolio achieved another quarter of strong growth. Notably, WELIREG sales increased 43% to $199 million driven by continued uptake from ongoing launches in international markets and increased use in certain patients with previously treated advanced renal cell carcinoma in the US. We look forward to potentially reaching more patients with renal cell carcinoma, following positive results from the LITESPARK-011 and -022 studies.

In Vaccines and Infectious Diseases, GARDASIL sales were $1.1 billion, a decrease of 22%, driven by lower demand in China and Japan, consistent with our expectations. In the US, sales declined 10%, primarily due to timing of CDC purchases, which was partially offset by price.

In Pneumococcal, CAPVAXIVE continues to progress well, with sales of $142 million, an increase of 31%. Outside of the US, sales were driven by uptake from ongoing launches in certain markets. In the US, growth was driven by increased demand from both retail pharmacies and non-retail customers, partially offset by a reduction in wholesaler inventory.

In Cardiometabolic and Respiratory, WINREVAIR continues to have a positive impact on patients with pulmonary arterial hypertension. Global sales were $525 million, a reflection of the continued strong demand for this important therapy. In the US, we continued to see steady progress with more than 1,600 new patients having received a prescription and an increase in usage by patients with background therapies do not include a prostacyclin. Outside the US, we continue to progress with securing reimbursement and ongoing launches. Sales of OHTUVAYRE, a novel maintenance treatment for adults with COPD, were $131 million.

As expected, sales were adversely impacted by the CMS reimbursement change as well as Medicare deductible resets. We are encouraged by the prescription trends, which began to recover in March. Consistent with our strategy to maximize OHTUVAYRE's strong potential, we are making investments to reach more patients and physicians, which we expect will accelerate growth in the second half of the year and beyond. Our Animal Health business delivered another quarter of strong growth, with sales increasing 6%. Livestock sales grew 8%, driven primarily by higher demand for ruminants and poultry products as well as price.

Companion animal sales increased 4% due to new product launches and price, partially offset by a reduction in vet visits. I will now walk you through the remainder of our P&L, and my comments will be on a non-GAAP basis. Gross margin was 81.9%, a decrease of 0.3-percentage-points. Operating expenses increased to $15.2 billion, including a $9 billion onetime charge related to the acquisition of Cidara Therapeutics.

Excluding this charge, operating expenses grew 2%, reflecting increased investments in support of our key growth drivers, partially offset by benefits of our multiyear optimization effort and recognition of a portion of the external funding for sac-TMT.

Other expense increased to $318 million, primarily reflecting financing related to recent business development transactions. Our tax provision was $957 million. As a result of the non-tax deductible onetime charge for Cidara, we had a pretax loss this quarter resulting in a tax rate of negative 43.5%. Taken together, we reported a loss of $1.28 per share which includes a negative impact of $3.62 per share from the onetime charge related to Cidara.

Now turning to our 2026 non-GAAP guidance. We have narrowed the range and raised the midpoint of both our full year revenue and EPS guidance. We now expect revenue to be between $65.8 billion and $67 billion, representing growth of 1% to 3%, including a positive impact from foreign exchange of approximately 1-percentage-point using mid-April rates. Our gross margin assumption remains approximately 82%.

Operating expenses are assumed to be between $36 billion and $36.8 billion. This range does not include the proposed acquisition of Terns or any additional significant potential business development transactions. Other expense is expected to be approximately $1.3 billion. We assume a full year tax rate between 23.5% and 24.5%, which reflects the nontax deductible onetime charge for Cidara. We assume approximately 2.48 billion shares outstanding. Taken together, we expect EPS of $5.04 to $5.16, including a positive impact from foreign exchange of approximately $0.10 using mid-April rates.

It is important to note that this guidance does not include the impact of the proposed acquisition of Terns, which is expected to close soon. We expect the transaction will result in a onetime charge that will increase research and development expense by approximately $5.8 billion or approximately $2.35 per share.

In addition, ongoing investment to advance TERN-701 and the assumed cost of financing will negatively impact EPS by approximately $0.12 this year. As you consider your models, there are a few items to keep in mind. For KEYTRUDA, recall that while growth benefited from the timing of wholesaler purchases in the first-quarter, we will face a corresponding headwind in the third-quarter.

For ENFLONSIA, consistent with the first-quarter, we expect minimal sales in the second-quarter, given the seasonal nature of the product and continued high levels of RSV monoclonal antibody inventory in the market. We are actively engaging customers in advance of the RSV season and remain focused on educating health care professionals and parents on the importance of protecting infants from this potentially serious disease and expect shipments to increase in the second half of the year.

Lastly, we expect SG&A expenses to increase over the remainder of the year as we invest to maximize the impact of our recent and upcoming launches. Now turning to capital allocation, where our strategy remains unchanged. We will prioritize investments in our business to drive near- and long-term growth, including new product launches and a robust pipeline. We remain committed to the dividend with the goal of increasing it over time.

Business development remains a high priority as evidenced by our recently announced acquisition of Terns. We maintain the ability within a strong investment-grade credit rating to pursue additional, science-driven, value-enhancing transactions going forward. We are on pace for approximately $3 billion of share repurchases this year, as previously communicated.

To conclude, we are confident in the outlook for our business driven by global demand for our innovative medicines and vaccines, including our many new product launches. We remain committed to bringing forward medically significant innovations that will enable us to deliver value to patients, customers, and shareholders well into the future.

With that, I'd now like to turn the call over to Dean.

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

Thank you, Caroline. Good morning. Progress continued with a steady cadence of clinical and regulatory development. Today, I will provide updates in cardiometabolic and respiratory, oncology, infectious diseases and ophthalmology then conclude with key upcoming milestones.

Starting with cardiometabolic and respiratory. The global burden of atherosclerotic cardiovascular disease remains significant. And with recently updated clinical guidelines recommending lower LDL-cholesterol thresholds, there remains a need for innovation that is broadly accessible.

At the American College of Cardiology Congress last month, additional Phase 3 data were presented for enlicitide, our investigational oral PCSK9i inhibitor. Enlicitide is designed to reduce LDL cholesterol in a similar manner to PCSK9i antibody therapies with the simplicity of a daily pill. The Phase 3 CORALreef AddOn study demonstrated statistically significant and clinically meaningful greater reductions in LDL-cholesterol at eight weeks compared to other oral add-on lipid-lowering therapies when added to background statin therapy.

Of note, enlicitide also showed statistically significant greater reductions across key secondary endpoints, including Apolipoprotein B and non-high-density lipoprotein cholesterol. The CORALreef program has generated compelling evidence for the efficacy and safety of enlicitide As a pill, enlicitide has the potential to democratize access to a potent lipid-lowering therapy.

With clinical guidelines targeting lower LDL-cholesterol targets, the field of preventive cardiology is increasingly energized and focused on early, aggressive LDL-cholesterol reduction. Also at ACC, we showed full results from the Phase 2 CADENCE trial, evaluating WINREVAIR in adults with combined post- and pre-capillary pulmonary hypertension and heart failure with preserved ejection fraction.

WINREVAIR met the primary endpoint of reduction from baseline in pulmonary vascular resistance compared to placebo. At the 0.3 milligram per kilogram dose, WINREVAIR prolonged the time to first occurrence of a clinical worsening event, which was an exploratory secondary endpoint with a hazard ratio of 0.18. Results provide compelling proof-of-concept and warrant further evaluation in Phase 3. This is an under-diagnosed condition with an extremely poor prognosis. There are currently no approved therapies.

Moving to Oncology, KEYTRUDA now has 44 FDA-approved indications across 19 tumor types as well as 2 tumor-agnostic approvals and continues to generate evidence further transforming cancer care. In the first-quarter, the FDA and European Commission approved KEYTRUDA in combination with paclitaxel, with or without bevacizumab, for the treatment of certain patients with platinum-resistant ovarian cancer based on the findings of KEYNOTE-B96.

This is the first PD-1 inhibitor based regimen to show a statistically significant improvement in both progression-free survival and overall survival versus paclitaxel with or without bevacizumab for these patients. We also announced findings from the KEYNOTE-B15 study demonstrated KEYTRUDA plus Padcev reduced the risk of event-free survival related events by 47% and risk of death by 35% for cisplatin eligible patients with muscle invasive bladder cancer. This is the first and only perioperative immunotherapy plus ADC regimen to extend survival for these patients.

Based on these data, the FDA has accepted supplemental BLA filings for KEYTRUDA and KEYTRUDA QLEX under priority review and is targeting an action date of August 17. KEYNOTE-B15 is the sixth study of a KEYTRUDA-based regimen to demonstrate overall survival in an earlier stage cancer and, if approved, would mark the 12 earlier-stage indication for KEYTRUDA.

We also continue to make progress across the broader oncology portfolio. WELIREG, our first-in-class oral HIF-2-alpha inhibitor initially approved for the treatment of certain patients with Von Hippel-Lindau syndrome has now shown additional clinical data for patients with renal cell carcinoma across multiple stages of disease. The LITESPARK-022 study evaluating WELIREG plus KEYTRUDA in the adjuvant setting, demonstrated a 28% reduction in the risk of disease recurrence or death compared to KEYTRUDA alone.

In addition, the LITESPARK-011 study, evaluating WELIREG plus Lenvima, demonstrated a 30% reduction in the risk of disease progression or death in certain patients with advanced RCC and versus cabozantinib. Supplemental applications for WELIREG in combination with KEYTRUDA or KEYTRUDA QLEX based on LITESPARK-022 were granted priority review by the FDA with the PDUFA date of June 19.

The FDA also set a PDUFA date of October 4 for WELIREG in combination with Lenvima based on the LITESPARK-011 study. As announced last week with our partner, Eisai, the combination regimens from the LITESPARK-012 study did not meet the dual primary end point of progression-free survival and overall survival for the first-line treatment of patients with RCC and compared to KEYTRUDA plus Lenvima.

The data from the study provides learnings to the broader program. Studies from the LITESPARK clinical program, including LITESPARK-033 and 034, evaluating WELIREG in combination with zanzalintinib, are ongoing. Together with our partner, Daiichi Sankyo, we announced that the biologic license application for ifinatamab, deruxtecan, or I-DXd, for the treatment of extensive-stage small cell lung cancer in certain patients with disease progression has been granted priority review by the FDA.

This was based on results from the Phase 2 IDeate-Lung01 trial, and the Phase 1/2 IDeate-PanTumor01 trial. The FDA has set a PDUFA date of October 10. As Rob mentioned, we continue to identify external opportunities to strengthen and diversify our pipeline, most recently with the proposed acquisition of Terns Pharmaceutical.

TERN-701, a novel oral allosteric inhibitor of the BCR::ABL oncogene is being evaluated for the treatment of certain patients with chronic myeloid leukemia and has the potential to be an important addition to our growing hematology pipeline. Clinical data has shown encouraging activity with promising rates of major molecular response and deep molecular response by week 24.

Importantly, this includes responses in patients with high disease burden, who previously received multiple lines of therapy. We are eager to get to work with the talented Terns team to advance this program in a timely fashion.

Turning to HIV. Last week, the FDA approved IDVYNSO, our once-daily, single-tablet two-drug regimen of doravirine and islatravir, a next-generation nucleoside reverse transcriptase inhibitor that blocks translocation, indicated for the treatment of certain adults whose HIV-1 is virologically suppressed based on 2 Phase 3 SWITCH study.

Approval was previously granted in Japan. IDVYNSO is the first approved 2-drug regimen that does not include an integrase strand transfer inhibitor. At CROI, additional data was presented demonstrating noninferiority and a similar safety profile at week 48 versus the 3 drug, INSTI-based regimen, Biktarvy, in adults who had not previously received antiretroviral treatment.

In addition, IDVYNSO was shown to maintain virologic suppression at week 96 in adults who switched some other oral antiretroviral therapies, including Biktarvy. Islatravir, a potent long-acting antiviral that forms an anchor for additional regimen is currently being evaluated in late-phase trials as a once-weekly combination with Gilead s lenacapavir, an HIV capsid inhibitor, and separately in combination with ulonivirine, an internally developed non-nucleoside reverse transcriptase inhibitor. We plan to present data from our HIV pipeline at an upcoming medical meeting. Next to RSV.

In February, positive new data were presented for ENFLONSIA for the prevention of RSV lower respiratory tract disease in infants and children under two years of age at increased risk for severe disease over two seasons from the Phase 3 SMART study. These findings will be shared with global regulatory authorities with the intent to obtain an expanded indication.

RSV is a leading cause of infant hospitalization globally and is especially serious for children under two years of age at high risk for severe disease. These data provide additional evidence for ENFLONSIA for the prevention of RSV in younger children who remain at risk entering their second season. Earlier this month, the European Commission approved ENFLONSIA for the prevention of RSV lower respiratory tract disease in newborns and infants during their first season, based on the Phase 2b/3 CLEVER and Phase 3 SMART trial.

Next, in ophthalmology. We remain focused on retinal diseases associated with vascular leakage and neovascularization, with emphasis on improving structural and functional outcomes for patients and helping reduce the burden of certain retinal diseases. This month, we initiated two pivotal Phase 2b/3 trials evaluating MK-8748, an investigational bispecific Tie-2 agonist/VEGF inhibitor for the treatment of neovascular age-related macular degeneration. The MALBEC and TORRONTES studies are the first trials in a broader late-phase development program for MK-8748. The decision to advance development is based on promising results from the Phase 1/2a RIOJA trial.

In closing, we anticipate multiple events and milestones across therapeutic areas in the coming months, including, in oncology, please mark your calendars for our annual investor event at the ASCO Annual Meeting in Chicago on the evening of Monday, June 1, where we will outline progress on our oncology pipeline and strategy.

On the regulatory front, as noted, potential approvals for KEYTRUDA plus Padcev in MIBC, WELIREG in expanded RCC settings and for I-DXd in extensive stage small cell lung cancer. In HIV, data from the Phase 3 ISLEND-1 and 2 trials evaluating islatravir and lenacapavir, a once-weekly oral 2-drug treatment regimen in collaboration with Gilead. In cardiometabolic and respiratory, the September 21 PDUFA date for WINREVAIR for the label update based on the Phase 3 HYPERION study and the Commissioner's National priority Voucher Process for enlicitide is progressing.

In immunology, data for tulisokibart, our TL1A inhibitor, based on the Phase 3 ATLAS trial in UC trial in ulcerative colitis and Phase 2 ATHENA study in SSc-ILD.

Finally, in ophthalmology data from the Phase 3 BRUNELLO study of MK-3000, our novel Wnt agonist, being evaluated in patients with diabetic macular edema and the Phase 2 portion of the RIOJA study of MK-8748 being evaluated for the treatment of patients with certain retinal diseases. I look forward to providing further updates throughout the year. And now I will turn the call back to Peter.

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

Thanks, Dean. Julie, we're ready to start the Q&A now. We'd appreciate if analysts would limit themselves to a single question today so we can conclude the call at the top of the hour. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Carter Gould, Cantor.

Carter Gould - *Cantor Fitzgerald LP - Analyst*

Maybe we'll start on the pipeline on MK-3000. How are you thinking ultimately about dosing? The one-year BRUNELLO data is likely not going to inform much on duration interval and the Lucentis comparison is going to leave lots of questions unresolved. I fully appreciate that 40% have suboptimal responses to VEGF, but can this reach your targets if it ultimately requires every four-week dosing? Or put differently, are there reasons you have conviction about every 8-week or every 12-week dosing?

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

Thank you very much. So just stepping back, MK-3000 is our potential first-in-class novel candidate targeting Wnt pathway for retinal vascular disease. Almost all the other mechanisms are based on VEGF. And as you've highlighted, up to 40% have suboptimal response to VEGFs.

In terms of dosing frequency, when one sort of does these trials, one starts at every q4 weeks and upon doing that, then you go further from that. So we believe that one should focus on Q4 weeks, but one should not only focus on Q4 weeks. So your question, which I think alludes to, are we considering other frequencies? The answer is absolutely yes, but the initial focus is on four weeks because that is very important to get into the label. I just want to also highlight really quickly that it's not just MK-3000, it's MK-8748, which is the novel bispecific directly agonizing Tie-2 that we're also excited about, and that as well is advancing in Phase 2b/3 trials in retinal vascular disease.

Operator

Jason Gerberry, Bank of America.

Jason Gerberry - *Bofa Merrill Lynch Asset Holdings Inc - Analyst*

Had an update or a question on the WELIREG clinical update on LITESPARK-012 recently provided. And I wanted to get your sense, does this provide any concerning read-through to some of the ongoing readouts for LITESPARK-022 and the ability to see OS benefit there? And also, you have another frontline study with WELIREG plus zanza, albeit in a post-PD-1 setting. So just kind of curious if you can speak to some of the read-throughs to some of the ongoing trials.

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

We were having a hard time hearing you, Jason. Let me restate the question. And then I think I'll get it. I think what you're asking, given the LITESPARK-12 outcome, how does that make us think about getting OS in some of the upcoming LITESPARK studies and what's our overall view as it relates to WELIREG. Dean, I think that's what he was trying to ask.

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

Thanks because I could not hear quite well. In relationship to the other ones like LITESPARK-022, LITESPARK-011, which have PDUFA date in June and October, I think we're very bullish in relationship to how those will turn out. And also in relationship to the question that you have of how -- what's the readout of this trial that had three agents involved, which is a PD-1, VEGF TKI and a HIF-2-alpha, I think we are studying that data, but I would be very cautious to sit there and say that has any negative implication to other trials where, for example, we have a VEGF TKI and WELIREG or a PD-1 and WELIREG.

Operator

Michael Yee, UBS Securities.

Michael Yee - *UBS AG - Analyst*

As we think about coming up to ASCO, where you will obviously have your sac-TMT featured in lung cancer, of course, obviously, PD-1 VEGF also featured in a plenary as well from a competitor. How are you thinking about the dynamic of a sac-TMT in the context of PD-1 VEGFs and your own LaNova asset and perhaps accelerating that? And maybe just give us a snapshot, Dean, as to where we stand on these two types of programs.

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

Yes. So I'll answer the question two individually, but I will also answer what I think you're alluding to is the possibility of combinations of the two. So in relationship to the PD-1 VEGF, we're very interested in the space. We shared some encouraging early data at AACR. And our construct of the leading PD-1 VEGF is most similar to ours.

And so we're looking at our own data. But to be frank, we're also looking at the broader field as well. And so we're eager to move PD-1 VEGF forward in our trials. And one of the issues that we think in our hands, a PD-1 VEGF, if it should be better than KEYTRUDA, we have a plethora of agents that would benefit from a combination with either KEYTRUDA or a KEYTRUDA plus or a PD-1 VEGF. So we're advancing that.

In relationship to sac-TMT, I believe that at the ASCO, our strong partner and collaborator Kelun will provide OptiTROP-Lung05 in first-line non-small cell lung cancer. And I think people will look at that data very carefully because it may reflect on our global trials, which are not just within China but throughout the globe.

In relationship to the question that you said is, is there any possibility of thinking about combining those two -- the answer is absolutely yes. And we're developing the information and also taking a scan to the outside world as to where and when to best combine a PD-1 VEGF with the rest of our portfolio.

Operator

Asad Haier, Goldman Sachs.

Asad Haider - *Goldman Sachs Group Inc - Analyst*

Congrats on all the progress. Maybe just a high-level one back to BD, you've been fairly active across a number of different areas, and you're saying you're ready to pursue additional transactions. So just level set us on where you still see the biggest gaps in your portfolio that could benefit from more BD as you scan the therapeutic landscape?

What's the sweet spot now in terms of deal size? And is there a point at which the BD lever starts to diminish in importance just given your growing confidence in the growth trajectory out of the mid part of the next decade with the portfolio transformation that's already underway?

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

Yes. Asad, I appreciate the question. I would just start by saying we are very confident in the assets we have, the new assets we bought in through business development as well as the continuing progress we're making with our pipeline. So that continues and that grows. That said, we also continue to focus on business development.

And as we've said in the past, we don't necessarily target specific therapeutic areas as the first question we ask. We always ask the first question, which is where do we see a significant unmet scientific opportunity where the science is compelling and can address. And in doing that, that allows us to think about where to focus. So we start with the science. We then ask the question, how does it fit strategically and then move to the value question and where we see science and value in line we move. So that has not changed. Our approach remains to be that as our focus. From a size perspective, we continue to look anywhere in the $1 billion to $15 billion range with that kind of being the sweet spot. But as we've consistently said, we have the capacity to go beyond that for the right strategic deal. And we will, if and when we see that. So that is where we're looking. As, far as the therapeutic areas where we do continue to see interesting science, obviously, oncology continues to be an area where there's a lot going on. We continue to look. Immunology is an area where we continue to see interesting opportunities as well as cardiometabolic is probably the three most likely areas, but we are willing to be opportunistic beyond that as well.

And I guess, Peter, did remind me one part. When will we have less urgency to do a deal? My view is we can always do better. We can always grow stronger. And if we have the capacity, we will continue to invest. As Dean has said, we think in terms of one pipeline, whether it's internal or external. And so that mix of internal plus external will be an ongoing part of our strategy, you will not see that change.

Operator

Vamil Divan, Guggenheim Securities.

Vamil Divan - *Guggenheim Securities LLC - Equity Analyst*

I just had going back to WINREVAIR. I appreciate your comments about the CADENCE data in ACC. Just curious if you could provide any updated thoughts on how the discussions with the FDA are going on moving forward the Phase 2 program there, you remain confident on the clinical listening being can be the primary endpoint of the Phase 3? And then just maybe any sort of rough estimate on how long you think you would actually take to execute a Phase 3 program in this indication.

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

Yes. Thank you very much. So in relationship to WINREVAIR, I mean it's reshaping the standard of care in PAH. And now the question is whether or not we can move it to a different segment of pulmonary hypertension, those people with heart disease. The patient population that we pick is a relatively small patient population of those patients who have pulmonary hypertension and heart disease.

But it's probably one of the biggest unmet needs that I know of in this patient population, who at least the way that I would describe it is a very different patient population than that of PAH. And one could actually say is more complicated, is older and has more comorbidity. We think that the CADENCE gives that proof of concept. As I had said previously, it's fine to talk about the primary end point reductions in PVR.

But at least for me, in this patient population, it will be very important to have the endpoints that allow someone and when I mean someone, I mean patients, providers and payers to really see a compelling conglomerate of endpoints in the time to clinical worsening. And -- and that's where we will be having our discussions with the FDA.

I think the other one that will be important is defining the inclusion criteria in relationship with the FDA and also the broader community in relationship to how do you actually operationalize the clinical trial, but also for everyone to be very clear that in our minds, this is a patient population that is an orphan patient population.

Operator

Daina Graybosch, Leerink.

Daina Graybosch - *Leerink Partners LLC - Analyst*

Yes. I want to go back to ASCO and the data we're going to see from Kelun on OptiTROP-Lung05. That's a China study. And I wonder what should we keep in mind as we look at those outcomes on how it could or could not translate globally any differences in what you're doing globally? Or any other things to keep in mind.

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

Yes. Thank you very much for that question. So just stepping up at a higher level, we think sac-TMT, it is a TROP2 ADC, but we think that it has some important differentiation. And we believe that the sac-TMT has a potential to be I think Eliav has often said a cornerstone and Marjorie has said a workhorse ADC. And we have 17 Phase 3 studies, 13 are in first movers. We have an in breast, non-small cell lung cancer, gyn, gastric and bladder. When we do our trials and when we speak to our close partner, Kelun, we use the fact that they are, in some sense, doing signal finding in registrational trials in China. And we recognize China is different, but these are important data for us. In relationship to the exact details of the sac-TMT and the Kelun, I would just remind you that the OptiTROP-Lung05, they will have data. But I think it's very important to sit there and go, if -- how one thinks through that in terms of how that would read out. We are following their data very much, but I think that we are guided by their results. I do want to emphasize that in their OptiTROP, it's sac-TMT plus KEYTRUDA versus KEYTRUDA in PD-L1 positive first-line non-small cell lung cancer. And it's very important that if one wants to do an ADC plus KEYTRUDA versus KEYTRUDA in the United States, ex China, one has to look at where a PD-1 and what's the range with which the PD-L1 cut-off is. And so for us, this is the first Phase 3 combination study of sac-TMT and KEYTRUDA to read out. We have 50% of our TroFuse studies are evaluating KEYTRUDA combos in our TroFuse-007, our global study sac-TMT and KEYTRUDA versus KEYTRUDA in TPS greater than 50% in first-line non-small cell lung cancer. And I emphasize that simply because in the United States and ex China, TPS greater than 50% is where KEYTRUDA has an indication.

Operator

Steve Scala, TD Cowen.

Steve Scala - *Cowen and Company LLC - Analyst*

What are the gating factors for FDA acceptance of the enlicitide application? And Dean, can you speak to the changes that you're pursuing on titration? What shorter durations are you pursuing? And is the 15 minutes you spoke to previously before or after administration of the drug?

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

Yes. So I would just say that the enlicitide, as we've said out is we want to have the first and best-in-class potent oral PCSK9i. It's designed in a very similar manner to antibody. And the data from the Phase 3 as you have -- as we have discussed, I think lay out the value statement and relationship to its potency in terms of all the important by proteins. In relationship to the CNPV, the issue in relationship with the CNPV is just for all of us to understand that the CNPV process is a little bit different, which is we -- it's almost like a rolling submission, sort of way to think about it.

And through that rolling ambition, at the end of that sort of rolling submission, that's when the FDA sits there and gives you a letter and a PDUFA date. And so we are actively in those discussions with the FDA. And then as we normally do when we get formal acceptance of the complete file, which is a little bit different in the CNPV, we'll make an announcement. I will emphasize. I will emphasize that in our discussion with the FDA, what is very important to them is us really showing them that the CNPV program is important that we're addressing an important US public health crisis that we're delivering innovative cures and we're increasing domestic drug manufacturer and supply chain resilient.

So those are all important to the FDA, and we are in really good conversations with them. And so I think that is going quite well, and it's progressing well. I would imagine that our estimation that we could get an approval at the second half of this year I see no reason to doubt that at this moment in time.

In relationship to what you said in relationship to this issue of how you would take it -- we're also in the discussion with the FDA as to what the exact label is in relationship to how they will talk about prescriptions and when to take it and how to take it. And I don't want to get ahead of that conversation because those are extremely active conversations as we speak.

Operator

Chris Schott, JPMorgan.

Christopher Schott - *JPMorgan Chase & Co - Analyst*

I just wanted to touch base on TL1A I think this one's got maybe a little bit less attention than some of your other late-stage readouts this year. But can you just talk a little bit about the role you're seeing TL1A playing in the IBD space? And maybe more broadly, when we think about immunology and IBD, there does seem to be more discussions about combination therapy as maybe the next step for the market. I'm just interested in Merck's approach here kind of building on the TL1A as I think about a broader pipeline?

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

Yes. So I would begin to say that throughout the immunology sort of field, there are certain nodes that are really important. IL-23 is an important node. TNF is an important node. And that's how the field is set up. We wonder whether TL1A is such a node and that -- and our hope is tulisokibart could be one of the first and best-in-class TL1As. So that's in that sort of framework.

The other thing that you've just said, I think is really important is that there is increasing interest in combining different of these nodes. This is something that was tried 10, 15, 20 years ago, and it didn't turn out well. But now the data suggests that in certain cases, you could begin to combine. When you look at the AE profile of tulisokibart, it's if you take the Phase 2 data, not just our Phase 2 data, but across the Phase

2 data, it is a member of the TNF superfamily, but from an AE profile, I might describe it as a kinder gentler AE profile than other NODO TNFs and with profound efficacy. So I think combinations will be employing. In relationship to what we hope to see in relationship to Phase 3 Ulcerative colitis and chronic and Crohn's disease, we have readouts coming out. We hope to be first mover, but I also want to emphasize that we also think that TL1A may be also distinguished not just to be an important node, but it may be important for not just inflammation or dampening but also for fibrosis. And we have Phase 2 data in SSc-ILD and in HS that's coming in 2026. And that hopefully will define the unique role or the unique position that TL1A has with all the other major nodes.

Operator

Louise Chen, Scotiabank.

Louise Chen - *Scotiabank GBM - Analyst*

I wanted to ask you about the CADENCE study. There was some debate on the results that you recently presented at a medical meeting. And I'm wondering what you think the street may be missing about the competitiveness of your product.

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

So I'm not sure I know everything that you're referencing. In terms of the competitiveness of our product, I don't know how else to answer it is, I don't know from a competitive standpoint that there's any treatment for this patient population. And when I look out, I'm not so sure that I see something that, that will break that barrier.

In terms of whether or not you can make a Phase 3, but sort of models what happens in the Phase 2. I think that's where the focus is. And that's been the focus in our conversations with KOLs, but also the FDA. And there is a clear understanding that this patient population, this patient population is one with a tremendous unmet need. And so I don't know that I would call it competitive sort of dynamic sort of thing. It's whether someone for the first time can have a compelling treatment for a patient population that is in dire need.

Operator

Umer Raffat, Evercore.

Umer Raffat - *Evercore Inc - Equity Analyst*

I wanted to touch up on some incremental information that came out on your turns deal, which I don't think we discussed on the call you as did earlier. And by my math, it looks like the incremental patients may have had an MMR achievement rate of something like 2 out of 10 or something along those lines. Could you just speak to the -- that drop and how does that change or not change your overall thoughts about the drug's profile? Because presumably, that's like the real target population early in the launch?

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

Yes. Thank you so much for that. So I would just say that in this -- in CML, there's multiple approved therapies, and it appears that there is significant unmet need. And the value proposition for us for TERN-701 is whether or not it has the potential to be a best-in-class allosteric TKI with high selectivity and improved therapeutic index. When data is presented at some of these meetings initially when they're early, oftentimes, they're stated in one way.

But for us, it's really important to always look at that data, whether it's especially when you go to ASCO, AACR or ASH, we look at it immediately in the eyes of how do you think in terms of registration. And it's very important to translate whatever the abstract says to, what I would say, a more conservative ITT population consistent with regulatory standards. Given that, what was laid out at these public congresses is Terns stated to 75% MMR and 36% DMR achievement rate. As the data evolved and we were looking at very specific patient-level data, we believe that the MMR will be north of 50% and within the confidence interval as had been publicly stated.

And we think that in MMR in that sort of range is extremely compelling. And then the other point that I would just highlight is we also think that the DMR rate is also very interesting to look at and whether or not this drug could not only create a best-in-class in relationship to MMR, but whether it could catalyze the field to increasingly think of DMR as a treatment goal.

Operator

James Shin, Deutsche Bank.

James Shin - *Deutsche Bank AG - Research Analyst*

Dean, have a question. Can you help us distinguish MK-6837 from sac-TMT? And then just going back to the TL1A question. Is there a view within Merck that TL1A could stand alone in immunology because from a market or commercial perspective, immunology seems to be very much a portfolio-driven strategy. Some of your peers have large portfolios, and there's a very competitive remote that's built with that?

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

Okay. So let me ask -- let me tackle the immunology question really clearly. We're very focused on TL1A, but if you ask me is TL1A -- is our ambition to stop at TL1A, would we use TL1A as a beachhead to expand and extend? The answer is we would undoubtedly move it to expand and to extend. We had expanded from IBD to other conditions, and we would advance it to conditions where the combination of immunofibrosis would be really important.

In relationship to other molecules, of course, if one had a leading TL1A that could advance through the series of different indications that we have, then in each one of those indications, you would immediately think of what's the combinatorial partner whether it be in IBD or HS or in SSc-ILD.

So we would immediately think about doing that as well. So we are focused on TL1A, but that focus does not create a situation where we're not thinking about not just whether we can be first and best, but what's next as well.

And I think the other question was related to MK-6837. Is that correct? I didn't catch the other one. MK-6837 is another ADC, which had a unique payload, and we have discontinued that especially when you see the profound impact of sac-TMT and also in relationship to -- we've always said that we're very interested in the ADC field in changing the target but also changing the payload and thinking about combinatory or cycling different payloads as the field moves on in the antibody drug conjugate field.

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

Maybe I could just add one little bit as a teaser, maybe to what you'll see as we go into next year and beyond. In our invisible pipeline, we often refer to, we have other assets in the immunology space that you're not seeing right now. So just to reinforce Dean's point, we aren't just a TL1A company. We have other things in development beyond that. And as we move forward in time, you'll start to get a better sense of that as we unleash that as it moves into Phase 2.

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

All right. Thanks, James. We'll squeeze one last question in before we end the call.

Operator

Geoff Meacham, Citibank.

Geoffrey Meacham - *Citibank - Analyst*

All right. Dean, in HIV, just given the recent approval of IDVYNSO, can you talk about how you guys see the competitive setup and related, I know you have PrEP coming up, but how much of a strategic priority is HIV and infectious disease when thinking about the overall BD strategy.

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

So in terms of our interest in HIV, there is a profound interest in really in our HIV program. And for those of you who've talked to Eliav Barr, the Chief Medical Officer, I think you can feel that just in his presence. Islatravir is a next-generation nucleoside reverse transcriptase inhibitor. It blocks translocation, and we have the daily program and increasingly, there is interest in going from a 3-drug daily program to a 2-drug. And of the 2-drug daily programs, I think we're the only ones without an INSTI backbone.

So I think that's very important. Critically also important is that we believe islatravir can anchor to weekly, and you see it in islatravir/lenacapavir, which is a 2-drug combo, which hopefully will be the first q-week and islatravir with ULO, which is in development, and there will be data being presented, I think, in due course, it could be the smallest pill, could be favorable DDI profile and be extremely effective.

And then as you said, to me, the monthly, if you could have 12 pills and protect people with MK-8527, I think that would just be such an important contribution as a commercial product, but also as a global product for public health throughout the world. So if the question is, are we committed and are we passionate about our HIV program? I hope that you heard from the tenor of my response, the answer is unequivocally yes.

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

Great. Thanks, Geoff, and thanks, everybody. Apologies for going over a few minutes. Give us a call if you have any follow-up questions. Thank you.

Operator

Thank you for your participation. Participants, you may disconnect at this time.
