Q2 2023 Earnings Call

Company Participants

- Caroline Litchfield, Executive Vice President and Chief Financial Officer
- Dean Y. Li, Executive Vice President and President, Merck Research Laboratories
- Peter Dannenbaum, Vice President, Investor Relations
- Robert M. Davis, Chairman and Chief Executive Officer

Other Participants

- Akash Tewari, Jefferies
- Andrew Baum, Citi
- Chris Schott, JP Morgan
- Chris Shibutani, Goldman Sachs
- Daina Graybosch, Leerink Partners
- Geoff Meacham, Bank of America
- Louise Chen, Cantor Fitzgerald
- Mohit Bansal, Wells Fargo
- Seamus Fernandez, Guggenheim
- Steve Scala, Cowen and Company
- Tim Anderson, Wolfe Research

Presentation

Operator

Thank you for standing by. Welcome to the Merck & Co. Q2 Sales and Earnings Conference Call. At this time, all participants are in a listen-only mode until the question-and-answer session of today's conference. (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, Vice President, Investor Relations. Sir, you may begin.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Cedric, and good morning, everyone. Welcome to Merck's second quarter 2023 conference call. 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 Merck Research Labs.

Before we get started, I'd like to point out a few items. You will see that we have items in our GAAP results, such as acquisition-related charges, restructuring costs, and certain other items. You should note that we have excluded these from our non-GAAP results and provide a reconciliation in our press release.

I would like to remind you that some of the statements that we make today may be considered forward-looking statements within the meaning of the safe harbor provision of the United States Private Securities Litigation Reform Act of 1995. Such statements are made based on the current beliefs of Merck'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 2022 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 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 Merck's website.

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

Robert M. Davis {BIO 6955931 <GO>}

Thanks, Peter. Good morning, and thank you for joining today's call. We continue to make great progress in bringing forward compelling science to help address the world's most urgent unmet medical needs. Thanks to the unwavering commitment and discipline of our global teams, we're advancing our innovative pipeline and executing operationally in support of our key growth drivers. Our science-led strategy is generating innovations that save and improve the lives of patients and animals around the world, and is delivering strong underlying growth for our business.

We're building on our strong track record and advancing our strategic priorities. We're progressing our deep pipeline, including sotatercept, for which we have completed our FDA submission, and augmenting it with further strategic business development, where we can add value by applying our clinical expertise and leveraging our global scale to accelerate broad access to patients.

An excellent example of this is our acquisition of Prometheus Biosciences, which we completed in June. We're now actively integrating the talented team and are moving with speed toward initiation of a Phase 3 clinical trial. The addition of Prometheus significantly strengthens our presence in immunology, an area with substantial unmet medical need, and builds on the significant scientific insight we have gained

in immuno-oncology. It also brings us a potential first-in-class, best-in-class novel TL1A inhibitor, which provides us the opportunity to transform the standard of care in a patient population suffering from debilitating immune-mediated diseases. With the foundation of great science and the legacy of commercial excellence, we're well-positioned to deliver sustainable value over the long term.

Focusing now on the short-term, we delivered strong underlying growth, excluding the year-over-year decline in LAGEVRIO sales, led by robust demand across key growth drivers in oncology and vaccines. We remain confident in our outlook for the remainder of 2023, which Caroline will address in just a moment.

Moving to our research organization, our promising late-stage pipeline continues to demonstrate tangible and impactful benefits for patients across a broad range of diseases. In oncology, we highlighted data from our expansive pipeline at ASCO, including for KEYTRUDA in earlier-stage lung cancer. The strong results of KEYNOTE-671 for the neoadjuvant and adjuvant treatment of patients with non-small-cell lung cancer support our aspiration to fundamentally shift the way cancer is managed by developing treatment regimens in the earlier-stage setting, where the potential for better outcomes is higher. Additionally, we're leveraging KEYTRUDA's wide-reaching benefit across a range of cancer types to identify and bring forward promising new candidates.

At ASCO, we shared positive data for KEYTRUDA in combination with V940, our investigational individualized neoantigen therapy in collaboration with Moderna in the adjuvant treatment of melanoma. And promising data was also presented by our partner, Kelun-Biotech, for MK-2870, our TROP-2 ADC in non-small cell lung cancer. Each of these novel candidates offer a glimpse into the future of cancer care and the potential to meaningfully improve outcomes for patients.

We have also made progress outside of oncology. We're advancing our population-specific approach to pneumococcal vaccination and are very pleased to have announced positive top line results for our adult vaccine candidate, V116. If approved, V116 would be the first pneumococcal conjugate vaccine specifically designed for adults. And Dean will speak to our progress in cardiometabolic disease, including positive data we recently presented for our GLP-1/glucagon receptor dual agonist.

I commend Dean and his team on the significant work being done to advance our broad pipeline and their commitment to Merck's purpose. Innovation is the core of who Merck is, and it's what our company strives to achieve every day. We're grounded in the relentless pursuit of advancing science and raising the bar of innovation to deliver value for patients.

With that in mind, I'd like to speak for a moment about the Inflation Reduction Act. We've consistently communicated our support for elements of the law that improve patient affordability and access, such as the Medicare Part D Reform, but which do so

without damaging the very promising long-term innovation potential of the biopharmaceutical industry.

Through the complaint we recently filed in U.S. District Court, Merck is taking a principled stand against the negative long-term impacts of the price negotiation provision of the IRA, which we believe amounts to unconstitutional price setting that violates several provisions of the U.S. Constitution.

This misguided policy does not strike the right balance between incenting investment and innovation and improving affordability and access. That said, we remain committed to working with the U.S. government to find a better approach to improve affordability and access, while protecting further drug breakthroughs that benefit patients facing unmet medical needs.

We know it is critical that we provide broad access both to our current portfolio of medicines and vaccines and to our future innovations, in order to serve the greatest number of patients possible now and for years to come. Our upcoming annual impact report will highlight accomplishments across our four priority areas, including access to health, where a portion of employee compensation will now be driven by metrics linked to our progress.

In summary, our science-led strategy is working. We're driving significant scientific, commercial, and operational momentum, which we expect will enable strong full-year growth. I want to thank our talented, dedicated, and diverse global team for their hard work and commitment to delivering value for patients, shareholders, and all of our stakeholders. With these efforts, I'm confident we will continue to drive sustained success well into the future.

With that, I'll turn the call over to Caroline.

Caroline Litchfield {BIO 20934609 <GO>}

Thank you, Rob. Good morning. As Rob noted, we delivered another very strong quarter with underlying growth driven by demand across our innovative portfolio. These results reflect the profound impact of our medicines and vaccines globally, and reinforce the confidence we have in the health of our business and in the outlook for continued strong underlying growth.

Now turning to our second quarter results. Total company revenues were $15 billion. Excluding the impact from LAGEVRIO and foreign exchange, the business delivered very strong growth of 14%. The remainder of my revenue comments will be on an ex-exchange basis. Our Human Health business sustained its strong momentum. Excluding LAGEVRIO, growth was 17%, driven by oncology and vaccines. Sales in our Animal Health business increased 2% across both companion animal and livestock products.

Now turning to the second quarter performance of our key brands. In oncology, KEYTRUDA grew 21% to $6.3 billion, driven by increased utilization from approvals in earlier-stage cancers and continued strong global demand from metastatic indications. In the U.S., KEYTRUDA grew across all key tumor types and continues to benefit from usage in earlier-stage cancers, including triple-negative breast cancer, as well as in certain types of renal cell carcinoma and melanoma. We are encouraged by the positive feedback from healthcare providers and initial uptake of KEYNOTE-091, reflecting the significant impact KEYTRUDA is having on patients with earlier-stage non-small cell lung cancer.

Outside the U.S., KEYTRUDA is maintaining its leadership in non-small cell lung cancer. Growth was driven by demand in metastatic renal cell carcinoma and certain types of head and neck cancer, as well as in earlier-stage cancers, including high-risk, early-stage triple-negative breast cancer and renal cell carcinoma, which saw continued uptake in recently launched markets.

Lynparza remains the market-leading PARP inhibitor. Alliance revenue grew 15%, driven by increased demand in certain international markets. Lenvima alliance revenue grew 6%, due to increased demand for the treatment of certain patients with advanced renal cell carcinoma and endometrial cancer in the U.S., partially offset by lower sales in China.

Our vaccines portfolio delivered exceptional growth, led by GARDASIL, which grew 53% to $2.5 billion. Performance was driven by strong global demand, especially in China, where we are benefiting from the expanded indication of GARDASIL 9 for girls and women 9 to 45 years of age. Vaccine sales also benefited from increased uptake of VAXNEUVANCE, following the ongoing pediatric launch, particularly in the U.S.

In our hospital acute care portfolio, BRIDION sales grew 19%, driven by increased market share among neuromuscular blockade reversal agents in the U.S.

Sales in our Animal Health business grew 2%. Livestock sales growth reflects price actions as well as higher demand for swine and poultry products, partially offset by lower demand for ruminant products due in part to reduced herd sizes. Companion animal growth reflects price actions, including for the BRAVECTO line of products, partially offset by supply challenges for certain vaccines.

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 76.6%, an increase of 1.9 percentage points due to favorable product mix, including a benefit from the lower sales of LAGEVRIO. Operating expenses increased to $15.9 billion, including a $10.2 billion one-time charge related to the acquisition of Prometheus. Excluding this charge, operating expenses grew 10%. This growth reflects increased investments in support of near-term opportunities for our in-line portfolio and disciplined investments for the future as we advance our exciting early and late-phase pipeline. Other income was $19 million.

Our tax provision was approximately $800 million. As a result of the Prometheus one-time charge, we had a pre-tax loss this quarter. This one-time charge is not tax deductible. Our tax rate is therefore a negative 18.4%. Taken together, we reported a loss of $2.06 per share, which includes a negative impact of $4.02 per share from the one-time charge related to the Prometheus transaction.

Turning now to our 2023 non-GAAP guidance. The underlying strength of our business has enabled us to raise and narrow our full-year revenue guidance. We now expect revenue to be between $58.6 billion and $59.6 billion, an increase of $800 million at the midpoint. This range reflects strong underlying year-over-year revenue growth of 10% to 11%, offset by the expected lower sales of LAGEVRIO, which we continue to estimate to be approximately $1 billion this year; and an approximate 2 percentage point negative impact from foreign exchange using mid-July rates. Our growth margin assumption is unchanged at approximately 77%.

We now estimate operating expenses to be between $34 billion and $34.6 billion. This range includes $11.6 billion of acquisition and upfront collaboration, research, and development expenses associated with Prometheus, Imago, and Kelun. Our guidance does not assume additional significant potential business development transactions.

We now assume other expense of approximately $100 million, which includes incremental financing costs related to Prometheus. Our full-year tax rate is expected to be between 30.5% and 31.5%, reflecting an increase due to the Prometheus transaction of approximately 15 percentage points. We continue to assume approximately 2.55 billion shares outstanding. Taken together, we expect EPS of $2.95 to $3.05, which includes the one-time charge for Prometheus, and a negative impact from foreign exchange of approximately 5 percentage points versus 2022 using mid-July rates.

Recall, our prior guidance range was $6.88 to $7.00, which we noted at the time excluded Prometheus. Had we included the $4.02 one-time charge and an estimated $0.14 to advance the assets and financing costs, our prior guidance range would have been $2.72 to $2.84, with a midpoint of $2.78. Our current guidance midpoint of $3 represents an increase resulting from the strength in our business of approximately $0.24, partially offset by an incremental headwind from foreign exchange of approximately $0.02.

Our guidance reflects our continued confidence in the strength of our business, driven by our key pillars, enabling us to deliver robust underlying growth while investing in our promising pipeline. As you consider your models, there are a couple of items to keep in mind. KEYTRUDA growth has been exceptional in recent quarters, outperforming our expectations, driven in part by robust uptake of recently launched earlier-stage indications. We continue to expect strong year-over-year growth of KEYTRUDA, but not quite at the levels experienced in recent quarters as a result of lacking launches and the impact of continued pricing headwinds, particularly as we launch new indications in key European markets.

In addition, there was a small benefit from wholesaler purchase timing in the U.S. in the second quarter, which we expect to reverse in the third quarter.

As we look out to 2024 and beyond, we continue to expect strong growth, including the impact of additional approvals. And as a reminder, while we expect the pace of growth of GARDASIL to be higher in 2023 than 2022, the rate of second-half growth is anticipated to be below the first half, due in part to the timing of shipments to China.

Now turning to capital allocation. We will continue to prioritize investments in our business and growing pipeline to drive near- and long-term growth across our portfolio. We remain committed to our dividends with the goal of increasing it over time. Business development remains a priority. We remain well-positioned to pursue the most compelling external science through value-enhancing business development to augment our pipeline. We continue to expect to execute a modest level of share repurchases this year.

To conclude, as we enter the second half of the year, we remain very confident in both the strength of our underlying business, driven by global demand for our innovative medicines and vaccines, and the excellent execution of our dedicated teams across all areas of our business, which will enable us to continue to deliver value to patients, customers, and shareholders now and well into the future.

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

Dean Y. Li {BIO 21985278 <GO>}

Thank you, Caroline. Good morning, everyone. It's my pleasure to provide an overview of the significant pipeline progress across multiple therapeutic areas since the first quarter call. Today, I will start with oncology, followed by vaccines and infectious diseases, and finally, on to our broader pipeline.

Starting with oncology, the development of meaningful treatment options for patients with earlier-stage disease, where there is greater prospect to improve outcomes continues to be an area of significant progress. Last week, we announced the Phase 3 KEYNOTE-756 trial evaluating KEYTRUDA in combination with chemotherapy in patients with high-risk, early-stage estrogen receptor-positive, HR-positive, HER2-negative breast cancer met one of its dual primary endpoints of pathological complete response following the neoadjuvant part of the neoadjuvant/adjuvant study. This is the first Phase 3 study to demonstrate a positive result for an immunotherapy-based regimen and early-stage breast cancer for this patient population.

Further, in women's cancer, and building on our progress in earlier stages of disease, we announced that the Phase 3 KEYNOTE A-18 Trial met one of its primary endpoints of progression-free survival for treatment of newly diagnosed patients with high-risk locally advanced cervical cancer. This is the first study of KEYTRUDA Plus

chemoradiotherapy or radiotherapy to show statistically significant and clinically meaningful improvement in progression-free survival.

At ASCO, as part of our investor event, we provided an overview of our clinical development pipeline and highlighted relevant data presentations. We have strong momentum as we evaluate the opportunity for KEYTRUDA in earlier stages of disease.

Detailed results were presented from the ongoing KEYNOTE-671 study, evaluating KEYTRUDA in combination with platinum doublet chemotherapy as neoadjuvant therapy, followed by adjuvant KEYTRUDA in patients with resectable stage 2, 3A, and 3B non-small cell lung cancer.

Treatment with KEYTRUDA and chemotherapy before surgery, followed by KEYTRUDA monotherapy after surgery, reduced the risk of disease recurrence, progression or death by 42% versus pre-operative chemotherapy alone. Subgroup analysis showed a consistent response regardless of PD-L1 expression, histology, and stage of disease. The PDUFA target action date is October 16.

With the approval of KEYNOTE-091, as treatment after surgery and adjuvant chemotherapy, along with the potential approval for Keynote-671 as treatment before and after surgery. KEYTRUDA will provide the optionality to benefit more patients with earlier stage non-small cell lung cancer.

Further data were also presented for Keynote-942 from our Phase 2B study of KEYTRUDA in combination with V940, an investigational individualized neoantigen therapy in collaboration with Moderna. The study showed a 65% reduction in risk of distant metastasis or death in patients with resected Stage 3 and 4 melanoma compared to KEYTRUDA alone. We are eager to build upon these findings and have started enrolling patients into the registrational Phase 3 trial for adjuvant treatment of high-risk Stage IIB-IV melanoma with plans to expand the program to additional tumor types, including non-small cell lung cancer.

Finally, data presented for MK-2870, our investigational anti TROP-2 antibody drug conjugate licensed from Kelun-Biotech showed encouraging anti-tumor activity in patients with relapsed or refractory locally advanced or metastatic non-small cell lung cancer, regardless of TROP-2 expression level. We are advancing a broad clinical development program for this candidate with global Phase 3 trials, scheduled in lung cancer and additional tumor types.

On the regulatory front, Lynparza, in combination with abiraterone and prednisone was approved by the FDA for the treatment of adult patients with BRCA-mutated metastatic castration-resistant prostate cancer, an important area of unmet need.

In addition, our supplemental biologics license application for KEYTRUDA in combination with chemotherapy for patients with locally advanced unresectable or

metastatic biliary tract cancer, based on findings from KEYNOTE-966, was accepted by the FDA for review. The PDUFA target action date is February 7, 2024.

We also announced new data from KEYNOTE-811, which demonstrated KEYTRUDA, in combination with trastuzumab and chemotherapy, showed a significant improvement in progression-free survival for the first-line treatment of HER2-positive advanced gastric or gastroesophageal junction adenocarcinoma in patients whose tumors was PD-L1 positive. Merck has discussed these findings with the FDA and is working to update the current indication for KEYTRUDA.

In addition, based on the data from KEYNOTE-811 study, we received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use.

Turning to vaccines and infectious disease. We have taken a thoughtful and evidence-based approach to establishing a pipeline of pneumococcal vaccine candidates to address the specific needs of different populations, including infants and children, healthy adults and at-risk subgroups, starting with VAXNEUVANCE and now continuing with V116.

Our investigational 21-valent pneumococcal conjugate vaccine for adults. V116 has potential to expand disease coverage to help protect against invasive pneumococcal disease in more than 85% of individuals, 65% and older, based on 2019 pre-pandemic CDC data. V116 includes eight serotypes, not currently covered by approved pneumococcal vaccines, which are responsible for approximately 30% of invasive pneumococcal disease, individuals 65 and older based on the same data.

Last week, we announced positive top line results from two Phase 3 trials evaluating V116. The STRIDE-003 trial demonstrated statistically significant immune responses in vaccine-naive adults, compared to PCV20 for serotypes common to both vaccines; and the STRIDE-006 trial demonstrating that V116 was immunogenic for all 21 pneumococcal serotypes in the vaccine among adults, who previously received a pneumococcal vaccine at least one year prior to the study.

We are eager to share these findings and plan to present detailed data at an upcoming medical conference. As Rob noted, if approved, V116 would be the first pneumococcal conjugate vaccine specifically designed to address the serotypes that represent adult pneumococcal disease.

In infectious diseases, we received FDA approval for PREVYMIS for prophylaxis of cytomegalovirus disease for adult recipients of kidney transplant, who are at high risk of CMV infection. Since 2017, PREVYMIS has been an important preventive option for CMV infection and disease in adult seropositive recipients of an allogeneic hematopoietic stem cell transplant. And we are pleased to build on the benefits it provides with this new approval.

Progress continues in the cardiometabolic space. As Rob mentioned, following the remarkable results from the STELLAR trial, we have completed the submission to the FDA of the Biologics License Application for Sotatercept for the treatment of adults with pulmonary arterial hypertension.

Sotatercept has been granted breakthrough therapy designation by the FDA, and we look forward to work with the agency on its view. We are advancing our broad cardiovascular program, enrollment in Phase 3 trials for MK-0616, our oral PCSK9 inhibitor is anticipated to start later this month.

In June, at the European Association for the Study of the Liver Meeting, positive results were presented from the Phase 2A randomized active comparator controlled, open-label study of enopegdutide, our investigational GLP-1 glucagon receptor dual agonist, in patients with non-alcoholic fatty liver disease.

Based on the findings from this study, enopegdutide was granted fast-track designation by the FDA. We have now started a Phase 2B study to evaluate efficacy and safety in adult patients with pre-cirrhotic NASH.

Lastly, the FDA has accepted our resubmission of the new drug applications for gefapixant, our P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough in adults. The PDUFA target action date is December 27, 2023. This follows the positive opinion from the CHMP in the European UN -- European Union.

And finally, as Rob mentioned, this past quarter, we are delighted to welcome our new colleagues from Prometheus to Merck. The team is focused on advancing the clinical development program for MK-7240, formerly PRA023, and leveraging our combined strengths and expertise to better serve patients with immune-mediated diseases.

In closing, we have established a regular cadence of late-phase pipeline progress and are proceeding with speed and rigor to advance a promising portfolio of diverse candidates, guided by science and focused on patient needs.

Moving forward, we are well-positioned to build on this momentum with further regulatory milestones, data readouts, and clinical catalysts across therapeutic areas.

And now, I turn the call back to Peter.

Peter Dannenbaum {BIO 20569031 <GO>}

Thank you, Dean. Cedric, we're ready to take questions. We'd appreciate analysts limit -- limiting themselves to one question, so we can get to as many as possible today. Thank you.

Questions And Answers

Operator

(Question And Answer)

Thank you. (Operator Instructions) Okay. And our first question comes from Geoff Meacham with Bank of America. Your line is open.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks so much for the question. Rob, you opened up the call with some comments on the IRA suit, so I wanted to ask you a little bit on that. I know it's hard to talk specifics on your strategy, but at a higher level, how important is it to get more companies to join the fray with Merck? And are there any milestones to watch for this fall in the suit, beyond the initial 10 drugs being named next month? Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes, Geoff, I appreciate the question. And with regards to the IRA, obviously, our concern, and I think it's just worth reinforcing, is about what we see as an untenable challenge to innovation in the industry. And that's really the principal reason that drove us to bring the suit.

But to your question, as you know, now, there are four drug companies actually in total, including Merck, have raised suits, all largely following the same types of arguments, in addition to -- we have the chamber filed a suit as well as the trade group pharma. So, we're all moving forward. And our belief is that the provisions, particularly the negotiation provision of the IRA is in violation of both the Fifth and the First Amendment of the Constitution and is not good policy. That's what brought us to bring the suit.

As we look forward, we're going to take this to the fullest, which means we'll take it through District Court, and if need be, into Circuit Court, and ultimately to the Supreme Court. So, really, that's the strategy.

I don't want to comment on other companies -- whether you're going to see additional companies come in beyond the four that are in now. As far as any kind of triggers to watch for, not really, because while, obviously, we have set dates for the initial discovery and some of the initial hearings. This is going to take a while to play out.

What I do think is highly likely is that we will be able to see this resolved by the time we get into the 2026 timeframe. That's really what we're thinking about and moving through the various courts as needed. But I wouldn't really think you're going to see any large indicator in the near term. This is a longer-term play.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Geoff. Next question, please, Cedric.

Operator

Yes. So, our next question comes from Mohit Bansal with Wells Fargo. Your line is open.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great. Thank you very much for taking my question. My question is regarding the one-time items. So, Caroline, you mentioned regarding China for GARDASIL as well as KEYTRUDA in the U.S. Would you be able to quantify this a little bit, just trying to understand the magnitude of how much (Inaudible) is impacted by those one-time items. Thank you.

A - Caroline Litchfield {BIO 20934609 <GO>}

Yes. Of course, Mohit. Thank you for the question. So first, talking about GARDASIL. There were no one-time items in the quarter for GARDASIL. We had exceptional growth. That growth was driven by every geography around the world.

As we think about the second half of the year though, we do expect shipments to China to be less than they were in the first half of the year. And therefore, expect the second half of the year growth to be slower than what we've achieved in the first half.

For KEYTRUDA, we had a very strong quarter and that strength was across all indications, including the earlier-stage cancer indications that we're launching. In the United States, we had sales of $3.9 billion, a growth of 21%. Now that growth included approximately $50 million of benefit, because wholesaler buy-in in the second quarter of 2023 was slightly higher than the buy-in we saw in the second quarter of 2022.

One of the distributors who has bought in, has indicated that they expect to buy out in the third quarter. And the quantum of that buy out has been indicated to be $150 million. That said, we continue to expect strong growth from KEYTRUDA, given the current indications we have as well as new launches to come.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Mohit. Next question, please, Cedric.

Operator

Yes. Our next question comes from Louise Chen with Cantor. Your line is open.

Q - Louise Chen {BIO 6990156 <GO>}

Hi, thank you for taking my questions. I just wanted to ask you on your Prometheus Phase III clinical trial, if you could give more color on the trial designs and then when you'll start those. And then if you'll pursue any other indications outside of IBD? Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. So I'll take that. Thank you very much for the question in relationship to the Prometheus. Again, I just want to level set. For inflammatory bowel disease, there's a lot of cycling of anti-cytokines and then other mechanisms, some of them actually have a black box. So we're very enthusiastic of moving forward with MK-7240 or the TL1A.

In relationship to the start of the Phase 3, the integration is going extremely well. We anticipate to be starting that Phase 3 this year for ulcerative colitis. And as other data comes in terms of Crohn's disease and other diseases, we'll adjust appropriately. So the start of the Phase 3, we are targeting this year. And the integration with our colleagues at Prometheus has gone extremely well.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Louise. Next question, please, Cedric.

Operator

Yes. Our next question comes from Seamus Fernandez with Guggenheim Investments. Your line is open.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Great. Thanks. My question actually is on the pneumococcal vaccine, V116. Dean, just hoping that you could clarify for us what statistically significant means, and if that actually implies superiority on individual serotypes, superiority on a new metric that perhaps could be an overall superiority to Prevnar 20 in the STRIDE-3 results? Or if this is simply implying that it was statistically significant because it met the non-inferiority margin? Just trying to get a little bit more clarification there.

And as a follow-up to that, just wanted to get a better sense of, if you believe the data, as it sits today, opens up a meaningful opportunity in international markets, where national immunization programs have been reluctant to use pneumococcal vaccines in the adult setting, largely because of herd immunity. Thanks.

A - Dean Y. Li {BIO 21985278 <GO>}

Yes. Thank you so much. So, I'll just, add a top line, just say I am pleased with the data and it gives me confidence in the path forward for V116. It's not just the data that's going to be presented, the data is going to be presented relatively soon at an international conference, but it's also the path to regulatory approval and eventually

in the U.S. to ACIP. So this data is strong and I just would recount that if approved, as you point out, it would be the first, the first adult-specific pneumococcal vaccine, and it covers 85% of all cases of pneumococcal disease in adults greater than -- or older than 65.

The way that I think about the vaccine, it's a 21-valent, is that there's 10 shared with PCV20 and there's 11 uniques with PCV20. And as one looks at the data that will be coming out, one would see that in the shared one, there, right, the question always in the shared one is, is there -- how does it compare with the shared ones with PCV20? And in that situation, it has met the non-inferior boundaries. And so I want to be clear about that.

Clearly, the 11 unique serotypes are unique to V116. And so the issue for that is whether they're statistically significant, whether they're clinically meaningful. And I'm confident as we move forward that that will be -- that will become clear. It's really hard to talk about superiority or anything like this when you're talking about 11 unique serotypes.

But I just want to step back because you sort of touched on it a little bit. It validates the strategy of having an age-appropriate serotype coverage. Just to remind everyone, V114 is a 15-valent, it has 22F, 33F, and has improved immunogenicity for serotype 3. And most importantly, it provides infants protection within the first year of life. So that's how we thought about that age-appropriate serotype coverage.

And then V116, clearly is 21-valent, 85% in place of pneumococcal disease, and then is driving toward the adult market. But I'll turn it over to Rob to give some view of the prospects commercially, how we see it.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. No, thank you. Thanks, Dean, and thanks, Seamus, for the question. As Dean just summarized, the data is pretty much about as good as you could expect. So as we sit here today, we're very confident in what this vaccine can offer, both in the United States, and we do believe there's a meaningful opportunity for us to take this internationally.

So, we're going to have to see how it plays out, but as we sit here today, we are excited about this product and ready to launch as soon as we get approval to do so. Because we do think, as Dean pointed out, we give 85% coverage. That's 30% better than Prevnar 20. It's also better than any other vaccine currently in development. So, we think this is an important drug, and when you combine it with what we have with VAXNEUVANCE, our pneumococcal franchise is a significant opportunity that we think could be multi-billion as we go out into the future. So this is something we're invested in, and we're going to continue to drive aggressively.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Seamus. Next question, please, Cedric.

Operator

Yes. Our next question comes from Akash Tiwari with Jefferies Group. Your line is open. Sorry, Jeffrey, your line is open.

Q - Akash Tewari {BIO 19249236 <GO>}

Hi. Can you hear me?

A - Peter Dannenbaum {BIO 20569031 <GO>}

Yes.

Q - Akash Tewari {BIO 19249236 <GO>}

Okay, good. So prior to Prometheus, you guys had a pretty limited presence in immunology. Is there any urgency to build out that part of the business externally via BD? And does your team have any view on the FcRn inhibitor class, how large it may end up being over time, and how maybe one of those assets could fit strategically with your plans in this category? Thank you.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. Akash, thanks for the question. I'll let Dean speak to the science side of this, but from a business perspective, we actually have had a presence in immunology. You might recall that across Europe and outside the United States, we sold Remicade. So, we've been involved in symphony. So we've been involved in this space.

As we sit here today, we don't see a significant commercial build. We think actually we can leverage a lot of the capabilities we have. We will invest in this area for success. And then Dean can comment, but we have been building on the science side. Obviously, we did the Pandion acquisition, building off the learning from immuno-oncology into the immunology space, and now with Prometheus, as well as we brought in some really top talent in both the discovery and development area in this area. So I think we're well positioned to drive this business.

And obviously, we're always open to continuing to look for additional business development, but it's not something I think we have to do to fill a gap. It's more of how do we continue to augment for further growth.

A - Dean Y. Li {BIO 21985278 <GO>}

Yes. I'll just answer scientifically. I mean, what we've done with external partnerships, or I should say acquisitions with Pandion and Prometheus, it should be very clear how interested we are in those fields. I would also note that each one of them has a lead compound that the focus is, but there are also follow-on compounds that come through, that will be important.

And especially in relationship to both of them, Prometheus and Pandion, we've been blessed by the fact that many of those top talent have chosen to continue with us.

So, we're very confident in this build. The other point that I would make is that separate to those external, there is an internal pipeline that is moving reasonably fast and will become more clear in the clinical space in the next few years as well.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Akash. Next question, please, Cedric.

Operator

Yes. The next question comes from Chris Schott with JP Morgan. Your line is open.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much. Just a clarification of an earlier question and a follow-up. Just on KEYTRUDA and growth moderating in the second half, I guess in addition to the U.S. wholesaler dynamic, I think you mentioned some EU price pressures. I just wanted to clarify, is that something incremental that you're expecting in the second half or more just a continuation of pressures you're already seeing in the first half of the year?

And then my other question was just on business development. Just more broadly, the company has been pretty active over the past 12 months to, I guess, 24 months. I guess, what are just the priorities at this point? And should we think about a pause in activity post-Prometheus? Or is it really still full speed ahead in terms of looking at further transactions? Thank you.

A - Caroline Litchfield {BIO 20934609 <GO>}

Thank you for the question, Chris. This is Caroline. In terms of the KEYTRUDA expectations for the remainder of the year, as we noted, we do expect continued price pressure in Europe, two elements to that. The first is, as we continue to launch new indications, we will see likely price reductions as we launch those new indications, but we'll see volume growth as we impact more patients and therefore drive revenue.

We also do have the impact of some austerity measures or changes in reimbursement measures in some of our European countries, specifically in Germany with the shortening of the AMNOG review timeline, as well as in the UK with the VPAS. So, as we look forward, we do see that those pricing headwinds sustain, but we are confident in the continued growth that we will provide for KEYTRUDA.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. And Chris, on the business development question, as Caroline noted in the prepared remarks, we continue to have ample firepower to do deals. And while I can tell you I feel very confident, and I know the team feels very confident, about the progress we're making with our internal pipeline and with the BD we've already done.

If you look forward, we're going to be -- we've either recently announced or will be announcing a number of important Phase 3 assets across oncology with basically every area of the business, cardiometabolic, what we see in vaccines, as well as important upcoming launches. We've talked about V116 data, sotatercept. We can go down the line. So I feel very good about the progress. That being said, we continue to have a priority to do business development, so you should not necessarily expect a slowdown.

If and when assets that bring important scientific opportunities present themselves, where we see an alignment with strategy, and where we can see value creation, we have the capacity and we will be and are willing to act on those.

So we're out actively looking and we'll continue to drive deals, because while I feel very good about where we are, we're talking about trying to build a sustainable engine well into the next decade and we want to continue to add to the firepower we have coming out of our own discovery in development labs as well.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Chris. Next question, please, Cedric.

Operator

Yes. Our next question comes from Daina Graybosch with Leerink Partners. Your line is open.

Q - Daina Graybosch {BIO 20659414 <GO>}

Hello. I have a question -- thank you for the question, on KEYTRUDA. I wonder if you could talk about how much remaining headroom you see for KEYTRUDA growth in some of the early stage markets that you've been mentioning, including triple negative breast cancer, RCC. I believe it's probably stage 2 melanoma and lung cancer, both in the U.S. and outside the U.S.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. So I'll start, and Caroline can add in, if I miss something here. But the high-level answer is we see a lot of room for continued growth, both in early-stage cancers, the ones where we have current indications, and importantly, ones that are still coming. So, kind of running through the list, triple negative breast cancer, obviously, has driven important growth, both in the adjuvant, neoadjuvant, and metastatic setting. It was a big driver of growth last year in the United States.

It's a driver of growth in the U.S. this year. That will slow into next year, in the U.S., but we're seeing it picking up outside the United States because we're, at an earlier phase in the launch across the world. So that will continue to be an important area. And then you saw today, we announced important data in KEYNOTE-756, so that is promising for a future indication that we could potentially see coming down the path in early-stage breast cancer as well.

If you look at lung cancer, we continue to expect growth. In fact, we're growing in lung cancer now, both internationally and in the U.S. But importantly, what's going to drive growth longer term is as we continue to penetrate into earlier lines of therapy. Obviously, we're early in the launch of KEYNOTE-091 in the United States and in certain markets outside the U.S. We're very excited about what KEYNOTE-761 could be and how that will help drive growth in non-small cell lung cancer.

And then across RCC, continued good growth in the adjuvant setting, good growth in metastatic. We have what's coming with Welireg, which is going to continue to broaden our opportunity there. Great growth coming in bladder cancer. I'll stop there because I could go on, but we want to get to other questions. The short answer is a lot of growth, a lot of opportunity with KEYTRUDA. We're going to make a big difference in a lot of patients' lives as we move forward with this drug.

Q - Daina Graybosch {BIO 20659414 <GO>}

Great.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Thanks, Daina. Next question, please, Cedric.

Operator

Yes, our next question comes from Tim Anderson with Wolfe Research. Your line is open.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. I have a question for Dean, on the TROP-2 asset from Kelun. Kind of a key debate, and the newer debate, has been the role of the TROP-2 biomarker and whether higher expression predicts better response.

And it's come into focus more recently, partly because of Astra's top-line on their lung trial, as well as the Phase 3 trial they started earlier this year. So I'd like to get your views on the role of this biomarker, and specifically, do you plan to include that as a stratification factor in any of your upcoming Phase 3 trials?

A - Dean Y. Li {BIO 21985278 <GO>}

Yes, thank you very much for that question about TROP-2 ADCs, especially in relation to the lung. So, as a broader picture, I would just say that initially the focus will be in the metastatic, and then depending on how those play out, it may go into earlier stages of cancer as well, more broadly.

But as we talk about lung cancer, the critical question that the field has to answer us and others, is whether or not you can dethrone KEYNOTE-189? So, we're all trying to dethrone Merck's standard of care, which is pembro plus chemo in first line, in metastatic non-small cell lung cancer.

I will just say, lots of people have tried to do it, including us, and it's a high bar to try to overcome. And so the issue for us is, how do you overcome that? Because I think if you can prove that an ADC can do that, that will be very important for the field.

And so, we have our data. It's -- we are very comfortable with the safety. But we think that it may be important to maximize the impact of the TROP-2 ADC, so that you can give something meaningful -- a meaningful benefit over KEYNOTE-189. So, I think the biomarker could be important, if what you're trying to do is displace KEYNOTE-189, because KEYNOTE-189 is a high bar to beat.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Tim. Next question, please, Cedric.

Operator

Our next question comes from Chris Shibutani with Goldman Sachs. Your line is open.

Q - Chris Shibutani {BIO 3202082 <GO>}

Thank you very much. With sotatercept, you acknowledged the progress of the filing completed in the third quarter here. Could you just remind us in terms of what your expectations are for potential label? Any nuances here, in particular, with regard to secondary endpoints that you think would be meaningful from a commercial standpoint?

And then recognizing that you have had some commercial footprint, what should we think about in terms of what's going to be required with a potential launch in 2024? And similarly with reimbursement for a new product, what should we think in terms of the cadence? We do recognize that physicians have been quite aware and enthusiastic about the data. Thank you.

A - Dean Y. Li {BIO 21985278 <GO>}

Yes. So, let me take the science part of that, Chris. In relationship to sotatercept in the STELLAR trial, I think the label in the U.S. will be reasonably clear and follow that of what the STELLAR trial is. I think one of the things that was really important is that when we declared it, we didn't just declare a six-minute walk, we declared time to clinical worsening and death, which was really important because, I think, that creates a different scenario for us than what we had predicted previously in our ability to go to markets outside of the U.S. So, I think that will be in the label within the FDA, but I think where it's important is that it may change the speed with which the international market adopts sotatercept[ph].

I hope that gives you that general sense. But as we move this forward, we are looking and I think we've said previously that we would have the file complete. And I think given the general sense, we thought that we would be launching at least within the U.S. in the earlier part of 2024.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. Chris, this is Rob. So on the question of our infrastructure to support a launch, we're actually well positioned. I would remind you that we currently market Adempas outside the United States, that is in NPAH. So outside the U.S., we're going to be able to leverage our relationships and our infrastructure there, obviously, we'll add to it.

And then in the United States, this is in its first indications anyway, more of a rare disease. You're looking at about 150 specialty centers in the United States that actually prescribe this. So we're not talking a large commercial footprint. This is more of a rare disease type of launch. And we've been focused on building out capabilities, particularly as we think about medical affairs, science liaisons, and how do we manage the relationships, kind of the complex journey of patients facing these diseases with their physicians.

A lot of work is already underway. So I'm quite confident we'll be prepared for a launch both in the U.S. and outside the U.S. Because as Dean mentioned, our belief what this can be globally is much bigger than when we originally did the deal, given what we expect to be the label we will see.

As far as the reimbursement goes, to your point, this drug, especially in the United States, is very well known. The specialists in the area already understand it. They're already waiting for it. We know there are patients waiting for it. So I think you could expect a pretty fast uptake of the drug, especially in the United States.

Outside the U.S., we're going to have to drive for reimbursement. That will take longer. But I think in both cases, our expectations and confidence in both the speed of uptake and the potential total volume or total revenue potential of this drug is more significant today than when we did the deal, just given the strength of the stellar results and what we continue to expect. So we're quite bullish on this.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Chris. We have time for a couple more questions, please, Cedric.

Operator

Yes. Our next question comes from Andrew Baum with Citi. Your line is open.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. A clarification for Dean, and then a question for Rob. So just in regards to the previous question about TROP-2, just so I'm clear, do you plan to stratify or select for TROP-2 expression in your first-line first, and second-line outcome trials, particularly for those patients with actionable -- without actionable genomic mutations. So, are you actually going to stratify or select within the trials aimed at that patient cohort?

And then, second, for Rob, if your efforts to repeal or amend the IRA are unsuccessful, would you delay the launch of your oral PCSK9 until you have outcome data in hand? Many thanks.

A - Dean Y. Li {BIO 21985278 <GO>}

Yes. So let me just take care. I don't want to get too ahead of what's on clinical trials, but as I've emphasized, especially when we're thinking about first-line non-small-cell lung cancer, given what we think is the standard-of-care, we think that it will be important to review that in the setting of a biomarker selection. And I just kind of want to leave it at that.

The precise design will come out as the teams actually roll it out, but we think that, as I've said before, the biomarker strategy will be very important for our push of TROP-2 ADCs into lung cancer.

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. And on the question of how we think about the oral PCSK9 and would we delay for an outcome study, I think it's too early to make that kind of decision, because frankly, how we think about the outcome study and whether or not -- and what kind of label we get before we have an outcome study is still something we're working through. So we need to understand the label. We need to understand the timing of the outcome study.

And until I know all those points, I wouldn't want to get ahead of where we would be. So more to come. We've got some time on that one.

Thank you, Andrew. So, last question, please, Cedric.

Operator

Yes. Our last question comes from Steve Scala with TD Cowen. Your line is open.

Q - Steve Scala {BIO 1505201 <GO>}

Oh, thank you so much. A question for Dean on the KEYTRUDA data in periadjuvant ER-positive breast cancer. Should we expect the EFS to read out well before the KEYTRUDA LOE, so the commercial opportunity can be realized? How do you think it stacks up to CDK4/6 inhibitors in the adjuvant setting? And is there potential to file for neoadjuvant approval in the meantime? Thank you.

A - Dean Y. Li {BIO 21985278 <GO>}

So, I'll just step back a little bit. So, the KEYNOTE-756, as you've noted, is ER-positive, HER2-negative. It's earlier stage. It is neoadjuvant/adjuvant. We've given, based on the data that we've given in a press release, that it's path CR in relationship to an interim. As you know, EFS is already event-based.

And so, the question is, how fast do you accrue events in relationship to that? And our hope is the answer to your question is yes, but we will just have to see, because they are event-based. I would just highlight, in KEYNOTE-522, which is triple negative breast, which is also earlier stage, which is also neoadjuvant, adjuvant, and also at a positive path CR, we've demonstrated that that path CR is a predictor of the future, followed up by EFS. And so, we'll have to just watch that data as that data advances.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thanks, Steve. Rob?

A - Robert M. Davis {BIO 6955931 <GO>}

Yes. Well, I appreciate everyone investing time today with the call. And just really maybe to conclude, I just want to reinforce how confident I am about how well positioned we are to continue to drive value creation for patients, for shareholders, and for all of our stakeholders well into the future.

And, again, I just really want to thank all of my great colleagues across the globe for their substantial efforts. We really do look forward to building on the progress we have in the second half of 2023 and beyond. And hopefully, what you took from our comments today, both prepared and in the Q&A is our confidence in the progress we're making, and in the -- really, the difference we can make for patients across an ever-broadening area of therapeutic possibilities. So it's exciting what we have in front of us right now. Thank you.

A - Peter Dannenbaum {BIO 20569031 <GO>}

Great. Thank you all.