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Q2 2020 Earnings Call

Company Participants

- Anne White, President, Lilly Oncology
- Daniel M. Skovronsky, Senior Vice President, Chief Scientific Officer & President of Lilly Research Labs
- David A. Ricks, Chairman, Chief Executive Officer, and President
- Joshua L. Smiley, Senior Vice President and Chief Financial Officer
- Kevin Hern, Vice President of Investor Relations
- Mike Mason, President, Lilly Diabetes
- Patrik Jonsson, President, Lilly Bio-Medicines

Other Participants

- Andrew Baum, Analyst
- Carter Gould, Analyst
- Chris Schott, Analyst
- David Risinger, Analyst
- Geoff Meacham., Analyst
- Louise Chen, Analyst
- Navin Jacob, Analyst
- Seamus Fernandez, Analyst
- Steve Scala, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst
- Vamil Divan, Analyst

Presentation

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Lilly Q2 2020 Earnings Call. And at this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. (Operator Instructions) As a reminder, today's call is being recorded.

I will now turn the call over to your host, VP, Investor Relations, Kevin Hern. Please go ahead, sir.

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Kevin Hern {BIO 20557573 <GO>}

Thank you. Good morning, and thank you for joining us for Eli Lilly and Company's Q2 2020 Earnings Call. I'm Kevin Hern, Vice President of Investor Relations. Joining me on today's call are, Dave Ricks, Lilly's Chairman and CEO; Josh Smiley, Chief Financial Officer; Dr. Dan Skovronsky, Chief Scientific Officer; Anne White, President of Lilly Oncology; Patrik Jonsson, President of Lilly Bio-Medicines; and Mike Mason, President of Lilly Diabetes. We're also joined by Sarah Smith and Mike Czapar of the Investor Relations team.

During this conference call, we anticipate making projections and forward-looking statements based on our current expectations. Our actual results could differ materially due to a number of factors, including the extent and duration of the effects of the COVID-19 pandemic as well as other factors listed on Slide 3 and those outlined in our latest forms 10-K, 10-Q and any 8-Ks filed with the Securities and Exchange Commission. The information we provide about our products and pipeline is for the benefit of the investment community. It is not intended to be promotional and is not sufficient for prescribing decisions.

As we transition to our prepared remarks, a reminder that our commentary will focus on non-GAAP financial measures, which exclude the financial contribution from Elanco during 2019 and present earnings per share as though the full disposition via the exchange offer was complete on January 1, 2019.

Now I'll turn the call over to Dave for some opening comments.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin. A lot has changed in the world since our last earnings call. Science has continued to advance our understanding of COVID-19, and efforts across the industry to develop treatments and vaccines are progressing rapidly. While some regions and countries have begun to reopen, COVID-19 cases and deaths are climbing in other places. Despite these challenges, Lilly continues to demonstrate resilience and resourcefulness to progress our mission of making medicines for the millions of patients we serve. I've never been more proud of the company and my 35,000 teammates.

This past quarter was unlike any other during my tenure as CEO, concurrently combating social, economic and public health crises. Economic uncertainty remains as high unemployment persists in many countries. As expected, our business experienced headwinds this quarter with patients unable to see doctors or access healthcare during periods when the economies were shut down to prevent the spread of COVID-19 and by the dwindling -- or the -- and by the unwinding of forward buying into Q1 that occurred. Overall, our year-to-date results are strong and indicate -- indicative of the underlying trends.

I'm proud of Lilly's efforts to ensure patients have access to their medicines, to find creative ways to ensure we advance critical research and to advance our ongoing efforts to develop treatments for COVID-19. We continue to staff our manufacturing facilities around the globe with essential personnel to ensure there are no disruptions in the supply

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of medicine. And in recent weeks, we resumed activity in the majority of our clinical trials, where enrollment had been paused.

We're resuming in-person promotional activities when it's safe on a country-by-country and on a state-by-state basis in the US. And we will continue to use these virtual engagement tools we've built to augment in-person promotional activities. Throughout Q2, we saw a steady increase in customer contacts and medical education touchpoints as we leveraged new platforms to reach physicians. We continue to see increase in interest and volume of virtual interactions from physicians and expect a hybrid model of in-person and remote engagement for some time in the US as well as internationally.

We also made good progress this quarter executing our R&D strategy, launching two new medicines in the US including Retevmo, the first therapy ever approved for patients with RET-driven lung and thyroid cancers; and Lyumjev, a fast-acting mealtime insulin for patients with type 1 and type 2 diabetes. Taltz in nonradiographic axSpA; Cyramza in combination with erlotinib for EGFR-mutated non-small cell lung cancer; and Tauvid, our new diagnostic for patients with Alzheimer's disease, were also approved in the U.S.

Several positive Phase 3 readouts this quarter include Verzenio in adjuvant breast cancer, now the first and the only CDK4/6 inhibitor to succeed in this population; mirikizumab in psoriasis compared to both placebo and head-to-head versus Cosentyx; and just today, in collaboration with Boehringer Ingelheim, Jardiance in heart failure patients with reduced ejection fraction both with and without diabetes.

We also continue to make progress on our potential COVID-19 therapies, notably the initiation of multiple clinical trials developing neutralizing antibodies both as monotherapy and in combination. Dan will provide you with more detail during the R&D update. The unprecedented pace at which we're executing this project across our development and manufacturing organizations is evidence of what we are capable as an innovative company.

As I mentioned earlier, our Q2 business results were negatively impacted by COVID-19. However, we remain confident in the underlying fundamentals of our business. COVID-19 had a meaningful impact on economic activity. And we observed the following trends in the US, a sharp decline in the number of patient visits to physicians dropping to roughly 50% of pre-COVID-19 levels; reduced visits translated into fewer new prescriptions with the peak impact in late April and early May in most therapeutic classes; a slow return to healthcare activity through a combination of Telehealth and in-person visits as IQVIA data showed patient visits were back to 85% of pre-COVID-19 levels in June; and new prescriptions slowly beginning to recover, although some variation across therapeutic areas. While the outlook for economic activity is uncertain, we remain optimistic that patients, physicians and hospital systems will continue to find ways to ensure patients can access the medicines they need.

Turning to our Q2 results. As expected, reduced patient visits and inventory dynamics were both a drag on otherwise solid total prescription trends. Revenue declined 2% compared to Q2 2019. And we estimated revenue was negatively impacted by the reversal

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of largely all of the $250 million of stocking related to COVID-19 that we experienced in Q1. While most existing prescriptions were maintained, new patient prescriptions declined in Q2 relative to pre-COVID-19 baselines. We estimate this impact to have been about $250 million across the portfolio. Taking into account current trends, we are on track to deliver the financial goals we established for 2020. The strength of our new products, our ability to scale them worldwide and our productivity agenda position us well to continue to deliver robust business performance and to create shareholder value.

Moving to Slide 5. You'll see the full list of key events since our last earnings call. Before Josh discusses our financial results, just a few comments about the executive orders that were announced last Friday. We all share the goal of making medicines more affordable and accessible to patients and believe concepts such as rebate reform and the sharing of savings within the eligible 340B patient population offer real opportunities to lower the out-of-pocket costs for patients quickly. However, as I've noted before, the concept of international price indexing is a bad policy. This policy will have almost no benefit to patient out-of-pocket costs, but together with reimportation will most assuredly have serious negative consequences for patients, for the safety of our supply chain and for the future of innovation. So now is the wrong time to introduce sweeping government actions that will at best distract and at worst cripple the same industry that's racing to discover vaccines and treatments to defeat COVID-19.

Now I'll turn the call over to Josh to review our Q2 results in more detail and provide an update on our financial guidance for 2020.

Joshua L. Smiley {BIO 19888026 <GO>}

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Thanks, Dave, and good morning, everyone. Moving to Slide 6 and 7. Our non-GAAP financial performance in Q2 and during the first half of 2020 was impacted by COVID-19 across many lines of the income statement. As Dave mentioned, revenue declined 2% this quarter compared to Q2 2019 and was negatively impacted by COVID-19 in two ways. First, largely all of the $250 million of COVID-related stocking in Q1 reversed as excess supply in the channel and in medicine cabinets was consumed and Q2 closing inventory returned to historically normal levels. Second, reduced patient visits due to COVID-19 resulted in lower new prescriptions across many of our brands, which we estimate had a negative impact on Q2 revenue of approximately $250 million as well. We estimate this impact to be a temporary step-down in market size, which we expect will return to pre-COVID levels over the balance of the year, with the pace of recovery varying by therapeutic area.

Given the stocking and destocking seen between quarters, our first half performance of 7% sales growth in constant currency is a more accurate reflection of underlying performance. Gross margin as a percent of revenue in Q2 was 79.6%, a decline of 140 basis points versus Q2 2019, driven primarily by the negative impact of price, which I'll describe in more detail in a moment.

Moving down the P&L. Selling, general and administrative expenses declined 9% this quarter compared to Q2 2019 as reduced marketing and travel and meeting expenses were only partially offset by investments in virtual tactics. Research and development

expenses declined 1% as the pause in clinical trials have shifted activity and expenses to the second half of 2020. In total, operating income decreased 2% compared to Q2 2019.

During the first half -- sorry, I'm just having a technical issue here.

David A. Ricks {BIO 16504838 <GO>}

Just take this one. We just had a system problem.

Joshua L. Smiley {BIO 19888026 <GO>}

So in total, operating income decreased 2% compared to Q2 2019. During the first half of 2020, operating income increased by 14% as revenue growth outpaced operating expense growth by 500 basis points. Operating income as a percent of revenue was 28% during the second quarter and 29.1% for the first half of 2020. We continue to adapt the way we allocate resources to efficiently operate in an environment where the threat of COVID-19 is likely to be disruptive for a sustained period of time. We're expanding our virtual capabilities to support executing our strategy and are committed to our 2020 full-year operating margin target of 31%.

Other income and expense was income of $447 million this quarter compared to an expense of $32 million in Q2 2019. This quarter's other income was primarily driven by the increase in value of investments in Asian biopharma companies as well as previously private companies that went public here in the US. We have investments across a range of private and public biopharma companies as a part of our external innovation strategy. And these investments allow us to nurture emerging science and access potential new medicines and novel modalities. As we regularly highlight, this line item can be volatile as public market valuations fluctuate.

Our tax rate was 13.4%, an increase of 340 basis points compared with the same quarter last year, driven by the mix of earnings in higher tax jurisdictions and a lower net discrete tax benefit than last year. At the bottom line, earnings per share increased 26% in Q2 as the sizable gain on public equities more than offset the decline in operating income. During the first half of 2020, earnings per share increased 29%.

On Slide 8, we quantify the effect of price, rate and volume on revenue. Worldwide revenue declined 2% during Q2 as volume growth of 6% was offset by price. Foreign exchange had an additional 1% negative impact on revenue growth. During the first half of 2020, revenue grew 7% in constant currency as volume grew 13% and price declined 7%, or 5% excluding the impact Alimta and Tyvyt had in China.

US revenue declined 3% compared to the second quarter of 2019. Volume growth of 4% was led by Trulicity, Taltz, Emgality and Verzenio. As mentioned earlier, we saw destocking at the wholesaler and patient level due to COVID-19 that contributed approximately $200 million of negative impact during the quarter. In addition, we estimate reduced new prescriptions due to COVID-19 negatively impacted Q2 revenue by approximately $150 million.

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Pricing was an 8% drag on US revenue growth this quarter, impacted by predominantly changes to estimates for rebates and discounts, most notably impacting Humalog, which was driven primarily by favorable Medicaid adjustments in the prior period and unfavorable commercial adjustments in the current period; then to a lesser extent, by higher growth across the portfolio in lower net price segments and increased rebates to maintain our strong commercial access, which was partially offset by reduced co-pay program utilization for Emgality and Taltz as a function of improved access versus last year.

As we've previously discussed, our quarterly pricing trends in the US fluctuate based on delayed invoicing from customers, seasonality of co-pay assistance and our obligations during the coverage gap in Medicare Part D. Excluding the impact of the onetime Humalog adjustment and focusing on trends that impact our business going forward, we saw an underlying pricing trend of low single-digit decline in Q2 versus Q2 2019. And this is consistent with our current expectation of mid-single-digit price decline for the year with the underlying low single-digit net price decline combined with onetime adjustments in the first half of 2020 and modest effects of COVID-19 in the second half of the year.

During the first half of 2020, U.S. revenue increased 5% versus last year, volume grew 11% and price declined 6%. We are encouraged by the improving demand trends in recent weeks and more normalized shipping trends. As we conclude 2021 U.S. contracting negotiations, we remain confident in our strong commercial and Medicare Part D access across the portfolio and our ability to maintain this going forward.

Moving on to Europe. Revenue declined 4% in constant currency as price and volume declined by 2% each. Strong volume growth from Trulicity, Verzenio and Taltz was offset by volume declines from Cialis, Forteo, Olumiant, Strattera and Humalog. We estimate European revenue was reduced by approximately $50 million due to COVID-19-related destocking in Q2 and roughly $35 million due to COVID-19-related lower new prescriptions. Despite fluctuation across quarters, the underlying trends are very strong as Europe posted volume growth of 11% during the first half of 2020 as our new products continue to scale.

In Japan, revenue declined by less than 1% in constant currency as 4% volume growth was more than offset by government-mandated price decreases effective April 2020. In addition, we estimate reduced new prescriptions due to COVID-19 negatively impacted Q2 revenue by approximately $35 million. The solid volume growth in Verzenio, Trulicity, Olumiant and Cyramza were the key contributors to growth, partially offset by the increased competition for Forteo and the impact of generic Straterra.

In China, revenue grew 8% in constant currency driven by 50% volume growth, largely offset by price. Volume and price were both affected by the inclusion of Tyvyt and Alimta in government-sponsored programs, which substantially increased access for patients to these important cancer medications. Outside of the oncology portfolio in China, we saw a rebound in new patient initiations and in-person customer interactions as the pandemic's impact began to moderate. Our newest launches, Trulicity, Taltz and Olumiant, are seeing good uptake. And Humalog, Cialis and Cymbalta are again exhibiting solid growth.

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Revenue in the rest of the world increased 7% in constant currency, driven by increased volume from our key growth drivers. Strong performance from Trulicity, Jardiance, Taltz and Verzenio was partially offset by decreased Cialis volume. Revenue was negatively impacted by COVID-related reduced new prescriptions by approximately $25 million, which was more than offset by the sale of a legacy product in Asia.

As shown on Slide 9, our key growth products continue to drive impressive worldwide volume growth. These new medicines delivered over 12 percentage points of volume growth this quarter. The strong volume growth -- volume trend in our key products was partially offset by a mix of competition and lower utilization of post-LOE products, Forteo and Cialis, as well as reduced Tradjenta royalties from the restructuring of our alliance with Boehringer Ingelheim that we announced last year. We exit the first half of 2020 pleased with the 16% year-to-date volume growth that our key products have delivered despite a challenging environment.

Slide 10 highlights the contributions of our key growth products. In total, these brands generated nearly $3 billion in revenue this quarter, making up 54% of revenue. While 12% volume growth from key products in Q2 is robust, the negative impact on new patient starts from COVID-19 pandemic and COVID-19-related inventory movements across quarters were a drag on growth in the quarter. We expect both of these impacts to be transient, and we are seeing new-to-brand prescriptions recover in June and July. The underlying business is robust. And while COVID-19 has impacted our therapeutic areas differently, our product-specific trends within the market backdrop are strong.

In diabetes, Trulicity remains the market leader in the U.S. GLP-1 market with over 45% share of total prescriptions. While new-to-brand prescriptions for the GLP-1 class were 32% less than pre-COVID-19 levels at one point during Q2, activity is trending in the right direction and now sits at around negative 16% for the week ending July 17. Total prescription trends have slowed some but were still robust through the class and grew by 27% in Q2 compared to last year. As the class leader, Trulicity is well positioned for future growth. And we look forward to regulatory action later this year on the higher doses of Trulicity. We expect the potential launch of additional doses to be an important option to allow patients to realize benefits while extending their duration of therapy on Trulicity.

In another large and fast-growing diabetes class, Jardiance maintained market leadership in the US. SGLT2 class with over 57% share of total prescriptions. The SGLT2 class saw a similar magnitude of reductions as the GLP-1 class in new-to-brand prescriptions as new prescriptions were 38% less than the pre-COVID-19 levels before recovering some in June and July. Current weekly trends are approximately 15% below pre-COVID-19 levels. Jardiance continues to be the catalyst for class growth in new and total prescriptions, growing over 12 percentage points faster than the market in Q2 with 32% growth versus last year. We're excited by the recently announced positive results of Jardiance in patients with heart failure in the EMPEROR-Reduced trial and look forward to the EMPEROR-Preserved trial readout in 2021. We estimate the addressable market from each trial is up to 3 million additional patients in the US, adding a potential new source of future growth for Jardiance.

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In oncology, Verzenio continues to show positive trends in the metastatic setting as U.S. share of market in new-to-brand prescriptions continued to increase above 20%. While new-to-brand prescriptions for the CDK4/6 class were more than 30% below pre-COVID levels at one point in the quarter, Verzenio fared better at negative 19%, and the most recent week of new-to-brand prescriptions is above the pre-COVID-19 average. Verzenio had positive momentum as the monarchE trial results add to the compelling existing data package. We look forward to presenting these data at a medical meeting later this year.

Tyvyt, our immuno-oncology product in collaboration with Innovent in China, posted another strong quarter of performance and was the biggest driver of China's 50% volume growth in Q2. Tyvyt was added to the National Drug Reimbursement List in January this year. And we anticipate strong sales momentum in the second half of 2020. We expect Tyvyt to continue to be an important driver of growth in China.

Our newest oncology medicine, Retevmo, had a strong launch despite debuting during a challenging external environment. We're encouraged by early demand signals. And initial customer feedback on the impressive safety and efficacy profile is very positive. Our sales force and medical science liaisons are actively engaging with 6,000 lung and thyroid specialists through virtual tactics. And our existing relationships with this customer base are leading to high-quality interactions and increased brand awareness for this first-in-class medicine. While still early in the launch, we're excited about the fast start and continue to believe we have a best-in-class product.

In immunology, we saw strong new-to-brand trends with Taltz early in Q1, followed by a sizable but more gradual impact of COVID-19. Compared to pre-COVID levels, new-to-brand prescriptions across immunology declined 36%. While this category has also been slower to recover, the most recent weeks have showed improvements in trends. However, new-to-brand prescriptions for the total market are still 21% below pre-COVID levels. Taltz continues to compete for leadership in dermatology new-to-brand share of market. And rheumatology trends are encouraging, although growing from a smaller base. Total Taltz prescriptions grew 11% in Q2 compared to Q1 and 35% versus Q2 2019. We remain confident that our compelling data package of head-to-head trials and recent approval in non-radiographic axSpA will deliver growth in a competitive field of immunology agents.

In migraine, we've also seen a more prolonged decline in new-to-brand prescriptions due to COVID-19. New-to-brand prescriptions in the injectable CGRP class have been 15% to 20% below pre-COVID levels since late April and through July. Emgality's share of market remains strong with over 38% of new and total prescriptions within the class. Although new-to-brand trends have been impacted by COVID-19, class growth for total prescriptions was robust in Q2, increasing 64% compared to last year and 12% versus Q1 2020. Given the importance of primary care physicians in driving growth with the return of active promotions from multiple competitors, we expect class growth to reaccelerate in the second half of 2020.

Also in migraine, our acute therapy, Reyvow, was significantly impacted by the lack of patient visits and in-person customer interactions related to COVID-19. While uptake so far has been modest early in the launch, we'll make investments to drive awareness and focus our promotional efforts in the coming quarters to drive uptake. While the field is

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competitive, we continue to believe our portfolio of both acute and preventative treatments with 2 mechanisms of action is a differentiator for our migraine franchise.

On Slide 11, we provide an update on capital allocation. During the first half of 2020, we invested over $4 billion to drive our future growth through a combination of business development, capital expenditures and after-tax investment in R&D. In addition, we returned almost $2 billion to shareholders versus share repurchase -- via share repurchase and the dividend. We remain well capitalized and have the ability to access debt markets at attractive rates. We expect to continue to enhance our long-term growth by acquiring first- or best-in-class pipeline assets and do not anticipate COVID impacts regarding travel or market uncertainty to affect our efforts.

Before we provide an update on our 2020 financial guidance, Slide 12 provides an overview of the composition of our U.S. business split by payer segment mix. This is a topic of frequent interest to investors and is pertinent as we monitor the currently high levels of unemployment and the potential for that to negatively impact our business. Based on gross sales during the first half of 2020, within our existing business, commercial plans make up the largest portion at around 40%. Medicare Part D is the second largest segment at approximately 20%, mainly due to our diabetes portfolio. Government and hospital segments make up roughly 15%. Medicaid is around 10%. Medicare Part B is nearly 5%. And then non-contracted business, uninsured and cash make up the remaining 10%.

So as we continue to monitor and analyze the potential impact of unemployment, causing people to lose their commercial insurance and potentially shift to Medicaid, our modeling suggests this will have a modest impact in 2020 and is contemplated in our financial guidance range. We expect these trends to have a larger impact in 2021. And the magnitude will be driven by: the size and duration of employment in the US; the quality of commercial or ACA exchange insurance plans displaced employees move from the majority of our products as newer products have smaller net pricing spread between Medicaid and commercial plans; and government stimulus or relief plans that may keep patients on commercial insurance.

While there is uncertainty on how all these factors will play out, at this time we anticipate increased utilization of Medicaid versus commercial insurance to be a moderate headwind to revenue in 2021 of approximately $200 million. This approximation contemplates peak US unemployment in the low double digits in 2020 and a gradual recovery in 2021 to high single-digit percent unemployed by year-end. We do not have an estimate on the impact of the executive orders on 2021 at this point. But given the uncertainty around them and our modest exposure to Part B, we expect the near-term impact to be limited. Given our view of 2021 pricing negotiations, we still expect mid-single-digit price impacts across the portfolio in 2021.

So now moving to Slide 13. You'll find our updated 2020 financial guidance. This is based on our best estimates at this time and similar to how we approach Q1. We're balancing transparency and insight into the current view of the business with the uncertainty we're all facing surrounding the extent and duration of the impact of the COVID-19 pandemic.

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Key assumptions supporting our updated guidance include: health care activity returns to normal levels in the second half of 2020 as doctors utilize telehealth or in-person visits to see patients despite potential additional COVID-19 outbreaks; the recovery in new patient prescriptions improves in the U.S., reaching and then growing above pre-COVID-19 levels by Q4 for most brands, noting the trends will differ regionally and by brand; price headwinds from increased utilization of patient affordability programs and changes in segment mix due to increased US unemployment continue to be modest; clinical trial sites remain open and active in enrolling patients; and promotional spend in the second half of the year constitutes a mix of in-person customer interactions, direct-to-consumer advertising and investments in supporting digital promotion.

While uncertainty remains regarding the continued spread of COVID-19 and the resulting impact on the pace of economic recovery around the world, we believe health care activity will continue to be a priority and that patients and physicians will find ways to access health care. We believe the stocking and destocking activity observed in Q1 and Q2 had largely washed out. And we are encouraged by the demand trends and more normal shipping patterns we're seeing with our customers. As a result, we're maintaining our revenue range, recognizing additional closures in the health care system could cause us to revisit that range later in the year.

Moving down the income statement. We're lowering our gross margin as a percent of revenue to be approximately 80% on a non-GAAP basis. This reduction reflects changes in geographic mix and lower realized prices. We expect our GAAP gross margin to be 78%. We're also lowering our range for marketing, selling and administrative expenses by $200 million to reflect savings from reduced travel meetings and in-person promotional activities, which are only partially offset by investments in digital capabilities. Our range for research and development expenses is unchanged. We expect savings associated with temporary pausing of clinical trial starts and enrollment to catch up in the second half of 2020 as we resumed activity in Q2.

Of note, if we see positive data in our neutralizing antibody treatments for COVID-19 that supports broader development, we plan to fully invest in registrational clinical trials anofd further scaling of manufacturing capacity. Under this scenario, our research and development expenses are likely to be on the high end of our range as Lilly is self-funding all of these programs. We believe these investments are important to help combat the impact of the global pandemic.

Our non-GAAP operating income as a percent of revenue goal of 31% remains as a reduction in total operating expenses offset the slightly lower gross margin percentage. We're updating the range for other income and expense to $350 million to $500 million of income, reflecting gains in our equity portfolio seen in the second quarter. As I mentioned earlier, this number is, of course, subject to volatility in the capital markets.

Turning to taxes. We're reducing our GAAP and non-GAAP effective tax rate guidance to approximately 14%, driven by the net discrete tax benefits we booked for the first half of the year. So earnings per share is now expected to be in the range of $7.20 per share to $7.40 per share on a non-GAAP basis. Our GAAP EPS is expected to be in the range of $6.48 per share to $6.68 per share.

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Q2 was certainly an atypical quarter. As I highlighted earlier, COVID impacted our financial results in a number of ways. However, our confidence in the strength of our underlying business and our demonstrated ability to overcome challenges gives us the conviction to reaffirm our robust outlook for sales growth and productivity.

So I'll now turn the call over to Dan to provide an update on our ongoing efforts to develop treatments for COVID-19, a summary of key data disclosures in Q2 and a pipeline update.

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Josh. Since our last call, we've had major life cycle readouts for three of our most important new medicines: Verzenio, Trulicity and Jardiance. All three were positive, all represent clinically meaningful advances for patients and all should help drive continued growth for these important brands. I'll speak briefly about each as well as a Phase 3 readout for mirikizumab, a molecule still under development. In addition to advancing our existing R&D portfolio, we have devoted significant efforts to creating and testing potential therapies for COVID-19. And here, too, we have made good progress this quarter. Before I go through the pipeline update, I'll provide an update on our COVID-19 therapies.

Moving to Slide 14. We provide an overview of the active programs we're pursuing to treat or prevent COVID-19. These programs have moved with unprecedented speed in hopes of finding new medicines to help blunt the impact of the virus. Baricitinib, our JAK inhibitor, has two ongoing Phase 3 clinical trials in patients hospitalized with COVID-19. The anti-inflammatory activity observed by baricitinib in other diseases is thought to be potentially beneficial in treating COVID-19. The first trial is investigating baricitinib in combination with remdesivir as part of the NIAID Adaptive COVID-19 Treatment Trial. And we expect to have data from this trial within the coming months. The second trial is Lilly-sponsored and is assessing baricitinib as monotherapy. We expect results from this trial later this year.

Second, we're pursuing a Phase 2 trial of an antibody that targets Angiopoietin-2, which has been observed to be elevated in patients with acute respiratory distress syndrome or ARDS. Based on trial enrollment, we now expect to have data in-house this fall to inform next steps.

While these 2 efforts may inform treatment of the symptoms of COVID-19, the approach I'm most excited about is virus-neutralizing antibodies for the treatment and prevention of COVID-19, both as single-antibody therapies and in combinations. We currently have efforts ongoing with LY-CoV555, which arose from our collaboration with AbCellera; and with LY-CoV016, which we licensed from Junshi Biosciences. The development status is summarized on Slide 15.

Both antibodies have completed dosing in their Phase 1 studies with safety and PK results that support advancing the molecules. Neither Phase 1 study was designed to collect efficacy data as the 555 trial only enrolled six patients per dose and 016 enrolled only healthy volunteers. 555 is further along in development and has progressed to a large dose-ranging Phase 2 study in ambulatory patients recently diagnosed with COVID-19.

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Here, we are focused on reducing viral load. The study is enrolling quickly, and we should have data to report by Q4. This will be our first opportunity to share human efficacy data from the neutralizing antibody program.

Based on safety and tolerability data gathered to date as well as taking into account the gravity of the unmet medical need here, we plan to initiate registrational studies in the coming weeks, even in advance of having efficacy data. We envision studies across several different patient populations, including a Phase 3 study for prevention of COVID-19 in residents and staff at long-term care facilities as well as additional registrational studies for a potential treatment indication in both the ambulatory and hospitalized settings. Once underway, the timing for data disclosures from these trials will be highly dependent on patient enrollment and any interim efficacy and safety data we may see.

In addition to the monotherapy trials I described for 555, we intend to test the combination of 016 with 555 in case such a combination is needed to combat viral resistance. We look forward to producing additional data for both programs. And we'll provide updates as we achieve program milestones or data become available. We continue to invest in manufacturing for these potential therapies at risk. And we're focused on ramping up our manufacturing capacity as quickly as possible.

While developing treatments for COVID-19 is an important priority for Lilly right now, we also continue to advance the rest of our pipeline to help people with diabetes, immune disorders, neurodegeneration and cancer. One particularly exciting development this quarter was the positive interim readout of the monarchE trial, assessing the use of Verzenio to reduce the risk of recurrence in HR-positive, HER2-negative, high-risk early breast cancer. Verzenio is the only CDK4/6 inhibitor to show a benefit in this setting, where another competing product failed at a futility analysis.

Our conviction in the differentiation of Verzenio from the competition continues to increase based on important data, including: safety and tolerability data and mechanism of action that have allowed for continuous dosing and therefore continuous target inhibition, this is a unique feature of abemaciclib; clinical efficacy that supports use even as a monotherapy in metastatic breast cancer, another unique feature of abemaciclib; the demonstrated benefit in overall survival in the metastatic setting in combination with fulvestrant, something not all CDK4/6 inhibitors have been able to show; and most recently, positive results in the adjuvant setting, another unique feature of abemaciclib. These data continue to support our convictions that not all CDK4/6 inhibitors are the same. The positive results in monarchE could significantly increase the opportunity for Verzenio.

Looking at the monarchE study clinical pathological criteria for enrollment, we estimate that approximately 20,000 patients in the U.S. would match these criteria. This represents a roughly 50% increase over the current addressable market in metastatic breast cancer, a market projected to reach almost $7 billion in 2020. In addition, we anticipate duration of therapy in the adjuvant setting will be longer. We plan to submit these data by the end of the year to regulators around the world and to present them at a major medical meeting in 2020.

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Moving to Slide 17. We also presented important Trulicity data at the virtual ADA and ENDO meetings this summer. In the on-treatment analysis, the 3-milligram and 4.5-milligram doses of Trulicity demonstrated statistically significant improvement in hemoglobin A1c reduction and weight loss versus the currently approved 1.5-milligram dose at 36 weeks. These doses could allow patients to receive additional clinical benefits and stay on Trulicity while still experiencing Trulicity's ease of use. We look forward to U.S. and EU regulatory action on the additional doses of Trulicity later this year.

At the virtual ADA, we also shared data which builds upon the existing body of evidence demonstrating the simplicity of the Trulicity patient experience combined with its powerful efficacy. In this real-world analysis of patients, after a minimum of 6 months of follow-up in the U.S., Trulicity demonstrated significantly higher adherence and persistence compared to 2 other weekly GLP-1s. In addition, significantly fewer people discontinued treatment on Trulicity compared to other agents. This real-world evidence complements the robust clinical data generated for Trulicity and provides further support for why Trulicity is the market-leading GLP-1.

Moving to Slide 18. You can see our select pipeline opportunities as of July 23. Movements since our last earnings call includes the previously mentioned U.S. approvals for Lyumjev, Retevmo and Tauvid; the U.S. approval of Taltz for non-radiographic axSpA, and Cyramza for EGFR mutated non-small cell lung cancer; the initiation of the Phase 3 tirzepatide cardiovascular outcome study, SURPASS-CVOT; the advancement of three new Phase 3 programs; the initiation of three Phase 1 programs; and the attrition of our first-generation KRAS G12C molecule. While we were excited about our initial KRAS program, we observed unexpected toxicity in the clinic that precluded further development. We're working to understand the mechanistic basis for the toxicity, and we are exploring a backup program.

Moving to Slide 19. We provided an update on our 2020 key events that have occurred during the quarter. In addition to the previously mentioned approvals, initiations and pipeline progress, we submitted Olumiant in the US for atopic dermatitis. As Dave mentioned earlier, we also announced positive Phase 3 readouts for Jardiance in heart failure and mirikizumab in psoriasis.

Beginning with Jardiance. We were optimistic about the likelihood of success in heart failure based on compelling CV data seen in diabetic patients in the EMPA-REG OUTCOME trial. We were pleased to see a positive outcome from the first heart failure trial to readout EMPEROR-Reduced. And we will present the data in August at the European Society of Cardiology and submit to regulators later this year. We look forward to additional Jardiance data readouts, including heart failure with preserved ejection fraction, the EMPEROR-Preserved trial, in 2021; and chronic kidney disease, the EMPA-KIDNEY study, in 2022.

We also announced a positive readout for mirikizumab Phase 3 in psoriasis, including success on the primary and all key secondary endpoints. It's particularly encouraging to see such robust data from mirikizumab in a head-to-head trial since trials such as these are the gold standard for comparing agents. Indeed, we've had a number of positive head-to-

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head trials with Taltz in psoriasis. And now we're pleased to see mirikizumab demonstrate superiority versus Cosentyx at 52 weeks on both PASI 90 and PASI 100.

Despite growing competition in psoriasis, Taltz remains an excellent option for patients that delivers clear skin fast. These new data suggest that mirikizumab also has the potential to be a meaningful treatment for people living with psoriasis. We look forward to submitting mirikizumab in this indication. And importantly, these data further our conviction in IBD, where we see the biggest opportunity. Given the relative priority of indications, we've been staging our investments in psoriasis. We have work ongoing to prepare for the psoriasis submission and plan to submit in the second half of 2021. Accordingly, we've also provided an updated time line for the Phase 3 data of mirikizumab in ulcerative colitis and Crohn's disease. We now expect the top line results for induction for ulcerative colitis in the spring of 2021 and for Crohn's disease in 2022.

Since we announced the pause of new trial starts and enrollment in many programs back in March, I'm pleased to report that we've reopened enrollment in the vast majority of clinical trials, and we are again initiating new trials. As we partner with clinical trial sites going forward, we've made a number of changes to how we run clinical trials that allow for many tests to be completed virtually. These new capabilities have come from necessity but are also improvements in the way clinical research is conducted and something we'll continue going forward. These are challenging times in drug development, but Lilly has demonstrated we have the creativity to adapt to the new environment, and we're committed to bringing new medicines to patients.

Dave, back to you for some closing remarks.

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David A. Ricks {BIO 16504838 <GO>}

Thanks, Dan. While mobilizing our resources to pursue treatments of devastating diseases is a natural part of our history and our company's purpose, on a separate note, I think all major employers are realizing we have a bigger role to play in the fight against systemic racial injustice. And as a corporate leader in diversity and inclusion, Lilly is committed to using our platform to speak up, speak out and work towards solutions to eliminate the racism and inequities that African-Americans and other minorities have experienced for far too long.

We are stepping up to bring people and organizations together to acknowledge the trauma of racial injustice, understand its many forms and create lasting change. To underscore our commitment to positive action, we also announced a pledge of $25 million and 25,000 employee volunteer hours over the next 5 years. The funding and volunteerism will be directed toward combating racial injustice and inequality primarily here in Indiana. And we plan to partner with other businesses and community groups to achieve our goals. While there's nothing easy about the road ahead, we can no longer accept systemic bias in any of its forms. And the time for platitudes is now behind us. The time for meaningful action, specifically by the corporate community, to drive lasting change is, in fact, now.

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So a busy quarter. Let me conclude with some closing comments on our progress in the first half of the year. As expected, our business experienced headwinds this quarter based on reduced new patient starts and changes in inventory we highlighted earlier this year. With that in mind, we are pleased that in the first half of 2020, we delivered strong volume-driven revenue growth of 7% worldwide in constant currency. We are cautiously optimistic about the recovery of both health care activity and prescription trends and expect both to accelerate during the second half of this year. We continue to find innovative ways to ensure our patients have access to the medicines -- to their medicines and that we can support physicians and hospital systems as they provide care. Our operating margin improved 200 basis points over the first half of 2019, and we made exciting progress on our pipeline this quarter. We saw 3 top line Phase 3 data readouts from important clinical programs. We had 5 U.S. approvals for NMEs and line extensions and achieved another -- a number of other clinical milestones that Dan just highlighted.

The COVID-19 global pandemic continues to be a disruptive force in the way we all work and live. Lilly and the broader pharmaceutical industry are working hard to develop new medicines to treat and to prevent the spread of COVID-19. We anticipate this disruption will continue until vaccines and new medicines can be used to manage the spread of the infection. While near-term challenges do exist, we remain confident in the long-term outlook for our company and the strength of our fundamentals. Lilly and Lilly people will continue to rise to the challenge. And I'm incredibly proud of our efforts to combat the global health crisis, social and economic crises we currently face.

This concludes our prepared remarks. Now I'll turn the call over to Kevin, who will moderate the Q&A session.

Kevin Hern {BIO 20557573 <GO>}

Thank you, Dave. We'd like to take questions from many callers as possible, so we ask that you limit your questions to two per caller. Kevin, if you can please provide the instructions for the Q&A session and then we're ready for the first caller.

Questions And Answers

Operator

Thank you. (Operator Instructions) We will now go to the first question and that will be from Seamus Fernandez, Guggenheim. One moment please sir. And sir, now your line is open.

Q - Seamus Fernandez {BIO 7525186 <GO>}

Yes, can you hear me?

A - Kevin Hern {BIO 20557573 <GO>}

Yes, yes.

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Q - Seamus Fernandez {BIO 7525186 <GO>}

Okay, great, thanks. So just a couple of quick questions. You know first for Dan. Dan could you help us understand a little bit more about the timing of your CoV-2 antibody data you know and also just wanted to get a little bit of the scientific discussion around your choice of pursuing a single antibody. I know that the AbCellera technology is unique, but just wanted to have a little bit more of a discussion around that. I think that would be helpful for investors as we think about the choice of the single antibody. I know you've talked about manufacturing as a driving choice there, but obviously the efficacy is paramount, so we just wanted to get a full understanding of that dynamic and that choice and how you hoped the study is going to read out.

And then, you know secondly, just as we think about the margin dynamics in the second half of the year, Josh I was just hoping that you could help us better understand the directional trajectory you know of how you're expecting the margins to shape up in the second half. How much of that is driven by meaningful revenue acceleration versus you know just an ability to kind of manage the expense line. Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. Dan, and then, Josh.

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Great. Thanks, Seamus, for those questions about the COVID-19 antibodies. Maybe just starting with timing. Of course, the timing of data disclosures depends on how fast the trials enroll and what the data show. We're committed to getting important information out to the public and the scientific community as quickly as it's available. With respect to the Phase 2 trial that is focused on viral load, I think this is going to be the first and probably a key indicator of potential efficacy for this approach. And I commented that we expect to have that data to disclose from this 400-patient Phase 2 trial in Q4. But again, that just depends on how fast we can enroll these patients.

Your second question there was around the rationale for a single antibody versus two or three cocktails of even more antibodies that have been proposed. And specifically, you asked around efficacy. So I think we and others have looked at monotherapy versus combination therapy in a variety of preclinical models of the disease and looking at neutralization of the virus infection of human cells, for example. And what you find is that combinations don't offer an efficacy boost. A single antibody can generally neutralize the virus just as well as combinations of antibody. The reason that people sometimes try combinations of antibody is because they're worried that over time resistance could emerge. So I don't expect to see any efficacy boost or efficacy diminution from having a combo or monotherapy in clinical trials. What we'll be looking for instead is whether or not there's emergence of resistance.

There are some factors that make that somewhat less likely here. I think the extremely high potency of 555 and its ability to effectively neutralize virus very, very quickly may decrease the risk of resistance. We've done some primate studies and we've not seen resistance emerge in those studies at all. But we'll be watching patients carefully. And we have the combination therapy that will move forward as a backup if resistance is seen. The

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advantages of monotherapy are obvious and you commented on them. It's simply that if you have one antibody, you can manufacture twice as much as a combo of two antibodies, three times as much as three antibodies. In a situation like this, I think there's societal tradeoffs that might indicate maximizing manufacturing capacity is a key objective. And so that's where we're aimed here. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Josh?

A - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Seamus. Yes. So if we look at our guidance for the year and think about the margin progression in the second half of the year, just a reminder, sales on a constant currency basis grew 7% in the first half. And our operating income percentage was a little bit over 29%. So to get to the 31% target we have for 2020, obviously we've got to see margin expansion in the second half of the year, but I think it's pretty straightforward. When we look at the sales range that we have, picking midpoints or wherever you want to pick, we're looking really at something close to 7% or 8% growth in the second half of the year. So while we expect an acceleration in sort of absolute sales on a half-to-half basis, it's not that much of a stretch from where we are.

We expect a little bit of a pickup probably in gross margin in basis points. And that's just a function of more normalized geographic impacts. As you know, we saw more of an impact in the U.S. in the first half of the year than outside the U.S. We expect those things to normalize a little bit in the second half of the year. And we're not anticipating any onetime pricing impacts, either up or down. So you'll see a little bit of a benefit there. But the big piece will come on the OpEx side and it's not from additional sort of cost savings moves. Our guidance range we provide for, again picking wherever you want to pick in the range, a couple hundred million dollars or so of increased investment in absolute dollars in combination of SG&A and R&D in the second half of the year.

So it's really just the absolute sales benefit that we'll see in the second half against a lower absolute increase but still an increase in OpEx. That gets us to something over 31% in the second half of the year. Put that together, that puts us at 31%. We feel like most of these things are certainly in our control. As I mentioned earlier and as Dan has talked about on COVID, we're going to invest fully behind those opportunities. That is contemplated in our guidance range. And to the extent we're higher on OpEx, at the higher end of the range, it's going to be primarily because of seeing good data and continue to move fast there. But we're confident in the margin expansion opportunity into the second half of the year for the reasons I just mentioned.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Seamus, thanks for your questions. Kevin, next caller please.

Operator

And that will be from the line of Geoff Meacham, Bank of America. Please go ahead.

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Q - Geoff Meacham. {BIO 21252662 <GO>}

Questions, I just had a few. On Verzenio I know we have yet to see data details, but can you speak to the real world duration of therapy today in metastatic and then what you would expect from the monarchE setting. And then, a quick drug pricing question for Dave. I know obviously you spent a lot of time on these issues, but you know what are the hurdles to getting IPI implemented and when you look across the Lily portfolio, can you speak to the category that may be more impacted from the executive order, other IPI rebates, etc. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks Geoff. We'll go Anne for the question on Verzenio and then Dave on IPI.

A - Anne White {BIO 20764375 <GO>}

Well Geoff, thanks for the question on Verzenio and the duration question is an important one and something that we're really excited about as part of the additional opportunity in EBC, and so we do expect the duration of treatment to be longer than the metastatic setting. And to your question, what we've seen in the RWE in the metastatic setting is about eight months. Now, we'll need to see what that actually is once the patients are being treated upon approval in the adjuvant setting, but obviously we're encouraged. The fact is the treatment duration in the study itself was 24 months. So we do expect it to be much longer than the eight months that we see in the metastatic setting.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Dave?

A - David A. Ricks {BIO 16504838 <GO>}

Yes. Thanks, Geoff. Well, I mean, we all observed last Friday's announcements. I think mostly these are not particularly new ideas. So my statements may be a repeat from prior calls. But on IPI specifically, this is being proposed under the CMMI model, Affordable Care Act. So that by itself is probably a problem, to seek to regulate the entirety of the US physician-infused market via that mechanism. And I think you expect the industry to vigorously challenge that authority. EOs don't create new authority. But if implemented -- and we have yet to see the text, by the way. I'm not sure the White House has put that out yet. But let's assume it's something like the 2018 blueprint proposal. We are relatively underexposed to this idea because it affects Part B physician-infused drugs.

Today, the two material medicines fit that in our portfolio, Olumiant,and Cyramza. Of course, Olumiant,, we expect a patent expiry in spring of '22. So you have a time window impact that's quite short; and Cyramza, which is obviously longer and a meaningful product, but a part of our growth story but not a cornerstone of it. Going forward, of course, if we looked at future medicines in the pipeline, there are infused medicines in immunology. And notably in Alzheimer's, should those succeed, that would -- you'd be concerned about. But I think drug companies have more ability to navigate on future products than they do on past -- products launched in the past because you can affect your primarily European pricing outlook perhaps with constrained demand in Europe but focused on a common floor price for the US. So we can navigate it.

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That said, it's horrible policy. And I think will -- sends a wrong message at a time when this industry is working literally day and night to help us all escape from COVID-19. Do we really want to be talking about this disruptive force? And the most well-capitalized companies are the least affected. Biotech, which we're not part of that small company group, but they will be severely affected. And investor interest in many of their companies could drop precipitously. I think that will be a real loss for what is an industry that's basically US-based. So we will fight it hard. And hopefully, it won't come to be.

On rebate, again this is an idea we've pursued and have been for, for some time as well as frankly we're not disappointed by the 340B pass-through idea that was presented as well. We think that the patients who drive the volume that plans negotiate discounts on should benefit from those discounts frankly as they do in every other part of the healthcare system, except medicines. So we think cost sharing and co-pay should be based on net price, not list, and these ideas forward that. Again, lots of barriers to implementation on those as well. And I'm sure other groups will oppose them. But we'll continue to support that concept of sharing the savings.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Geoff, thanks for your questions and next caller please?

Operator

Tim Anderson, Wolfe Research. Please go ahead.

Q - Tim Anderson {BIO 3271630 <GO>}

I have a commercial question on CDK4/6 class. So Pfizer's Ibrance is the market leader. But it is the only CDK4/6 that failed to show a survival benefit in formal Phase 3 trials in metastatic. And of course, it failed an adjuvant. Does Lilly think that the metastatic share that Ibrance has is materially a risk to competitors like Verzenio? Or will there realistically be stickiness to this segment? Pfizer said that its real-world study that show an OS benefit will protect it. But wondering what your view is. So it's really a question on the metastatic segment.

And then on tirzepatide, how do you characterize your level of confidence that the first upcoming Phase 3 results are going to be data that really wows investors like the Phase 2 trial results did? It's notable that analysts already carry about a $5 billion estimate for tirzepatide in the consensus model.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim. We'll go to Anne for the question on the CDK 4/6 class and then Mike Mason for the question on Tirzepatide.

A - Anne White {BIO 20764375 <GO>}

Well, thanks for the question, Tim, on Verzenio. And I -- we believe we've seen really positive trends with Verzenio in the metastatic setting. And I think Josh mentioned those in some of the intro. And we've really capitalized on the positive overall survival data from

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MONARCH 2 in the combination with fulvestrant. And so what we've seen versus Q2 2019 is worldwide growth of 56% in revenue and U.S. growth of 35%. And then if we look globally, we now had 49 approvals worldwide. And I think probably an important metric is the Japan NBRx share of market now at 58%. And so we've seen a very strong launch in Japan.

And so we believe, obviously, that with statistically significant survival data, that's really the gold standard in this class. And so we believe that more and more physicians will be trying Verzenio and we've seen that in the continued increase in the NBRx. And so we'll continue to share that message. We believe that this is the best-in-class agent. And I think it just goes to that whole picture of the differentiation that we see with Verzenio over time. And I just think that, that will shift physicians' minds.

The positive results from monarchE, as Dan mentioned, really do differentiate it from both CDK4/6s. And then we've got statistically significant results, not just in the overall population but then in the hard-to-treat populations, those with visceral disease and primary endocrine resistance. And again, you didn't see that with some of the other CDK4/6s. So I think we're starting to feel pretty strongly. And I think physicians are starting to agree with us that we have a differentiated agent here. And so you'll continue to see us press in the metastatic setting because we have that survival data. And now we get to make the move into the adjuvant study.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Mike?

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A - Mike Mason {BIO 18347681 <GO>}

Okay. For tirzepatide, we're glad to see that you were wowed by our type -- our Phase 2 data in -- for patients living with type 2 diabetes. I think the best thing really to do is to go back and take a look at the Phase 2 clinical studies. I mean we saw at the 15-milligram dose up to 2.4% A1c reduction and weight loss up to 12.7% versus placebo in just 6 months of study. So we're excited to see how tirzepatide can perform in this patient population and longer studies in Phase 3. There's nothing to tell us that we won't see exciting data coming out of the Phase 3. We don't have any new information to suggest otherwise. So we are incredibly confident about tirzepatide, not only in type 2 diabetes, but also we're excited to see its potential in NASH and obesity. So our enthusiasm remains very, very high. Thank you for the question.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Tim, thanks for your questions. Next caller, please.

Operator

And that's Umer Raffat, Evercore. Please go ahead.

Q - Umer Raffat {BIO 16743519 <GO>}

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Thanks so much for taking my question. Dan, I'm just trying to reconcile the positive commentary around your COVID mAb heading to registrational trials versus perhaps lack of any data -- efficacy data visibility from Phase 1. And if you could possibly speak to any trends you've seen already, that would be really helpful.

And then on KRAS, if you could -- I might have missed it, but if you could just add some more color on whether you ran into a therapeutic index challenge before efficacy kicked in. And if you could speak to what's the highest dose you actually dosed patients with on your KRAS. Because it seems like other KRAS inhibitors too didn't really have any efficacy until a very high dose and all of it kicked in at a certain dose. So it would be really helpful.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Umer. Dan, you'll take both of those?

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yes. Sure. Umer, thanks for both of those questions. So on the COVID mAb, you're sort of asking about the rationale of going to registrational studies without having seen efficacy data. It's not something we usually do. You're right. Of course, here, it's, as I said, the gravity of the situation and the rapidity with which we desire to test these therapies that have driven us to that decision. You asked about sort of trends that might have encouraged us from the Phase 1 study. And unfortunately, the answer is we don't have anything to talk about. We had one Phase 1 study that was in healthy volunteers. So they didn't have COVID-19, nothing to see there. And the other was so small in the hospitalized patients, 6 patients per dose group. And I think what we saw there is basically what you would expect across doses and placebo. All of the patients actually did really well and got better and left the hospital. That's not atypical for a Phase 1 study here and the population that physicians typically pull into those studies are some of the better patients who might be at the end of their disease course. I wouldn't expect antibodies in any case to have much effect in people whose viral load is already low and their immune system is already clearing the disease. So that's where we are.

I think the Phase 2 study, on the other hand, is patients who are early in the disease course. They're just within a few days of getting diagnosed. My expectation is they'll have high and, in many cases, increasing viral loads in the absence of therapy. And the goal here is to show that the therapy decreases the viral load. So that's the important readout. But as I said, we'll have started the Phase 3s by then.

On KRAS, this is an issue of off-target toxicity. So it's not related to the KRAS target itself is our view. That does, therefore, kill the therapeutic index and not possible to proceed with that drug. I don't think we, at this moment, give details on the exact nature of the toxicity or the highest dose that we tested. But we didn't feel we could proceed based on the doses at which we saw that tox. And we're trying to resolve that. In the backup program, we have some preclinical models for the tox. We'll see if they bear out or not.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Umar, thanks for your questions. Next caller, please?

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Operator

Andrew Baum of Citi, please go ahead. Mr. Baum, your line is open now.

Q - Andrew Baum {BIO 1540495 <GO>}

Hello. Can you hear me?

A - Kevin Hern {BIO 20557573 <GO>}

Yes.

Q - Andrew Baum {BIO 1540495 <GO>}

A question on US drug price reform. There are a number of live propositions. Obviously, the executive order referencing rebate reform, which obviously Lilly has supported, but it requires a positive CBO score in order to move forward. First question is do you think there's any possibility that could be achieved given the history of the CBO score and the belief required of an overall reduction in pricing through market-based competitions to get there and the CBO to reflect that? So that's number one.

And number two, an alternate proposition has got bipartisan support in the Senate. But it's stopping from reaching that Senate floor by Mitch McConnell. I know you have some concerns over that bill. But as a potential way forward to mitigate a more deleterious solution under either of the potential options going forward, can you see this progressing?

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A - Kevin Hern {BIO 20557573 <GO>}

Thanks Andrew. We'll go to Dave for both of those.

A - David A. Ricks {BIO 16504838 <GO>}

Yes. Thanks, Andrew. On the EOs, you're talking about rebate reform and the idea of pass-through. And the history here is, as you pointed out, the CBO score was extremely negative. In our math, largely driven by the one assumption you noted, which is that rebate value would essentially accrue back to manufacturers and thus raise premiums, it's a deeply flawed assumption. Of course, we'll compete. But the whole idea would be to move the basis of competition from sort of discriminated prices that are private to list price or other means to deliver pricing directly to consumers, discounts that pass-through, for instance. So that, of course, requires industry actors to change their practices. And that's not something that can be coordinated or messaged very well due to antitrust laws.

So we're sort of in this catch-22 on committing to deliver on sharing the savings but not being able to do that publicly. I think that's a problem. And it's particularly a problem for legislation. Of course, the executive order method has other problems in terms of legal power. But if enacted under administrative rules, there isn't necessarily a requirement to square the budget. So savings can be assumed in other ways and there's a different authority doing the math. That said, I think there are headwinds on this point, both within the executive branch as well as on the Hill. Nonetheless, it's the right thing to do. And I

think we need to continue to push for ways that everyone would have confidence that the industry would compete in a way that would lower consumer out-of-pocket costs. I can tell you, that's the goal when we advocate for this policy. And we need to find ways to provide that assurance, I think, to get movement.

You talked about Senate Finance, and Grassley reintroduced a version of his bill to try to make one last push. I believe his chairmanship is ending, in any case, at the end of this Congress. So it's understandable why he's doing that. I don't think that, that package has much of a chance to advance. There are always ways stars get aligned, and there's a number of health extenders due at the end of this Congress. But it's a pretty big piece of legislation to throw on an extenders package. The only possible way is that it does produce a positive budget impact, so in terms of it used to pay for other things. But probably, you don't need the whole package. So I think that's still a narrow path. And the most likely scenario is that these EOs can't take force and don't take force prior to a new presidential term, a new Congress sitting and that Senate Finance doesn't go anywhere either, nor does HR 3. I think that's sort of the probable planning scenario.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Andrew thanks for your questions. Next caller please.

Operator

That will be from the line of Louise Chen of Cantor. Please go ahead.

Q - Louise Chen {BIO 21301405 <GO>}

Hi, thanks for taking my questions. So my first question is, is there any way to quantify the operating margins what we would have seen in the first half '20 without R&D COVID spending and also headwind sales from the pandemic? And the second question I had was do you -- how do you think about tirzepatide as a single solution for diabetes, NASH and obesity?

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Louise. We'll go to Josh for the first question and then Mike for the second one.

A - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks, Louise. I think in the first half as I mentioned, our operating margin was 29.1%. I think if you add back some of the lost prescriptions, but then also keep in mind we had some savings associated with promotions, you know we're probably closer to 30%. We said as we came into the year, we expected margin expansion through the year. So that's still on track, but yes we're probably off by somewhere in the range of 50 to 100 basis points or something there.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Mike?

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A - Mike Mason {BIO 18347681 <GO>}

It's a great question on tirzepatide and I think we have a, just a phenomenal opportunity to not just be able to provide glucose control for those living with Type 2 Diabetes, but really affect their overall metabolic health. And so I think the contributions of both GLP and GIP can provide the opportunity to really provide improved metabolic health across Type 2 Diabetes, obesity and NASH that are related. And so it's a great question and I think it's a good opportunity for us to expand our focus beyond just helping someone living with Type 2 diabetes, better control their glucose. So a great question and obviously an area that that we will focus on. There will be people living with Type 2 diabetes that are in our NASH and obesity studies.

A - David A. Ricks {BIO 16504838 <GO>}

Maybe just to add to that. It goes maybe without saying, but I'll say it. The current utilization of GLPs in the total diabetes population in developed markets is something like 1 in 8 or 1 in 10 patients. And so the hope here is that we can rearrange the priorities and the sequence of treatment in a way where this powerful category, and here a dual-acting GIP/GLP, could be used earlier and more broadly to manage disease outcomes in a very different way. Today, type 2 diabetes is disease of failure. And perhaps this technology could help doctors and patients find success much earlier in the disease course.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike, Davis. Louise, thanks for your questions. Next caller, please.

Operator

Terence Flynn of Goldman Sachs. Please go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Great. Thanks for taking the questions. Was wondering on another one on Verzenio, if the monarchE data is going to be at ESMO or San Antonio Breast. And then if you think penetration in the adjuvant setting will be higher, lower or the same as in the metastatic setting over time. And then Josh, just on contracting, you talked about how those discussions are wrapping up now. Anything notable in terms of Trulicity or Taltz that we should consider as we think about those contracts for 2021?

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Terence. We'll go to Anne for the question on MonarchE and then Josh around the contracting.

A - Anne White {BIO 20764375 <GO>}

Yes, so thanks for the question Terence. So on the presentation we will be presenting at a medical meeting later this year. Unfortunately I can't confirm which one yet, but we will be presenting at the meeting this year. As far as on the penetration, well that's I think what's exciting about this opportunity, is that we are the only CDK 4/6 to have positive results in the adjuvant setting. And so I think our penetration for the high risk patients, which is the

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population that we had in MonarchE will be extremely high. So as we're hearing people ramp even to the top line opportunity, we're seeing that there's a lot of enthusiasm for having CDK 4/6 this setting, and so we look forward to sharing those results as I said later this year. Again, we see I think Dan and others mentioned in the introduction, we see this as an opportunity of only about 20,000 patients here in the U.S., as we matched our criteria in the study to the Sierra database.

So, I think we see a pretty significant opportunity. It's really probably half again of what we have in the metastatic setting, which has been significant. So to answer your question, we do expect strong penetration in this space over time.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Josh?

Q - Joshua L. Smiley {BIO 19888026 <GO>}

Yes. As you know, Terence, we won't sort of talk specifically about individual contracts or anything at this point. But I think for what we have seen, first, I'd go back to the earlier comments that we see a pretty similar pricing environment in 2021 to what we're seeing here, which would be modest net price declines, meaning we're providing slightly more rebates than what we're anticipating in terms of list price increases. And then we couple that with the other dynamic factors that we've mentioned. I think -- if you think about Trulicity, we've said sort of expect something plus or minus 5% net price declines over time. I think that's how we're viewing next year. It's a very competitive environment, of course. But we're focused on maintaining access, not looking to trade price per share or anything like that. So I think those negotiations are going as expected.

With Taltz, we've been focused on upgrading our access. And so to the extent that we're able to do that, you'll see that as a net price decline potentially but compensated for by increased access. Again, I think we're happy with the progress we're making this year and continue to focus on improving where we can for next year. But overall, again I'd say the general trend is we have fierce competition in the classes we're in, but we're focused on maintaining at least the access we have today and when we have the chance upgrading in areas like immunology.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Terence, thanks for your questions. Next caller, please.

Operator

Next will be Chris Schott, JPMorgan. Please go ahead.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks so much for the questions. Just maybe first on Verzenio, you highlighted 20,000 patients potentially in the US. Maybe just give us similar metrics about how you're thinking about the size of the eligible population in developed ex-U.S. markets? And then second question, very helpful color in terms of kind of a mix of unemployment headwinds

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for 2021. Any updates in terms of how you're thinking about potential international price pressures from some of the budget deficits we are seeing globally? Is that a '21 headwind to think about as well or is that going to take a little bit longer to manifest itself? Thanks so much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We'll got to Anne for Verzenio and then to Dave on the international question.

A - Anne White {BIO 20764375 <GO>}

Great. So thanks so much for that question on the Verzenio eligible population. So as I said in the U.S. about 20,000 eligible patients, which is about 10% to 15% of the HR positive, HER2- EBC positive. Outside the U.S. the pathology is similar and we estimated. So we estimated patient numbers in Europe about 10% larger than the U.S. and then Japan is about one-fourth of the side of the U.S. So I hope that answers the estimate questions outside the U.S.

A - David A. Ricks {BIO 16504838 <GO>}

Great. And on international pricing, I think we've talked about this before, but we don't have that many proxies for this kind of situation. But what we do know is economic activity, particularly in Europe and Japan, has fallen like in the US tax receipts accordingly. And if we use 2008 as a proxy, really it took almost three years for the policy implications of that to show up in drug pricing health budgets. And that's natural because there's a lag in tax receipts and then there's a lag in policymaking in response to it. I would expect that to happen. And the normal things that occur are clawback mechanisms and methods to keep the medicines budget within some proportion of the health budget. I think that will be a headwind the industry will face over the next two or three years.

I would say though that if history follows, and I don't see any reason why it wouldn't because Europeans in particular were successful at capping drug spending growth in the early part of the last decade, the burden of that tends to follow -- fall disproportionately on older products that are scaled and perhaps with more competition in the categories, whereas newer products, I think, actually weren't really affected. They're more driven by health technology assessment and the procedures to get an initial price. And they don't really drive much budget pressure versus end-of-life. As you know, we continually advocate for more biosimilar and generic adoption in these markets as the first lever to pull. And so I think also for products that are exposed to biosimilars and generics, you probably would see more pressure on the back end of this as well.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Crist, thanks for your questions. Next caller, please.

Operator

The next question is from Vamil Divan from Mizuho. Please go ahead.

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Q - Vamil Divan {BIO 15748296 <GO>}

Great. Thank you and thanks for taking the question. So a couple, if I can. So one, on -- just on the margin discussion, specifically on SG&A. Wondering if you have any comments you can share just in terms of your sort of more virtual promotional efforts here the past few months and a sense of how productive they've been. And really just trying to get a sense, as you think about going forward, is your spending on SG&A potentially going to be less than what you're thinking before if you go to more of a hybrid sort of model? Or do you expect within kind of year or so, your SG&A spending would be essentially what it would have been before the pandemic?

And then the second one is just maybe more on the business development side. Just given some of the volatility you're seeing from the [trends] around COVID and also drug pricing. And just any changes to how you're thinking about potential licensing or acquisitions in terms of size? And also curious in terms of therapeutic areas, are there any sort of areas where you could have more need or desire or take capacity to bring in additional assets?

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Vamil. We'll go to Dave for your first question, and then Josh for the second on BD.

A - David A. Ricks {BIO 16504838 <GO>}

Yes. Vamil, for some years now, we've been on a journey to build out the capabilities to reach customers where they want to be reached and have relevant information at that time as well as around launches and key data readouts to be able to expand our capacity beyond just the sales channel to reach customers. That has proven pretty useful during this pandemic. And I would say, overall, the conditions, which, as I mentioned in my prepared remarks, are variable around the world in terms of being able to safely send reps into the field and actually even be able to be let into medical buildings and facilities. I think there's a constraint there. So we've leaned into this. We've accelerated some of the plans we had to increase volume and the richness of this capability. Overall, I think the results are -- I think we prefer to run the hybrid model everywhere where we have sales reps and these capabilities. Where we can't send sales reps, these capabilities have been useful.

Is it as productive? I think it's certainly more efficient and it's more scalable. Whether it's as impactful, I think we'll need to watch through time. We have different markets we serve. And I can say that in specialty markets, where you've got a smaller number of physicians and you can target your efforts extremely well, we mentioned Retevmo launch on this call, which is kind of a first thing for us was an approval and launch during the pandemic, I think we're pretty pleased with the progress there. On the other hand, primary care brands, it's a little more challenging because of the way these practices are run and the variability and physicians' accessibility. So I think the whole industry is probably learning this. But on the other side of this, we'll have a much more enhanced capability. And you can bet we're spending huge amounts of time on a global basis lifting that up now in a way that's pretty rigorous. So more to come there, productivity to be seen; efficiency, yes; effectiveness, we probably see a lot of variability right now.

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A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Josh?

A - Joshua L. Smiley {BIO 19888026 <GO>}

Yes. So on business development, our strategy hasn't changed. We continue to focus on acquiring potential first-in-class or best-in-class projects or products in our therapeutic areas. There's a high bar there. We've had great progress in our internal pipeline. But we remain committed to finding those kind of opportunities. We have -- we're generating very strong cash flow. We've got good investment-grade ratings and good liquidity, good access to capital markets. So even with all the disruption related to COVID, I don't see any change for us. And then our ability to interact with smaller companies or access potential projects hasn't changed. That's not impacted by COVID. So it's really just a function of finding the right opportunities and ensuring that we can structure the deals in ways that create value for both sides. And we'll continue to focus on that.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Vamil, thanks for your questions. Next caller, please.

Operator

Next is Carter Gould of Barclays. Please go ahead.

Q - Carter Gould {BIO 21330584 <GO>}

Hi, good morning. Thanks for taking the question. I guess two for Dan. First, on the baricitinib studies in COVID, can you maybe just sort of frame sort of how you're thinking about these studies, your level of confidence in light of some of the other agents repurposed from RA that have failed albeit upstream of JAK inhibition? And then as far as on the N3pG antibody side, are sort of time lines still intact? Should we still expect that data to read out early next year? And any commentary on how you're thinking about the hurdle to move into the pivotal studies?

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Carter. Dan?

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yes. Sure. Thanks. On baricitinib, of course, we're encouraged. And the reason we did this trial is based on preclinical data around the mechanism of action of baricitinib. And I think the clinical effects of immune modulation in hospitalized patients with COVID-19 has been mixed. As you pointed out, there have been some failures. There've also been some promising efficacy signals and even success, of course, with dexamethasone. So I think we just have to wait and see how this works. Treating patients in the hospitalized setting is important. If we can reduce length of stay or decrease mortality, that will be an exciting result and maybe a stopgap measure until we have medicines that actually can fight off the virus, like I hope the neutralizing antibodies will.

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As for N3pG, yes, we're still on the same time line as we've always been. The trial will wrap up at the very end of this year, which means we'll have data internally and likely some kind of top line just in the very start of next year. I think given the size of the study, we have a reasonably high hurdle rate. We are hoping to see a large effect size. We base that belief on the level of plaque clearance we can get. We get deeper and faster plaque clearance than has been shown with any other agents. So if clearing plaques is important to stopping disease progression, we should have a strong effect. It's noteworthy that we also designed this trial to select a very careful patient population based on their tau levels at baseline. So we also expect a smaller standard deviation because the population should have a more uniform progression. I also note that we started a second trial with N3pG already.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Carter, thanks for the questions. Next caller, please.

Operator

Next, Steve Scala of Cowen. Please go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Thank you. When we see the data from monarchE, can you reassure us that the disease-free survival improvement won't be an underwhelming 1% to 2%? Really seems excited about the data, so I would assume it's going to be stronger than 1% to 2%, maybe 3%, 4%, 5%. And then secondly, Roche announced last week that it will have data from a large Phase 2 trial of a tau antibody very soon. Should the Roche study fail, can you highlight any differences between the Lilly and Roche molecules and/or the study design that could sustain optimism for the Lilly program? Or if the Roche molecule fails, should we assume that the Lilly molecule likely will follow a similar fate? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Steve. We'll go to Anne for the question on monarchE and then Dan for the question on tau.

A - Anne White {BIO 20764375 <GO>}

Well, Steve, thanks for the question. Obviously, we just shared the top line at this time. So I can't go into detailed data, as you know, prior to the data disclosure. But what I can tell you is that we do believe that the positive results from monarchE are clinically meaningful and will add to the existing body of evidence that Verzenio is differentiated from other CDK4/6s. And this is a major milestone for Verzenio and we believe does have the potential to change the paradigm of how early breast cancer is treated. So we really look forward to sharing the data with you at a meeting later this year.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Dan?

A - Daniel M. Skovronsky {BIO 15349505 <GO>}

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Yes. Thanks. And with respect to the tau antibody, again here, I'll just say we're still on track for the data readout. This will come in the second half of next year. I'm excited about this mechanism. But we don't have clinical data yet. The Roche readout will be important and we'll be watching it carefully. And of course, on behalf of patients and the mechanism, we'll be hoping for their success. But there are some differences, as you pointed out, both in molecule and trial design that make readthrough more complicated. One, I think, important aspect of molecule design is that there's lots of different species of tau in the brain. There's a lot of soluble tau that is monomeric and probably not involved in the pathogenesis of Alzheimer's disease that can sop up antibody and sort of reduce the effective amount of antibody available to get the bad kinds of tau. Our antibodies are designed specifically to bind to aggregated tau. So we think that should improve its ability to actually hit the target. Very high doses of these antibodies are generally used to overcome this soluble monomeric tau problem. So that's one difference between that Roche antibody, and in fact all of the competitors, and ours.

Second difference is around trial design. And here again, we've used our unique expertise in tau imaging and biomarkers to select a patient population that we think: a, will be more uniform in its disease progression, allowing us to see signal better; and b, be more likely to be responsive to a tau therapeutic. It's likely these therapies will be effective, if they are effective, at stopping the spread of tau rather than removing preformed tau. And so I think it's important to have patients who are in the midst of spreading tau, not patients in whom tau has spread throughout the entire brain. So we'll watch them carefully, but there will be caution on readthroughs.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Steve, thanks for your questions. Next caller, please.

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Operator

Navin Jacob, UBS. Please go ahead.

Q - Navin Jacob {BIO 20931208 <GO>}

Hi, thanks for taking my questions. Just a couple on some launch products. Retevmo, selpercatinib, just wondering how that launch is going. What is the diagnosis rate for RET right now? And where do you see that will reach over the next 1 to 2 years? And then just time lines for Retevmo in ex U.S. markets. And then separately, with regards to your migraine franchise, just want to get some color on how you view the CGRP market growing from here going forward as well as tied to that, lasmiditan. I know it's still early in the launch, but the launch does seem to be a little bit slower than some of the competitors out there. Just wondering what the dynamics you're seeing in there, understanding that COVID-19 is also making things a little bit challenging in the neurology setting. Thank you so much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Navin. We'll go to Anne for the question of Retevmo then Patrick on migraine.

A - Anne White {BIO 20764375 <GO>}

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Well, thanks, Navin, for the questions on Retevmo. So the launch is going well, as Dave mentioned in his introduction. And so we're encouraged by the early demand signals that we've seen with Retevmo. And the initial customer feedback on the data has been very positive. So they're impressed by the efficacy and the safety data across multiple indications and lines of therapy that we were able to get into the label. And it's the largest, obviously, RET inhibition population that's been studied in 700 patients. We don't have Rx data to report yet. But we're aware of patient starts in a number of our top accounts, which is supported by the downstream channel orders. So it's clear that our first-to-market advantage is resulting in the treatment of patients, who have identified RET even in previous testing.

So that kind of leads to your question around diagnostic testing. So what we've seen historically is that RET is showing up on panels probably about 30% of the time. So you've hit on one of the key criterias of the launch is to continue to drive that testing rate up. And so it's been very much a focus of our efforts, both to work with pathologists out in the U.S. on making sure that they have RET on their panels now. We have an actional -- very actionable biomarker for them to test against. Our goal is essentially to eventually see testing rates like we see in some of the other targeted therapies, which approach 80%. Now the question that we'll all have to assess is how quickly we can get there. But our goal is to drive that up as quickly as we possibly can. And so that's a big focus of the launch.

And we have partnerships with Thermo Fisher and Illumina and other things in the works to really drive that up across the industry. Because we do believe that, that's actually the best care for patients, regardless they were treated with Retevmo or other targeted therapies, that we want patients to get the right therapy for them. As far as the time lines, so as you know, we've submitted in Europe. And so we're waiting regulatory action there. That submission was accepted at the beginning of this year. And then we look to submit in Japan and China, either late this year or early next. So still working with the regulatory authorities there.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Anne. Patrick.

A - Patrik Jonsson {BIO 21139959 <GO>}

Thank you very much. Well, the overall CGRP market continue to grow very nicely. And when we look at on the market growth year-to-year, we're talking about a growth of 64% versus last year while Emgality actually continued to significantly outperform the market with growth of 151%. And even if we look at the last quarter, we see that the CGRP market continued to grow with 12% despite the significant decline in terms of new-to-brand. And we continue to remain very confident in the future of Emgality and aiming for a market leadership in the preventive market. And we see also a strong market leadership, particularly in primary care, where we have expanded our efforts in 2020 and with quite a few new trials. So very, very optimistic in terms of the CGRP market for Emgality.

If we look at on Reyvow launch, I think it's fair to say that we are not pleased with the performance so far. But we need to have in mind that we had approximately 1 month in the marketplace prior to we were hit by COVID-19. And we made a conscious decision to actually pull back from our promotional efforts both in the field as well as in terms of

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[seeking] promotion overall. We have started to start up virtual proactive detailing. And we remain very confident in the molecule, taking into account that it's the only one that actually can offer a strong relief from the most painful physical symptoms as well as the most troublesome symptoms associated with migraine. And we know that there is a huge opportunity. Out of the 6 million people being treated in the U.S. today, 35% to 40% of those are not responding to the treatments. And in terms of efficacy and relief, with one single dose, we believe we have a unique value proposition but still a work to be done -- lot of work to be done.

Operator

And that's from the line of David Risinger, Morgan Stanley. Please go ahead.

Q - David Risinger {BIO 1504228 <GO>}

Thanks very much. So I have two questions, please. First, for Dan, if you could just help us understand a little bit better regarding the AbCellera antibody 400-patient Phase 2, which was initiated mid-June. Just curious, given the primary end point is at day 11, why would results not be revealed until the fourth quarter? And then second, for Josh, could you comment on the swings in other income? I guess it's really more on a go-forward basis since you already discussed what happened in the second quarter. Just to maybe provide any modeling suggestions to us for modeling other income in future quarters.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. We'll go to Dan and then Josh.

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A - Daniel M. Skovronsky {BIO 15349505 <GO>}

Yes. Dave, thanks for the question on the timing of the Phase 2. You're right. It's a 400-patient study that initiated last month. It got up to a bit of a slow start. I think as we saw at that time in the country that pandemic shifted in geographies. We shifted our efforts accordingly. It's now enrolling very quickly. The timing of data disclosure depends on that rate of enrollment, though. So it could, in fact, be sooner than Q4. I think I'm confident it will be by, of course, sometime during Q4 at the latest. As you point out, the day 11 time point is the critical point. So 400 patients enrolled and then 11 days later nasopharyngeal swabs and viral assessment and database lock and analysis and reporting, all that will just take probably a couple weeks from the end of the study. So we'll keep investors updated and the community updated on the progress of the study. That's where we are today.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Josh?

Q - Joshua L. Smiley {BIO 19888026 <GO>}

Thanks. Yes. On our OID, of course, in the first half of the year and particularly in the second quarter, as I mentioned, what we're seeing there is the mark-to-market gains from the roughly $2 billion of investment securities we hold. Again, we hold these as a function of business development deals and venture capital deals to stay abreast of breaking science. And obviously, we're making good decisions there, at least as of Q2. We don't

anticipate or we don't forecast gains going forward there. So really, if you keep that neutral, Dave, what we're really thinking about then is we're in a net debt position, so we pay interest costs on the debt. And then the only way we see anything that's positive is if we see investment gains change.

So I think for modeling purposes, look at our sort of net debt position. We've got great rates against the debt. So it's pretty modest negative cost. But that's sort of what we assume. And then any unusual items that flow through there, of course, we'll report. And we tend to just, as you saw on Q2, let those flow through. But we're not anticipating anything significant in the second half of the year. So mostly, you're just going to see the negative impacts of our net debt position.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh, David. Thanks for your questions and now we'll go to Dave for the close.

A - David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin. Well, we appreciate your participation in our earnings call today and a remarkable quarter and thank you for your interest in Eli Lilly. Please follow-up with our IR team if you have any additional questions that we didn't address today and hope everyone stays well. We'll talk to you soon.

Operator

Thank you. Ladies and gentlemen, that does conclude your conference. We do thank you for joining. You may now disconnect. Have a good day.

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