Q1 2020 Earnings Call

Company Participants

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

Other Participants

- Andrew Baum, Analyst
- Carter Gould, Analyst
- Chris Schott, Analyst
- Dave 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. Welcome to the Lilly Q1 Earnings Conference Call. At this time, all participants are in a listen-only mode. Later, we will have an opportunity for questions and answers with instructions given at that time, as well as now. (Operator Instructions) As a reminder, your conference call today is being recorded.

I'll now turn the conference call over to your host, Vice President of Investor Relations, Kevin Hern. Go ahead, please.

Kevin Hern {BIO 20557573 <GO>}

Good morning. Thank you for joining us for Eli Lilly and Company's Q1 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 [ph] and Mike Czapar of the Investor Relations team.

In addition, I would like to welcome Anat Hakim, who recently joined Lilly as Senior Vice President and General Counsel. Anat joins Lilly with a wealth of experience in the healthcare industry and more broadly across the legal profession. Her prior experiences include General Counsel at WellCare Health Plans, Associate General Counsel at Abbot, as well as working for a number of years at Foley & Lardner, and Latham & Watkins.

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 1st, 2019.

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

David A. Ricks {BIO 16504838 <GO>}

Thanks, Kevin. Well, these are challenging times for all of us, as the COVID-19 pandemic has affected the way we live, the way we conduct business, and most importantly, the health and wellness of millions of people. Like all of you, we're hopeful that the decisions to implement social distancing will be effective to curb the spread of COVID-19 as our industry works urgently to enhance testing and speed therapies to market to treat and then prevent the virus.

Today's call will have a different structure than normal. Before we discuss our Q1 results, we will describe the impact of COVID-19 and the pandemic, in general, it's having on our business and the actions we've taken to respond to the resulting global crisis.

Our Q1 results were driven by very strong fundamentals with additional benefit from increased inventory across the supply chain, including at the patient level. This is as a result of the COVID-19 pandemic. Despite that near-term benefit, the COVID-19 pandemic is likely to have a negative impact on our business in the future. We expect headwinds later in 2020, and potentially beyond such as destocking as supply chains normalized

from the recent demand surge, decreases in new prescriptions as a result of fewer patients visiting physicians' offices, potential changes in segment mix in the US due to rising unemployment and pricing pressures resulting from the (inaudible) on government-funded healthcare systems around the world.

What we do not yet know the extent and duration of these impacts. Like everyone around the world, we're hopeful that the massive mobilization of scientific and technical resources occurring across this industry and in collaboration with government and academic labs will yield multiple effective therapies in the coming months, and an effective vaccine in calendar '21.

While it's difficult to predict the specifics of how the world manages through this pandemic. It seems clear, our industry will play a leading role. In the midst of the outbreak and in its aftermath, it seems equally clear that investing in research and development to address and then conquer human disease has never been more important, and this is likely to remain true for some time.

As we've navigated the crisis, we've acted with speed and agility, focusing on the needs of patients, our employees and the communities we serve and operate in. I'll provide a summary of our response then Dan will describe our ongoing efforts to develop a treatment for COVID-19, and Josh will walk through potential financial impact of our outlook going forward.

Slide 4 summarizes our strategic approach and actions to date. As you can see, we focused on five areas, maintaining a safe supply of and access to our medicines, reducing the strain on the medical system, developing a treatment for the virus, keeping our employees safe and supporting our communities.

To ensure that 40 million-plus patients we serve have access to their medicines early in the outbreak, we took a number of steps to maintain the supply of medicines around the world. To limit their exposure to the virus, we reduced personnel at our manufacturing sites to the bare minimum required to operate our facilities and enhanced already robust precautionary measures for safety and cleanliness. The majority of our supply chain is multi-sourced and for materials, we supply from one source, we keep sufficient inventory on hand to avoid disruptions.

Even with increased demand and customer stocking, we have sufficient inventory and production capacity for all our products. This includes all forms of insulin. And we don't currently anticipate any issues meeting patient needs through the remainder of the pandemic. Our manufacturing sites in the US, Europe and China have remained operational through this crisis. We're proud of the extraordinary efforts of our manufacturing colleagues, who have worked diligently to supply medicines to patients around the world who depend on them.

In addition to the numerous programs currently available through the Lilly Diabetes Solution Center, we announced the introduction of the Insulin Value Program. This allows patients with commercial insurance or without insurance to limit their monthly out-of-

pocket expenses for insulin to $35 per prescription. Of note, the solution center has seen a significant increase in daily calls, since this new benefit was announced.

Patient affordability continues to be a top priority and we remain committed to helping people access to medicines they need. We've also made a number of decisions which reduce the strain on the medical system and these include pausing new clinical starts and enrollment for most ongoing programs, suspending our in-person customer visits to physicians, repurposing our labs to conduct diagnostic testing here in Indiana for COVID-19, and creating a drive-through testing facility for healthcare workers and first responders in the Indianapolis area.

We took these actions because they are the right thing to do during these challenging times, and to do our part to combat the spread of COVID-19. Dan will give a more complete pipeline update later, but I would like to highlight that we do not expect significant changes to the timelines for our ongoing late-stage studies, except for the previously announced delays for the GI indications of our IL-23 antibody, mirikizumab.

In terms of addressing the significant unmet need of treating COVID-19, we've acted upon several opportunities, which we hope will result in a treatment option. These include partnering with AbCellera to develop potential antibody therapies, which we expect will enter the clinic this summer, participating in the National Institute of Allergy and Infectious Disease Adaptive COVID-19 Treatment Trial with our JAK inhibitor baricitinib, initiating a Phase 2 clinical trial with an antibody targeting Angiopoietin 2 to explore its potential use in reducing the progression of acute respiratory distress syndrome related to COVID-19.

The need for new medicines is urgent and we mobilized our development team at a record pace. Keeping our employees safe and healthy and our Company running smoothly is of course also a top priority. We've implemented remote work practices, added health and wellness benefits and provided additional compensation for those essential employees routinely coming to our sites such as those in manufacturing. We've also created opportunities for employees to volunteer during work hours to support our medical system, including helping staff drive through testing facility.

To date, Lilly has tested nearly 30,000 people for COVID-19, which represents over a third of all test conducted in the state of Indiana, while absorbing all associated expenses. We are building on this capacity by developing serological antibody tests that will be critical in the next phase of the pandemic. In addition, we've been supporting our local communities by funding or contributing to public health awareness campaigns, as well as providing assistance and deploying available resources to fight the pandemic.

I would also note our appreciation for the high level of responsiveness in cooperation from the FDA and other government agencies in the US and abroad, as we partnered together to fight COVID-19 and to minimize the negative impact to drug development timelines for our other innovative medicines.

Across the biopharmaceutical industry, we are working around the clock, collectively driving forward to address the acute medical need created by the COVID-19 pandemic.

And to further elaborate on that, I will turn the call over now to Dan to provide more details on the ongoing efforts to treat COVID-19, and a regular pipeline update.

Daniel M. Skovronsky {BIO 15349505 <GO>}

Thanks, Dave. I'm proud to highlight the ongoing efforts we have to compact COVID-19. As Dave mentioned earlier, we're moving at an unprecedented pace as part of an industry-wide effort to develop a treatment for COVID-19. As a scientist and as a physician, I'm incredibly impressed and thankful for the ways our teams at Lilly are working to make an impact against this new disease. We've demonstrated how nimble a large organization can be when truly focused and united behind an important cause.

Slide 5 provides an overview of the three active therapeutic programs we are pursuing, first is baricitinib. This is our JAK inhibitor in collaboration with Incyte. It is recently -- we have recently announced it is part of the National Institute of Allergy and Infectious Disease Adaptive COVID-19 Treatment Trial. Based on the known anti-inflammatory activity of baricitinib, recent data in preclinical studies and case reports from investigator-sponsored clinical trials, we believe, baricitinib could have the potential to dampen the cytokine storm, that occurs when hospitalized COVID-19 patients are fighting to combat the inflammation in their lungs, which often leads to requiring a ventilator.

While we are cautiously optimistic about the potential of baricitinib to help treat patients with COVID-19, it's important to also note, the approved rheumatoid arthritis indication includes warnings about the risk for developing a serious infection. The baricitinib arm of the study begins this month in the US with planned expansion to Europe and Asia, and results are expected in the next two months.

Next, we started a Phase 2 trial with a monoclonal antibody against Angiopoietin 2, or Ang2 in pneumonia patients hospitalized with COVID-19 who are at a higher risk of progressing to acute respiratory distress syndrome or ARDS. The Ang2 level in plasma is strongly correlated with ARDS risk and severity based on multiple studies in humans. Our trial will test whether inhibiting the effects of Ang2 with monoclonal antibody can reduce the progression to ARDS, or the need for mechanical ventilation. This trial has already begun enrolling patients at centers across the United States. We expect results from this trial in the coming months.

Our third and potentially most significant program is part of our previously announced collaboration with AbCellera, where we are pursuing antibody therapies for the potential treatment and prevention of COVID-19. Our scientists have been working together with AbCellera, NIH and academic partners to characterize virus-neutralizing antibodies, obtained from one of the first US patients who've recovered from the virus.

The most advanced antibody in this program shows potent neutralization of live virus and has now entered GMP manufacturing. We plan to submit an IND to the FDA by the end of May to allow start of clinical testing in patients. The pace of which we've advanced these potential treatments has been possible due to the tireless efforts of our research and development colleagues in partnership with a number of private and government partners.

The need for treatment options to battle COVID-19 is staggering, and we are leveraging our financial resources and our very significant scientific capabilities to rapidly pursue solutions. The challenges facing our society and our economy are great, and the pharmaceutical industry is rising to the challenge.

I'll now provide a brief pipeline update. Slide 6 shows select pipeline opportunities as of April 20th. Movements since our last earnings call includes the approval of Lyumjev in the EU and Japan, the US approval of Taltz for pediatric psoriasis, and previously mentioned COVID-19 trial initiations for baricitinib and Ang2, one program advancing Phase 1, the attrition of an early phase project, and the removal of empagliflozin for Type 1 diabetes based on a complete response letter from the FDA.

Moving to Slide 7, we'll provide an update on our 2020 key events that have occurred during the quarter. In addition to the previously mentioned approvals, we also announced the first of two Phase 3 trials studying mirikizumab in psoriasis met its primary endpoint; the submission of tanezumab in Europe for moderate to severe osteoarthritis pain in collaboration with Pfizer; the DIAN-TU trial for solanezumab which did not meet its primary endpoint, and galcanezumab received a negative opinion from the CHMP for cluster headache in Europe.

Before I close the R&D update, I'd like to emphasize that in addition to our ongoing efforts to come back over COVID-19, we remain committed to advancing important new medicines across our entire portfolio. Although, we announced our pause to new trial starts and enrollment in most programs, we remain committed to discovering and developing new treatments for the patients we serve. With the exception of mirikizumab for GI indications, our late-stage portfolio remains on track to deliver important clinical trial data in line with our previously communicated timelines. Of note, the tirzepitide SURPASS program in Type 2 diabetes is fully enrolled, and we expect to share the first Phase 3 trial results later this year.

These are challenging times around the world, but I'm encouraged by the unprecedented response by the scientific community and the pharmaceutical industry to rapidly develop potential new treatments and vaccines for COVID-19, and to sustain advancements across all diseases.

Now, I'll turn the call over to Josh to discuss the impact of COVID-19 on our Q1 financial performance and our outlook going forward.

Joshua L. Smiley {BIO 19888026 <GO>}

Thank you, Dan, and good morning, everyone. As Dave shared earlier, we are confident that our business fundamentals are strong and that we're well-positioned to navigate the obstacles ahead. However, there undoubtedly will be a near-term impact to our industry and our Company, so the length and magnitude of the effects are uncertain. So I'll spend a few minutes discussing the financial impact of COVID-19 on our Q1 performance and providing a framework for how we are thinking about this potential impact going forward, before then providing a more detailed review of our financial results.

We began 2020 with positive momentum and observed robust prescription trends in January and February. As COVID-19 spread throughout the world and economic activity slowed significantly in many cities and regions, we've observed the following changes in behaviors that affected our business. Patients refilled existing prescriptions earlier than normal or by the larger supply to ensure that they didn't run out, wholesalers and retailers increased the level of inventory on hand to ensure adequate supply, reduced hospital visits resulted in a preference for medicines that do not require administration in the physician's office or at a hospital, patients abandoned fewer prescriptions at the pharmacy counter, mail order utilization increased which typically has a larger number of units per prescription in those filled at retail pharmacies, and new therapy start slowed as patients largely avoided hospitals and clinics unless they were seeking treatment for COVID-19.

We estimate the net impact of these trends resulted in an increased patient and channel stocking which increased worldwide sales by roughly $250 million in Q1 with approximately $200 million of that impact in the US. We think the majority of the US impact occurred in our diabetes portfolio and notable products where we believe increased stocking impacted our Q1 US results include insulins by approximately $70 million to $80 million, Trulicity by approximately $30 million to $40 million, and Taltz by approximately $20 million to $25 million.

While we expect much of this stocking to reverse in future quarters as the excess supply in the channel and in-patient medicine cabinet is consumed, the timing and ultimate levels are uncertain. We continue to closely monitor these factors and utilize our quarterly earnings calls to provide updates to our outlook.

Slide 8 lists a number of factors we are monitoring that may impact our financial performance. While reduced new therapy starts had a negligible impact during Q1, this impact could grow in future periods as fewer new starts translate into fewer total prescriptions. In the US, we are starting to see an impact as IQVIA reported new to brand prescriptions across the industry declined by 42% for the week ending April 10th versus pre-COVID-19 averages. For our portfolio, we anticipate this impact to be more pronounced for our immunology and pain products and less so for oncology and diabetes. However, we expect this impact to be temporary, as patients will return to seeing their doctors as social distancing restrictions are lifted.

Over the mid-term, this significant increase in unemployment we are seeing could be a headwind. Increased unemployment may result in a shift of patients from commercial insurance to lower net price government insurance in the US or to being uninsured. We're monitoring this dynamic closely, and while it could create headwinds in the near-term, this effect should lessen when the global economy eventually strengthens.

Given the significant benefits, our products provide to 40 million patients around the world, we remain confident in our long-term outlook for revenue growth and margin expansion. In terms of managing capital, our balance sheet and liquidity are strong and we have investment-grade ratings from both Moody's and S&P. We're confident in our ability to generate substantial operating cash flow, and I have not seen an impact to our ability to access capital markets, including commercial paper at reasonable rates.

Financial strength is a valuable asset during this period and we intend to maintain our current credit ratings while using our balance sheet capacity to invest in the business and pursue business development opportunities that enhance our future growth prospects.

I will provide more details on our 2020 outlook shortly. But in summary, we do expect the impacts on our financial results through the remainder of the year and potentially into 2021, but the underlying strength and momentum in our business is strong. While combating the COVID-19 pandemic is a top priority, we remain focused on executing our strategy of developing new medicines for patients.

We exited 2019 with very strong momentum in revenue growth and margin expansion, driven by the uptake of our newer products. On Slide 9, you will see that momentum continued in Q1 2020, as we delivered strong underlying business performance, augmented by the estimated COVID-19 related buying patterns from patients and customers I just described it.

Revenue growth accelerated in Q1, increasing 15% versus Q1 2019, or 16% in constant currency. This strong performance was driven by volume, which contributed 22 percentage points of growth. Net of the estimated COIVID-19 impact, revenue growth was 11% for the quarter in constant currency. Our newer medicines continued to be the driver of this growth, representing more than half of our revenue in the quarter.

We made good progress in Q1 on our productivity agenda as operating income grew 32% versus last year. Our non-GAAP operating margin improved by 390 basis points to 30.1% as revenue growth outpaced operating expenses. The estimated impact of COVID-19 buying patterns on the quarter also had a positive impact on our non-GAAP operating margin. But as we discussed during our 2020 financial guidance call, we expect our 2020 operating margin to build throughout the year and to achieve our 2020 target for the full year of 31%.

We've announced multiple pipeline milestones since our Q4 2019 earnings call, including approval of Lyumjev in Europe and Japan, and new indications for both Trulicity and Taltz in the US.

During Q1, we've returned approximately $1.2 billion to shareholders via share repurchases and the dividend. As previously announced, we increased the dividend by 15% for 2020. At this point, we do not expect to make additional share repurchases in the near-term in order to maintain a cushion of liquidity and capacity for investment and continued dividend growth.

Finally, we closed the acquisition of Dermira, a company focused on developing new therapies for chronic skin conditions, enhancing our Phase 3 pipeline with the addition of lebrikizumab, which is complementary to our dermatology business. Slide 10 includes a summary of key events since our last earnings call.

Moving to slide 11, our Non-GAAP financial performance in Q1 was robust, even when adjusting for the COVID-19 impact described earlier. In addition to strong topline

performance, gross margin as a percent of revenue was stable versus Q1 2019 at approximately 80%, as favorable product mix and greater manufacturing efficiencies were partially offset by price and increased costs associated with COVID-19.

Moving down the P&L, operating expenses grew slower than revenue, at 7% versus last year's quarter. Marketing, selling and administrative expenses increased modestly by 2% as cost containment and productivity measures offset investments in key growth products. Travel restrictions and the suspension of in-person customer interactions late in the quarter did result in lower travel and meeting expenses. However, these were offset by a higher US branded prescription drug manufacturing fee that we recognized in Q1.

R&D expenses grew 13%, reflecting higher development expenses for late-stage assets that increased throughout 2019. Our pause on clinical trial starts had a limited impact in Q1. Operating income increased 32% compared to Q1 2019, as sales growth outpaced expense growth, resulting in operating income as a percent of revenue of 30.1% for the quarter.

We began 2020 with good momentum executing our strategy and are on track to achieve our 2020 full-year operating margin target of 31%. Other income and expense was income of $89 million this quarter compared to income of $86 million in Q1 2019. In both quarters, this was driven by investment gains on public equities.

Mark-to-market gains in Q1 of 2020 were primarily generated by prior equity investments in companies that are now pursuing vaccines for COVID-19. As we regularly highlight, this line item can be volatile as public market valuations fluctuate. Our tax rate was 13.6%, an increase of 70 basis points compared with the same quarter last year, driven primarily by the mix of earnings in higher tax jurisdictions, partially offset by an increase in net discrete tax benefits. So at the bottom line, earnings per share increased 32%.

On Slide 12, we quantify the effect of price, rate and volume on revenue growth. As mentioned early -- earlier, worldwide revenue grew 16% in constant currency during Q1, driven by strong volume growth of 22%, which we estimate at 17% net of the impact of COVID-19 buying patterns. This was partially offset by price. Foreign exchange had a modest negative impact on revenue growth this quarter.

Price declined 3% net of the price impact from the inclusion of Tyvyt and Alimta in government-sponsored programs in China. US revenue grew 15% compared to the first quarter of 2019. Volume growth of 19% was led by Trulicity, Humalog, Taltz, Alimta, Verzenio, Emgality and Basaglar. As I mentioned earlier, we saw stocking at the wholesale and patient level due to COVID-19 that contributed approximately $200 million of revenue this quarter. While the situation remains fluid, we do expect this impact to largely reverse over the course of 2020.

Pricing was a 4% drag on US revenue growth this quarter, in line with our 2020 guidance. This was driven primarily by growth in lower-priced segment, primarily driven by our diabetes products, which was partially offset by changes to estimates -- for rebates and discounts for Taltz, and reduced utilization of patient assistance programs for Emgality due

to increased commercial reimbursement. We have strong commercial and Medicare Part D access across the portfolio and that remained intact throughout Q1.

Moving to Europe. Revenue grew 21% in constant currency, driven by 24% volume growth, partially offset by the negative effect of foreign exchange in price. Volume growth was led by Trulicity, Olumiant, Taltz and Verzenio and also benefited from the divestiture of a legacy product in Spain. We estimate total international results were impacted by approximately $50 million of stocking due to the impact of COVID-19 in Q1, and significant majority of this occurred in Europe. However, the underlying trends are very strong, as our newer products have continued to scale.

In Japan, revenue grew 8% in constant currency, driven by volume growth, somewhat offset by a modest pricing headwind due to government-mandated price decreases that went into effect in 2019. Verzenio, Cyramza, Trulicity, Olumiant and Alimta were the key contributors to growth, partially offset by increased competition from Forteo, and the impact of generic Strattera.

In China, revenue grew 30% in constant currency, driven by 93% volume growth, partially offset by pricing concessions associated with the inclusion of Tyvyt and Alimta in government-sponsored programs. We are very pleased with the significant volume increases we saw for these products and our ability increased access for patients to these important cancer medicines.

Outside of Tyvyt and Alimta, our business in China saw a meaningfully -- a meaningful decline in new patient starts during Q1 as the COVID-19 spread peaked during March. As this situation appears to be moving toward more stability, we are cautiously encouraged that new patient initiation and in-person customer interactions have begun to resume.

Revenue in the Rest of the World increased 14% in constant currency, driven by increased volume from our key growth drivers. Trulicity, Jardiance in collaboration with Boehringer Ingelheim, Taltz, Cialis and Cyramza drove growth in Q1.

As shown on Slide 13, our key growth products continued to drive impressive worldwide volume growth. These new medicines delivered nearly 20 percentage points of growth this quarter, while also benefiting from the increased stocking that I described earlier.

Slide 14 highlights the contributions of our key growth products. In total, these brands generated nearly $3 billion in revenues this quarter, making up 51% of total revenue.

On Slide 15, we provide an update on capital allocation. In Q1 2020, we invested $2.4 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 approximately $1.2 billion to shareholders via dividends and share repurchase. We remain well capitalized and closed Q1 with approximately $4 billion of cash and investments and the ability to access debt markets at attractive rates.

Moving to Slide 16, you will find our updated 2020 financial guidance. This is based on our best estimates at this time as we are balancing transparency and insight into the current view of our business with the uncertainty surrounding the extent and duration of the impact of the COVID-19 pandemic.

Key assumptions supporting our updated guidance include, the Q1 stocking benefit largely reverses over the course of 2020, the near-term reduction in new patient prescriptions peaks in the second quarter in the US and much of Europe, healthcare activity returns to more normal levels in the second half of this year as doctors resume seeing new patients, price headwinds from the increased utilization of patient affordability programs and changes in segment mix due to increased US unemployment, and enrollment in existing studies, as well as the initiation of new clinical trials, resumed mid-year, and near-term spending on travel, in-person customer interactions and direct consumer advertising decreases, and investments in digital promotion and support increase.

We do believe the reduction in new patients starts will be temporary but will impact our 2020 performance. The potential impact from increased unemployment will likely be more muted in the near-term, but the impact could be more pronounced in 2021, depending on the shape of an economic recovery and the US government programs to stimulate employment.

While the extended duration of impact from COVID-19 drives the most uncertainty around outlook, the positive underlying momentum in Q1, in our business, augmented by the additions to the estimated additional revenue benefit from COVID-19 related buying patterns, gives us confidence that the potential downside for the remainder of the year is accommodated within our previously communicated revenue range. While there are scenarios that could cause revenue to fall outside either end of our range, we believe the revenue range accommodates most of the uncertainty we see today.

In addition to the impact of unemployment, in the pace of economic recovery described earlier, the main variables we will monitor are the impact on new prescription trends during social distancing periods and the timing of resumption of non-COVID-19 healthcare activities. While we currently anticipate the most from an announced [ph] impact on new prescriptions to occur in Q2, the headwinds are likely to show up in Q3 and Q4, as inventory levels normalize and the impact of fewer new prescriptions compound.

Moving down the income statement, we're confirming our prior expectations for gross margin as a percent of revenue to be roughly 81% on a non-GAAP basis and 79% on a GAAP basis. We do anticipate higher manufacturing costs associated with the extraordinary measures we are taking to keep our manufacturing workers safe and to keep medicines flowing the patients around the world, we expect this to be offset though by benefits from higher manufacturing volume.

We are maintaining our range from marketing, selling and administrative expenses, as savings from reduced travel and decreased promotion are anticipated to be offset by

investments in digital capabilities and increased marketing expenses in the second half of the year for growth [[ph] products. Our range for research and development expenses is also unchanged as savings from the positive clinical trial activities are offset by our investments to pursue therapeutic treatments for COVID-19, as Dan described earlier.

Therefore, there is no change to our non-GAAP operating income as a percent of revenue guidance of 31%. We're updating the range of other income and expense to zero to $150 million of expense, reflecting Q1 gains in our equity portfolio. Obviously, this number has some volatility going forward and we'll update accordingly.

Turning to taxes, there is no change to our GAAP and non-GAAP effective tax rate guidance of approximately 15%. Earnings per share is now expected to be in the range of $6.70 to $6.90 on a non-GAAP basis. Our GAAP EPS is expected to be in the range of $6.20 to $6.40. We are increasing the range to reflect the uncertainty of the impact to our business through the remainder of the year.

Our performance in the first quarter, net of COVID-19 benefit highlights the strength of our underlying business fundamentals, and as Dave mentioned in his introduction, we remain confident in the long-term outlook for our business.

So, Dave, I'll turn it back to you for closing remarks.

David A. Ricks {BIO 16504838 <GO>}

Thanks, Josh. The COVID-19 global pandemic has impacted us all in unforeseen ways. Although near-term challenges exist, we do remain confident in our long-term outlook for the Company and the strength of our fundamentals. Times of great crisis can bring out the best in people and in companies. And Lilly will continue to rise to that challenge.

While a great deal of uncertainty remains, there are few certainties to which I would draw your attention. First, the collective spirit, expertise and commitment of my Lilly colleagues around the world is inspiring. Despite challenging circumstances and disrupted work routines, they have rallied to fulfill our mission of discovering and supplying medicines that make life better for people around the world. They are exceptional.

Second speed and agility continue to be critical to the success of our business. We've moved swiftly, pivoting our focus to join the fight against the COVID-19 pandemic by leveraging our deep scientific capabilities and expertise on both the testing and therapeutic fronts.

And lastly, I've never been more certain of the importance of a healthy and vibrant biopharmaceutical industry. While it will take time to exit the current situation, we will recover, and the pharmaceutical industry will be the primary catalyst, developing new treatments and a vaccine to combat COVID-19, allowing people across the world to return to living their lives more normally, and enabling economic activity to grow. It's clear we are a vital part of any long-term solution for fighting this or any future pandemic.

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

Kevin Hern {BIO 20557573 <GO>}

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

Questions And Answers

Operator

Absolutely. (Operator Instructions) Our first question will come from the line of Terence Flynn with Goldman Sachs. Go ahead.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. Maybe first, I was just wondering, Josh, if you could expand on how the environment changes your approach to capital allocation. I know you mentioned will -- maybe [ph] less share repurchases in the near-term. But on the BD M&A side, do you actually think there could be an increasing number of opportunities, and does it change how you think about size?

And then the second, I had was just where you stand with regulatory interactions and launch prep for selpercatinib, just wondering if COVID changes, that all your go-to-market strategy? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Terence. We'll go to Josh for the first one and then Anne for the question on selpercatinib.

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

Hi, Terence, thanks. On capital allocation, we really are sticking to our strategy. And as we've outlined, we do see external innovation or business development as a key component of our long-term growth strategy. But what we're really focused on -- continue to focus on our key opportunities in our therapeutic areas where we can bring in first or best in class type of assets into the pipeline.

We're continuing -- I think that work continues. I haven't seen anything slowdown as a function of not being able to travel or work from home types of activities. Certainly, there are smaller biotech companies that may have different views in terms of their cash runway or ease and to the extent that, that helps to in general, [ph] more discussions will take advantage of that.

I don't think it changes anything in terms of how we think about size. Our business is strong, as I mentioned, and we don't see benefits in large scale types of acquisitions. So

we'll continue to focus on the things that we are focused on. And I think for as long as we're in these kinds of social distancing restrictions, I don't see that is impacting our ability to transact.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Anne?

A - Anne E. White {BIO 20764375 <GO>}

Yeah. Terence, thanks for the question on selpercatinib. So I'm pleased to share that there has been no delay in the regulatory timeline for selpercatinib. And the FDA has been extremely collaborative and responsive in working through these challenges time. So we just thank them for the speed and the commitment they've had. They've continued to progress the application, and as you know, we submitted in December. It's currently under priority review, so we expect to have regulatory action by the PDUFA date in Q3.

Regarding your questions on launch, it is interesting times obviously, and as a Company, as Dave shared, we continue to prioritize combating the spread of coronavirus and we recognize that this is also the case for healthcare professionals. And we're incredibly aware of the load that they're carrying at this time and need to express our appreciation for all of their efforts on behalf of their patients.

So with that, we also though recognize that selpercatinib has shown striking efficacy and really a very favorable safety profile in treating lung and thyroid cancers with RET fusions or RET mutations. And so we think it's -- still it's very important that patients and physicians are aware that there is a new medicine available, and the first to specifically target RET alterations.

So what we're doing is launch activities. They will look different, but we're committed to making sure that patients who are good candidates for selpercatinib have access. So assuming that in-person interactions are still on hold when we launch, we're going to focus initially on making sure that we inform customers of the approval and the key efficacy and safety data via email and other digital channels that we have. We're also going to make sure that are quick to engage in virtual product details when the customer requests those and gives them more information. And then when appropriate, we're also going to make sure that we leverage virtual peer-to-peer programs to provide thought leaders, the opportunity to share the data with their colleagues. And in addition, of course, we'll be sharing the data through a top tier journal publication, as well as in upcoming medical meetings.

So we'll make sure that the -- the goal here is to make sure that physicians and patients are aware and inform that we have now incredible new medicine that's specifically targeted for RET. It's just been an incredible partnership with Loxo and -- the Loxo and Lilly teams. If you think about it, this medicine started Phase 1, first patient dosed in May of 2017, and we're looking at approval here in 2020, so it's remarkable. And our thanks really goes to the FDA for the speed at which they're moving through the review.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Our next question will come from the line -- one moment, please. Yeah. I'm having some equipment difficulty and I seem to have lost my queue. So just give me one moment, please.

Ladies and gentlemen, we seem to have lost the queue for the question-and-answer session. (Operator Instructions) Just one moment, please. One moment, please. Ladies and gentlemen, we are having some technical difficulties. We are restarting the question-and-answer session. (Operator Instructions) My apologies to everyone on the conference call.

We'll move next to the line of Chris Schott with J.P. Morgan. Go ahead, please.

Q - Chris Schott {BIO 6299911 <GO>}

Great. Thanks very much and I appreciate all the color on the call today. Just my two questions. First on disruption to near-term prescription, you mentioned diabetes is an area less impacted relative to areas like pain and Immunology. But I do have a specific question on Trulicity. I guess when I think about that product and the GLP-1 category in general, we've been seeing very healthy growth here, we've seen significant new patient starts. Is this a product and a market may be more broadly that you anticipate could see a slowdown as we go through 2Q as the impact of some of the reduced physician visits start to build?

And then my second question was on payer mix over time. Can you help us frame the magnitude of impact you could see to net price in the US from adverse payer mix as we look out over the next year or so? I guess specifically, is this something that could cause price to meaningfully deviate from this low-single-digit price erosion we're seeing, so could that become more like a mid to high single-digit erosion? Or are you thinking about a more modest impact from that? Thanks very much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Chris. We'll go to Mike Mason for the question on Trulicity, and then Josh, the question on payer mix.

A - Michael B. Mason {BIO 18347681 <GO>}

Okay. On Trulicity, it's difficult to predict long-term impact of the COVID-19 crisis given the uncertainty on the length and the impact on economy and patient visits. And also, it's unclear how patients who live with diabetes, who are at greater risk for complications from COVID-19 will that change the compliance they have with the medication and increase that.

But what I can tell you is, little over a month into the crisis that the GLP market and Trulicity TRx volume remain strong. It's currently at 30% and so we haven't seen the impact at the

TRx level yet. We have seen the impact on NTS and NBRx [ph] volume in kind of post-COVID, both for Trulicity end the GLP market. Josh can share that the overall pharma market had seen in a decline of 42% in NBRx. What we're seeing in the GLP-market is a 30% decline for NBRx. Now we haven't seen that manifest itself in the TRx volume yet.

If you take a look at the NBRx and -- for Trulicity, it's only 5.6% of the TRx rate, which is a really relatively low turnover for the marketplace. So we think that Trulicity relative to other products, other therapeutic areas will have kind of a slower impact from the COVID situation. But again, it's hard to predict as we have uncertainty on the link, the impact on the economy and patient visits.

What we can say is that we're very confident in Trulicity's strong fundamentals. We saw a 32% volume growth in Q1 and 40% revenue growth in Q1. So we're very confident and the very strong fundamentals of Trulicity. So Chris, thanks for your question.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Mike. Josh?

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

Thanks, Chris. On your question on what could happen to net price going forward given what we're seeing in the US with the economy, and first, I think it's too early to make too many predictions. There is a lot to still see. And as you highlighted in your question, we've already assumed that we're going to see negative net prices in the US for -- between now and 2025, that's already in our current guidance. So I would see whatever happens here is probably a moderate impact on that.

I think what we have to keep in mind first for Lilly's portfolio, we're spread across multiple payer segments. Certainly, in general, a move from a well insured commercial patient to Medicaid is a net negative. But many of the commercial patients -- is my assumption who are losing in the first wave losing employment, they may not be in great commercial plans to begin with their exchanges and other things. So there is a lot to still see what happens here.

Our view is, we'll ensure that the patients who are losing insurance have access to our medications and programs. We -- Dave mentioned and announced that $35 change to our diabetes program. So we're looking at everything we can do to ensure that people can stay on our medications and have access to them. And believe that some of these impacts will be temporary, and then we'll have a much better sense by the end of the year on what 2021 looks like. But I'd say overall, our expectation is this, continue to trend in net price declines, but not a fundamental change to how we're thinking about the business.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We will move next to the line of Andrew Baum with Citi. Go ahead.

Q - Andrew Baum {BIO 1540495 <GO>}

Thank you. And same topic, and you have a high exposure relative to your peers to the commercial book. For your full-year guidance, could you help us on what kinds of US unemployment rates you're assuming as well as some magnitude of the volume lost and potential Medicaid expansion, anything you can say about the rest of 2021?

And then separately on Olumiant, baricitinib for COVID-19, I'm just trying to understand which patient population you're targeting as the literature talks to both a potential anti-viral effect as well as an anti-inflammatory effect which would suggest potentially two different patient populations, the earlier than respiratory distress. Where are you going here with the clinical trial? Many thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Andrew. We'll go to Josh for the first question and then Dan on bari 19-COVID. [ph]

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

Thank you, Andrew. I think as it relates to 2020, our sales guidance range on the -- as we -- I describe sort of the factors we're looking at. And I'd say, if we're on the lower end of that sales range, we do include in our thinking there some incremental impact from pricing. Again, I think it's probably will be pretty muted this year, and then I think we'll just have to look and see what next year looks like. And I think it's not just absolute levels of unemployment, it's what programs are in place to bridge the gap and otherwise.

So this year, again, I think our range, given the strong position we're starting from in Q1, our range accommodates potential incremental pricing impacts for potentially short-term moves to un-insurance or Medicaid. But I think at this point, it's a little early to have rollout specifics around this one.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Dan?

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

Yeah. Thanks, Andrew for the question on baricitinib and mechanism of action and potential on COVID-19. You're right in your comments about a potential for dual mechanism of action for baricitinib. I think first publication on the potential role of baricitinib in COVID-19 came from a group called BenevolentAI, where they modeled out that the effects both on viral entry and on inflammatory response could be beneficial in this disease. The trial that we discussed that is the adapted COVID -- adaptive COVID-19 trial with NIAID is in hospitalized patients. So it's rather later in the disease progression and the design of the trial is primarily to look at the effects of baricitinib on that inflammatory cascade.

It's notable that, that trial currently has conceived as a factorial design with remdesivir. Of course, in addition to looking at the clinical outcomes of these patients have a viral load and other factors will also be evaluated. I think if we see success there, that could give us the confidence to go earlier in the disease course. But given sort of the mix mechanism action here, right now, we're looking at those hospitalized patients.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will come from Dave Risinger with Morgan Stanley. Go ahead, please.

Q - Dave Risinger {BIO 1504228 <GO>}

Yes. Thanks very much. So I have two questions. First, in the event that baricitinib and/or the Ang2 succeed in June, what are the next steps, would you be filing for approval at that time? And then with respect to the Ang2, could you just discuss the manufacturing capacity and the amount of volume you could produce later this year?

And then second, with respect to clinical trials when do you expect to restart enrollment in the majority of your trials? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks. Dave will go to -- Dan for both of those.

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

Yeah. Thanks, Dave. So starting out with the expectations for what if any of our molecules are successful in COVID-19, baricitinib is probably the most straightforward to answer. It's a small molecule that can be produced at large capacity and it's already approved in geographies around the world for rheumatoid arthritis. So depending on the quality of the data and the benefit-risk that we see in COVID-19 patients, you could expect that could potentially move very, very quickly if it's successful.

Ang2 is sort of the opposite end of the spectrum. This is investigational monoclonal antibody, production is more constrained and lead times are longer, and this is a Phase 2 type trial. I think though the one that we're most focused on which you didn't directly ask about in your question is the neutralizing antibodies against COVID-19. I think that's where we see a relatively high probability of technical success given success with neutralizing antibodies against other viruses and also given what we've seen pre-clinically with our project. And that's also one where you can imagine a broad treatment paradigm. Antibodies like this are likely not only to work in sick patients but could potentially have a prophylactic use, which then sort of demands large quantities.

I think in all of these programs, you just also note that these aren't chronic therapies. They're one-time use or short period of time in the case of baricitinib. But still, I think for the antibody, we're working very diligently to expand our manufacturing capacity that

would be ready to deploy both internally and with partnerships if the neutralizing antibodies are successful. We're making those investments in advance. I mentioned we started GMP manufacturing already at our facilities to support the clinical trials and we're prepared to scale quite rapidly if we see a positive signal with the neutralizing antibody.

Your second question was on clinical trial restart timelines. I think it's important to think about the context for why we stopped enrolling new patients and starting new clinical trials. It wasn't so much of problem with our ability to maintain the clinical trials. In fact, I'm quite confident -- even more confident today than I would have been a month ago in our ability to meet all of our sponsor obligations, our ability to deliver drug to sites or even directly to patients where it's needed to measure outcomes either at the sites or by other means directly with patients. So I'm really confident in our ability to carry out the trials.

It's a desire to relieve the sites and the hospitals of the burden of running clinical trials. So we're watching our clinical trial sites carefully. Many of them are already starting to ask the same question you are, when they can restart. We'll make decisions along with them based on the burden of COVID-19 that they're having and how much time and attention they can devote to clinical trials.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Seamus Fernandez with Guggenheim. Go ahead, please.

Q - Seamus Fernandez {BIO 7525186 <GO>}

A couple of here. There -- HMA is a consulting group that estimates the -- sort of medical -- Medicaid enrollment increases. So I guess, I'm just hoping that you guys could put a little bit more granularity around your estimates for expectations for Medicaid enrollment. This group estimates that Medicaid enrollment could increase by 11 million to 23 million, [ph] uninsured could increase by 10 million to 11 million. [ph] And just maybe if you can just help us put a little context around the percents of volume -- of Lilly's volume that flows into Medicaid currently versus the percent of sales that flows into Medicaid currently. Can you just, I think, help us understand a little bit of the context in that regard.

And then the second question for Dan. Dan, I think we were expecting the Phase 2 Alzheimer's data in the second half of this year for the NGC antibody. Could you just update us on that and how that's progressing? Is that still expected in the second half of this year? Or should we anticipate that in sort of a 2021 timeframe? Just an update there would be great. Thanks so much.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Seamus. We'll go to Josh for the first question and then Dan for your question on donanemab readout.

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

Sure. Thanks, Seamus. In terms of -- across our entire portfolio in the US, about 10% of our volume is Medicaid right now. About 40% is commercial insurance, 20% Part D, and then the rest is Part B or hospital-based or uninsured or other types of volumes. As we talked about before, I think that the biggest sort of challenge would be a really well insured commercial patient move into Medicaid. There are a lot of steps in-between those things happening. As I mentioned in a prior question, we are anticipating in our sales guidance for 2020 that we could see some net impacts as a function of that.

But again I would say, it's and we've looked at all those estimates and in terms of what the long-term look could be and we'll provide more update on that for 2021 when we have a better sense. But again, I'd say that our sales guidance right now does accommodate the fact that we may see some near-term moves to increase Medicaid or increase uninsured.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Dan?

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

Thanks, Seamus for the question on our Alzheimer's Phase 2 portfolio. You asked specifically about donanemab, or anti-N3PG Abeta antibody. This is a really robust plaque clearing antibody we know that can clear plaques to quite a great extent and quite quickly as well. It's 18-month Phase 2 study designed to demonstrate efficacy in a relatively large and homogenous population of Alzheimer's patients.

This study is fully enrolled. It's proceeding along previously communicated timelines, which means that the last patient visit will be in the end of this year, as you said, and most likely, then we'll have data to talk about shortly after that, although probably in January rather than in December. But no changes to our timelines on that trial. Similarly, the Tau antibody, as well as our symptomatic D1 PAM, those are all Phase 2 studies designed for efficacy, similarly fully enrolled and moving along the previously communicated timelines. So no change in the Alzheimer's portfolio there.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will be Steve Scala from Cowen. Go ahead.

Q - Steve Scala {BIO 1505201 <GO>}

Good morning. Thank you. It was mentioned that most clinical programs are paused for new starts; a couple of questions related to this. First, I realized that every trial is different, but generally speaking, how long will pause have to last to impact the long-term outlook for Lilly's sales vision, say, through 2025?

And then second, according to clinicaltrials.gov, only five of 155 Lilly trials that are actively recruiting have had recruitment status changed in the last five weeks. Just wondering about this relative to what you said and what the release said, I believe companies are obligated to reflect any changes within 30 days, so I'm just curious why really no changes have been reflected. Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Okay, Steve. We'll go to Dan for both of those questions.

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

Thanks, Steve for those questions. So the first question was just about like how long does the delay in new enrollment have to be before it starts to impact our long-term financials. Look, I think you know very well that clinical trial timelines and enrollment timelines are often estimates. We give those rounded usually to the half a year, sometimes just calendar year. So, for now, you can think of these as a worst-case scenario, being a day-to-day delay. So for every day that we pause enrollment, there is a delay to when we get the data.

Now our ambition is to beat that and there's a couple of reasons why we think we can do that. There is sort of latent demand to be in these clinical trials, that's accumulating. So when we put the switch again to allow enrollment, we think we'll see both of patients and be able to make up some lost time on enrollment, that's one of the reasons.

Another reason why we can even make up some time and be better than day-by-day is the fact that we can stagger our enrollment in different geographies, not everywhere in the world it's similarly affected by COVID-19. So while our comments on pausing enrollments might apply to the majority of our geographies, there could also be certain countries where we continue to enroll or even shift enrollment more to those countries.

As for the clinicaltrials.gov updating, you're right that there is a time lag in that update. There's also a time lag really in stopping enrollment because you can imagine that although we say no new enrollment, there are patients who could be part of the way through the screening. And on a case-by-case, trial-by-trial, geography-by-geography basis, we often allow those patients who are already undergoing study procedures to continue those procedures and enroll in the trial.

So it takes a little bit of time for all this to trickle through the system. But I am -- as I said earlier, looking forward to the day when we can turn this back on when the hospitals and clinical trial sites have gotten beyond the burden of treating COVID-19 patients.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will be Navin Jacob with UBS. Go ahead.

Q - Navin Jacob {BIO 20931208 <GO>}

Great. Thank you so much for taking my question. Just on, Trulicity, if I may. And sorry to beat a dead horse here, but want to understand relative to the negative 5% price pressure that you had guided to in the US, how we should be thinking about that now? And related to that is -- I know you've spoken about -- spoken to insulins being very profitable in Medicaid channel. Is that true for Trulicity as well? I'm assuming it's not as onerous as it is for insulins if that switch were to happen, but just any kind of color would be helpful with regards to Trulicity.

And then just a quick question if I may on Taltz. It looks quite strong. You also mentioned changes in rebates and discounts, any kind of color around pricing for Taltz as well would be helpful.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Navin. We'll go to Josh for both of these price-related questions on Trulicity and Taltz.

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

Thanks, Navin. First, our outlook at the beginning of the year for US price was net declines in the low-single digits. And as I mentioned in the range that we're looking at now, I think we're still in the low-single-digit that could add in the more pessimistic case, maybe that adds a point or something. But it's still in the same range.

To your question specifically about products, what we've said is insulins are not profitable in Medicaid. We pay in effect 100% rebates for patients who are on our mealtime insulin in Medicaid. So that's the place where you see a real challenge I think to the extent that the patients are moving from commercial insurance to Medicaid.

On Trulicity, it's less of an issue. It's still net positive, but Medicaid, just in general is a lower price segment than commercial plans. But it wouldn't be as big of a move, as it would be for commercially insured mealtime insulin patients. On Trulicity, I think we've highlighted through the last few years that Trulicity access is not as strong as it is for the rest of our portfolio. And what we have -- what we do in many cases is Trulicity patients have to step-through various PAs or restrictions in their plans. We make estimates on our utilization on how things are going to transpire there. What we found in Q1 is, we were actually getting more net price for a segment of our patients than we had estimated, so we got a little bit of a benefit there.

I think for the year, we're still, sort of assuming the same that we maintain the kind of access that we have now at relatively constant prices. And you'll see these ups and downs, and it's a little bit challenging in Taltz for the reasons as I mentioned. You'll see sort of the quarterly ups and downs, but the underlying trend that we see is pretty stable pricing, pretty stable access.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will be Geoff Meacham with Bank of America. Your line is open. One moment, please. Mr. Meacham, we seem to have lost your line here. Would you please repress one then zero?

A - Kevin Hern {BIO 20557573 <GO>}

We can just go to the next caller and catch Geoff up in a minute if he is not in?

Operator

All right. Thank you. Next question will be from Umer Raffat with Evercore. One moment, please.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my question. I hope everyone staying safe. There has been some concern about GIP safety after European paper, and I just thought it'd be helpful if you could speak to the blinded CV event rate you're seeing across your Phase 3 program, and whether it's in line with what you would have expected.

And secondly, I know Josh, you've got only 25 questions on it, so let me just ask the 26. You mentioned pretty stable pricing in the diabetes business. Can you speak to whether patients in high deductible private plans still produce the same net price for Lilly as those in Medicaid? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Umer. We'll go to Dan around at GIP safety and then Josh for pricing.

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

Yeah. Thanks, Umer for the question. Surely, you're referring to sort of a small epidemiological study that looked at a risk of GIP polymorphisms. I don't think that's directly applicable to what we're seeing with tirzepitide. Here we're studying this in a population that has diabetes. And we know from our Phase 2 trials that the physiological effects of tirzepitide, which obviously is combined GIP and GLP are quite beneficial, and they look like they would have a strong effect on improving cardiovascular outcome. So we're super confident about that.

In terms of the blinded event rates in our ongoing studies, that's not something that we disclose or talk about. But certainly, though the rate of those events is the rate-limiting factor in our submission. So that's the long tail in our submission is waiting to get enough events to discharge any cardiovascular safety risk so we can submit tirzepitide.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Josh?

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

Hi, Umer, thanks for the question. And I think you're building on one of the comments I made which was, I don't think you can just look at sort of a move from commercial to Medicaid. It's very much driven by planned dynamics and otherwise. And I think without getting into too much detail, yeah, it is fair to say that patients in high deductible plans, when they are in that deductible phase, you know that we and other pharmaceutical companies have co-pay cards and other things to try to alleviate the -- sort of the cash burden at the retail pharmacy. So we do -- the net price for those specific prescriptions to us is very low and probably in many cases could be lower than a Medicaid prescription.

But again, I think that gets back to what I was saying early -- earlier, it's -- I think, it's way too premature to make assumptions around what a move from commercial to Medicaid may look like. There are lots of complexities here and I think lots of things still to be learned about the economy and what 2021 will look like. But it's not -- we're not as I think on a math [ph] basis as concerned as probably it looks like when you just look at just general commercial to a Medicaid force for one of the reasons that you're sort of implying in your question.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

We will turn to the line of Geoff Meacham with Bank of America. Go ahead.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys, thanks so much for the question. Josh, a number of P&L questions for you. You quantified the pull forward COVID impact for a few products, just wanted to ask you, are those things since [ph] happening today in the US? And do you expect the OUS dynamic to eventually mirror the US? And then on your guidance, would you expect normalization of the market to be more of a 3Q or 4Q type of event?

And then real quick Dave, you highlighted at the end, but how would you characterize your discussion with policymakers today versus the beginning of the year, just with respect to headwinds on drug pricing, and clearly industry response at COVID is having somewhat of a halo effect. Thanks, guys.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Geoff. Okay. Josh, over to you and then Dave.

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

Thanks, Geoff. So just on the $250 million we estimated in Q1, as we mentioned about $200 million of that is in the US, and we talked about the three big product categories. I think the rest -- the product they didn't mention is sort of spread nominally among those

others. As we look at that $200 million in the US, only, less than one-third [ph] of that is that is at the wholesale -- wholesaler level. So we saw some modest build at the wholesaler. Most of that estimate we're making is that -- is either in the retail channel or all the way down to patient -- in patients' homes.

So I think it can be pretty difficult. I mean we're assuming that that will turn around, but I think being able to sort of make a prediction at this point is top. I would assume the wholesaler piece will start to normalize more quickly and I think we're seeing that. The retail and patient piece, I think will be -- some of it will be a function of what happens in social distancing otherwise and some of it who knows. It may be a little bit more -- we have a long tail associated with that.

What we saw in Europe, there was about $50 million, and I think most of the estimate is around our diabetes portfolio. And I think that one we probably assume is a little more likely to normalize in the second half of this year. So I think, Geoff, we'll try to be transparent about this as we move through the quarters. But I think there is going to be some variability in that USP sits in the retail channel or all the way to patient homes.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Josh. Dave?

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

Yes. On the policy side, I mean, I think you have it right there, maybe just a little subtext. There's sort of two pressures that prior to COVID, I think we are feeling. One was a broad acceptance across both sides of the aisle that, there were certain behaviors and actions which are undesirable by the industry and should be curved. Many of these actually Lilly agrees with. So this is about (inaudible) and strategies that involve using a system designed to create incentives in a way that perhaps is the best case in poor taste and maybe worst case abusive. [ph] There is a bunch of Senate related actions to curb these and I think we're generally for them because we don't do those things. And I think they do create a suppression of the respect for and trust in the industry.

I actually think those items will continue after [ph] the COVID crisis, maybe even the amplified because as solutions come from the industry, which they will, it's clear that the producers of those solutions will be under a lot of scrutinies to make sure there is broad access and affordability, and that we're acting reasonably. But I have to say, I'm speaking to my peers across the industry on many collaborative projects, and within our own company, nobody is really focused on the pure commercial side of this.

It's really about solving the problem. And the spirit of collaboration and response has been tremendous. But I think that pressure will be there and some, there could be actions coming quickly that could strike in those areas. Again from a Lilly perspective, we're less constructive on those. In fact, we -- before in [ph] many of those proposals.

On the other hand, there is -- I think from the -- more the far left in the US and in certain OUS circles, this idea that perhaps the industry itself is flawed and profit motive in pharmaceuticals is a bad thing. Of course, we merely disagree with that point of view. And

I do think those voices are significantly quieted today as everyone realizes that the built-up capacities of this industry are the very thing that will allow the world to escape COVID-19. And well, in the absence of a pandemic, those may seem like a premium. In the presence of a pandemic, those seem really scarce and important. And so I'm more bullish on that more extreme view being significantly dissipated for some time to come. We need to behave ourselves appropriately and with good taste, if I can use that word, and with kind of balance to our actions, as we solve the problem. But I'm encouraged by that so far.

So I think we've got a unique -- as I said in my comments, Geoff, kind of once in a generation opportunity to reset the reputation in the industry and to put in place policies that makes sense and balance profit motive, which we think clearly as a place to create new medicines, not just for COVID, but others with curbing abusive [ph] behaviors and making sure we're earning the respect from patients and policymakers alike.

So anyway, we'll work on that certainly over the next couple of years, but first, we need to work on solving the pandemic problem, and that's got all my energy right now.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will be Louise Chen with Cantor. Go ahead.

Q - Louise Chen {BIO 21301405 <GO>}

Hi. Thanks for taking my questions here. So my first question is, if there is any way you could give us a sense of the underlying earnings growth if you extract the impact from COVID and any non-operational items, even if it's just qualitatively? And then second question is, are you expecting any economic benefit for your COVID candidates in development if they do work? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Josh?

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

Yeah. Hi, Louise, thanks. I think if you just -- at a very high level, if you just take out the revenue for Q1 that we're attributing to -- the $250 million we're attributing to buying patterns and sort of hold everything else the samem we get down to earnings EPS growth on a more normalized basis of about 18% or so. So I think that's probably a reasonable look at the business. And as with every quarter, there are other things that we could normalize out of there, but I think that's probably a good sort of starting point. And as we've mentioned with that -- we're expecting that $250 million to normalized some time through the year, at least in our guidance for now. But that's where we are.

I think then on the question around economic benefits, no, there is no benefit assumed in our guidance from any of these treatments more -- much more interested in getting these

treatments to patients at this point. And frankly, I'd say at this point, we're probably just assuming some costs for sure associated with investment in the trials that Dan had mentioned in the scale-up in manufacturing and otherwise. So some of that thinking is already embedded in our line items now.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

Yeah. It will be Vamil Divan with Mizuho Securities. Go ahead.

Q - Vamil Divan {BIO 15748296 <GO>}

Great. Thanks for taking my questions. Thanks for the color on the call. May I just got a couple of questions on the pipeline. So one, mirikizumab, you mentioned the positive initial top line data in psoriasis. I guess I've been wondering about sort of differentiation for that product relative to the other IL-23, maybe there is anything more you can share now that you have some of the top line data, and just in the update on timing, especially on the GI trials? Or I think [ph] you've talked about that being a kind of more unique opportunity, potentially.

And then going back to Alzheimer's, I appreciate your comments from before. Just regarding (inaudible) and also from gantenerumab, you mentioned the plaque reduction that you've seen with donanemab. does the (inaudible) results in any way change your thoughts around sort of plaque reduction in the biomarker impact -- and impact it might have on the clinical outcome at the end of the day, just because we do not see that correlation in that trial? I know it's a small trial, but any perspective would be helpful. Thanks.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Vamil. We'll go to Patrick for the mirikizumab question, and then Dan for the Alzheimer's question.

A - Patrik Jonsson {BIO 22620517 <GO>}

Thank you very much. We announced that the Medicare some met all the coprimary and key secondary endpoints, and the first OASIS-1 trial, which is a placebo-controlled 52 weeks trial in psoriasis. And that is what we expected as well. We are setting the bar extremely high in psoriasis with Taltz who have been able now to demonstrate in five head-to-head trials superiority, any three of those in psoriasis, both in terms of time to onset at the level of clearance and the sustainability of the clearance. So we are waiting now for the second Phase 3 trial, which is a head-to-head trial versus zagotenemab, a 52-week data. And I think that will particularly inform our decision on how we progress with the psoriasis indication.

For miri, I think, we have also stated very clearly that the big excitement is around ulcerative colitis and Crohn's disease. And we really believe that in ulcerative colitis, there

is a big unmet need, and we have a potentially first-in-class and best-in-class asset in mirikizumab. And we also know that biologic penetration is relative low. And we have previously shared that we expect the top line readout for the induction data in Q4 this year, and the maintenance top line in 2021.

For Crohn's disease, we have announced earlier that we will do a top line announcement in 2022. As this time with COVID-19, we are certain that there will be a delay in one or both of those programs. However, we believe it's also premature to quantify the impact. And as the situation evolves, we will have a better understanding of the impact, as well as our ability to mitigate those.

And the delay here that's important state is, it's driven by difficult -- difficulties to access the study sites, particularly infusion centers, and the ability for some of those centers to conduct and perform endoscope. So overall, the high level of excitement still for both ulcerative colitis and Crohn's disease, and the head-to-head data versus (inaudible) will guide our decision moving forward on psoriasis.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Patrik. Dan?

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

Yeah. As for Alzheimer's DIAN to you, I mean, of course, this is a really heroic and difficult effort to study effects of drugs in the dominantly inherited Alzheimer's population. I think unfortunately, there's just a small number of patients who completed the trial, especially at the higher dose for solanezumab, so tough to make conclusions about any clinical effects to sola there. As you point out, sola is not a plaque lowering antibody. It works on (inaudible) so can't draw conclusions about plaque lowering from solanezumab data.

I think though the most important things to look at in DIAN are the biomarker outcomes. And perhaps if you think about the biomarker outcomes, you could add a little bit of confidence around plaque lowering. But once again, it's a small study and hard to draw those conclusions.

I look forward to the results from our Phase 2 trial, which I think should be a clean trial -- a clean test of the hypothesis in a relatively homogenous population. That data is not very far off right now.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dan. Vamil, thanks for your questions. And we're going to the next caller, please.

Operator

That will be from Tim Anderson with Wolfe Research. Your line is open.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you. A couple of questions please. On tirzepitide, you've mentioned results in 2020 and everyone knows that I think. Is that just likely to be top line or we likely to see a more complete set of results in some form or another, whether's publication or presentation?

And then second question is on Tyvyt, your PD-1 in China, I feel like over time have gotten mixed messages from the Company on the importance of this product. Maybe a year ago I was talking to one of the members of senior management, and that was kind of described as a China-only product of smaller importance. But I don't know if that's still the current point of view. I've asked about it last quarter. I didn't get much of an answer.

So the question is really twofold on Tyvyt. The development program from here in China in terms of next tumor types and perhaps, more importantly, your plans to take this outside of China into developed markets, US, Europe, or anywhere else that's traditionally consider developed.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Tim. We're going to Mike for the tirzepitide question, and then Dave will take the question on Tyvyt.

A - Michael B. Mason {BIO 18347681 <GO>}

Yeah. Thanks for the question. Just directly, we do believe we'll have our first top line readouts of the SURPASS program for the first trial in Q4 of 2020, and then additional readouts, top-line as well as at medical meetings going into '21. Thanks for the question.

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

Yeah. Tim, as relates to Tyvyt, I don't think you read the prior commentary is wrong. I think we originally collaborated with Innovent as a China-only play for biologics and cancer, and a few other biosimilar opportunities. But there two things have changed which I think -- and today we're breaking out China for the first time, so maybe that -- that's a third thing that's changed. But one is that Tyvyt was the only PD-1 put on the PDL nationally in China, so that does change the economic profile of it for us, and certainly for the Chinese business.

And the second is the positive data that was released in the combination with pemetrexed in first-line non-small cell lung cancer, which is very encouraging, and I think does change the trajectory of that certainly in China.

Of course, right now, we're very focused on the Chinese opportunity and that remains our focus in the short-term. And as Josh mentioned, I think in his remarks, there is a great volume growth in China for oncology portfolio and Tyvyt is a key part of that. So anyway, a great partnership with Innovent. They do a great job and it's been a successful way to think about building our business which is a little bit under-represented in China, a decade ago through local partnerships with local innovators and we're really pleased with how that's progressed.

A - Kevin Hern {BIO 20557573 <GO>}

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

Operator

That will be Carter Gould with Barclays. Go ahead.

Q - Carter Gould {BIO 21330584 <GO>}

Good morning. Thanks for taking the question. I just wanted to, I guess, dig into the comment over the inevitable fiscal pressure on government-funded healthcare, specifically thinking about Europe and the pressure on budgets there. I guess, are you guys viewing is a possibility, probability or likelihood this incremental pricing pressure in Europe, I guess looking out later this year into next? I appreciate any thoughts there.

And then following up on the Tyvyt data -- Tyvyt discussion, when could we expect the ORIENT-11 data to be presented? Is that something that could still come in first half this year? Or will we have to wait until the back half of the year? Thank you.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Carter. We'll go to Dave for the question for Europe, and then Anne for the question about the Tyvyt ORIENT-11 data.

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

Yeah. As it relates to Europe, and I would say this extrapolates to other government-run health systems like Australia, Canada, Japan as well, we saw a policy response in nearly every jurisdiction following the '08-'09 fiscal crisis. Well, this isn't a fiscal crisis. It's -- there will be a fiscal crisis brought on by the pandemic. In many of these economies, it will lower tax receipts, and then the governments will need to look for methods to reduce their spending. I think we can predict that with almost absolute certainty.

One of the items on the list is orphan drugs because it's an input that can be negotiated or in many cases, they don't need to negotiate. They just change their rules. And we saw that certainly happen and create a three or four-year series of policy moves depending on the relative strength of the economy that suppressed drug pricing in places like Europe and Australia, Canada. So we're projecting that in the future. As Josh mentioned, we don't see a lot of that happening in '20, probably tax receipts falling in '21 lead to legislative actions in '21 and '22, which leads to suppressed pricing beyond that. That's to me uncertainty across the industry.

And then the real question is how relatively innovative is your portfolio because a lot of these policies tend to be using leverage governments can have when there's relative subsidy ability. So the more innovative portfolio, the more immune you become to these things. And obviously, we're working hard on that side of the equation and hopefully, we'll be on the positive end of the industry. But I suspect as an industry as a whole, there will be -- these international pressures will present themselves across everyone's portfolios to some degree or another.

A - Kevin Hern {BIO 20557573 <GO>}

Thanks, Dave. Anne?

A - Anne E. White {BIO 20764375 <GO>}

Yes. Thanks for the question on Tyvyt. So with the Phase 3 ORIENT study, as you know, is an interim analysis that was positive and we're very excited about initiating that submission with Innovent to the regulatory authorities in China, and we will be submitting that data for a medical meeting in the second half of this year, so you'll see it in the second half of 2020.

A - Kevin Hern {BIO 20557573 <GO>}

Great. Thanks, Anne. Carter, thanks for your questions. That's we've exhausted the queue, so I'll go to Dave to close.

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

All right. Thank you all, and we appreciate your participation in the call and your interest in the Company. Obviously, different times today, and just on a personal note, I know many of the sell-side communities are based on the East Coast, and we hope you're all well and your families are functioning and certainly healthy through this crisis.

As usual, any follow-up calls or questions can be directed to our really incredible Investor Relations team. And again, I hope you all stay well and we'll be in touch soon. Take care.

Operator

Ladies and gentlemen, that will conclude your conference call for today. Thank you for your participation and for using AT&T Executive Teleconference Service. You may now disconnect.