Q1 2020 Earnings Call

Company Participants

- Arvind Sood, Vice President of Investor Relations
- David M. Reese, Executive Vice President, Research and Development
- Murdo Gordon, Executive Vice President, Global Commercial Operations
- Peter Griffith, Executive Vice President and Chief Financial Officer
- Robert A. Bradway, Chairman and Chief Executive Officer

Other Participants

- Alethia Young, Analyst
- Carter Gould, Analyst
- Chris Raymond, Analyst
- Cory Kasimov, Analyst
- Dane Leone, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jim Birchenough, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Schmidt, Analyst
- Michael Yee, Analyst
- Mohit Bansal, Analyst
- Robyn Karnauskas, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Tim Anderson, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst

Presentation

Operator

My name is Ian, and I will be you conference facilitator today for Amgen's First Quarter 2020 Financial Results Conference Call. All lines have been placed on mute to prevent

any background noise. There will be a question-and-answer session at the conclusion of the last speaker's prepared remarks. (Operator instructions).

I would now like introduce Arvind Sood, Vice President of Investor Relations. Mr. Sood, you may now begin.

Arvind Sood {BIO 4246286 <GO>}

Okay. Thanks, Ian. Good afternoon everyone. Thanks for joining us for our Q1 call. I hope you and your families are staying safe. We are (Technical Issues) with the COVID-19 pandemic. I know, I speak on behalf of all my colleagues at Amgen, when I say that it's a source of great pride, that we work in an industry that can be a part of the solution.

Before we start, I would like to recognize those who are new in their coverage of Amgen, including Tim Anderson of Wolfe Research, Carter Gould of Barclays, and Michael Schmidt of Guggenheim, welcome. Over the past few weeks, I've talked with many of you and you have expressed concerns and posed questions about how this COVID pandemic will impact our business, including supply chain, clinical trials, commercial operations and growth outlook.

As our growth outlook will be defined by how these variables unfold in the future, we have modified the order of presenters today. So you can get a good sense of how we are dealing with the uncertainties and remedial actions we are taking to run our business effectively. Our CEO, Bob Bradway will commence the call with some opening comments, followed by our Head of R&D, Dave Reese, who will provide a pipeline update. Our Head of Commercial Operations, Murdo Gordon will give you a state of the business. And then, our CFO, Peter Griffith will bring it all together by helping you understand what all this means in terms of our growth outlook.

By the way, consistent with the recommendations for social distancing, we are all in different locations today. So please bear with us as (Technical Issues) the best we can. Just a quick reminder that we will use non-GAAP financial measures in today's presentation and some of the statements will be forward-looking statements. I would direct you to our 10-K and subsequent filings, which identify factors that could cause our actual results to differ materially. So with this, I would like to turn the call over to Bob. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Good afternoon, everyone. I want to acknowledge upfront that this has been an extraordinary quarter for all of us. Global pandemic, economic disruption like none of us have seen before, and of course financial volatility that has been dizzying at times. But I hope you're keeping well and we're certainly grateful to you for joining the call.

(Technical Issues) results. We're managing through the COVID disruption quite well and feel we're operating from a position of strength with a healthy balance sheet, a strong portfolio of products and an organization that has proven itself time and again to be innovative, resilient, and able to adapt quickly to changing circumstances.

I want to take a few moments to share how we've been responding to COVID-19, and then we can dive into the details of the first quarter and what we see for the remainder of the year. We've mobilized our company around four priorities. First, taking care of our staff, our 23,000 staff around the world. Second, continuing to serve patients with an uninterrupted supply of our commercial and clinical medicines. Third, leveraging our core genetics, immunology and antibody expertise in the fight against COVID-19. And finally, supporting the communities where we live and work.

Our first priority from the beginning of the pandemic has been to ensure the safety of our people and their families. To encourage social distancing, Amgen staff worldwide are mostly working from home now. We're encouraged that in a few markets, conditions have improved to the point where we've begun returning our people to the workplace and we hope to expand our back to the workplace activities in the coming (Technical Issues).

I would also note that about a quarter of our staff are engaged in the central manufacturing and R&D activities that have required them to continue coming to the workplace every day. We're taking every possible measure to keep these employees safe and we're grateful to them for their commitments to patients into our business.

All our staff are performing really well as you can see from our results. At a time when healthcare systems around the world are being stretched to their limits, we're committed to working collaboratively with our partners in the healthcare ecosystem. We need to make sure that we're both responding to COVID-19 and meeting the ongoing needs of other seriously ill patients. (Technical Issues) healthcare crisis that we as a society never intended.

From a supply chain perspective, we've not experienced any significant disruptions and we don't currently anticipate any shortages of our medicines due to COVID-19. With respect to clinical trials, our pivotal studies, including for AMG 510, Otezla, tezepelumab and omecamtiv mecarbil are fully enrolled and expected to readout this year as previously announced. Other programs such as our BiTEs in oncology have also continued to progress and we're encouraged by the accumulating data there.

Where programs have been interrupted by the COVID pandemic, we're busy making plans to get them restarted as soon as appropriate with patient safety and regulatory perspective. By now, it's clear that overcoming this pandemic will require innovative science. While the virus may have gotten the jump on us at the outset, the good news is that the community of innovative biopharmaceutical companies is moving on speed and scale never seen before. And we're gaining ground on the virus with each passing day.

While our research does not include antivirals, we have a role to play in this battle, leveraging our genetics, immunology and antibody expertise to do so. As previously announced, we are harnessing the molecular epidemiology work done by our deCODE subsidiary and working with our partners at Adaptive Biotechnologies to develop an antibody to prevent or treat COVID-19. If we're successful, our industry leading manufacturing capabilities will play an important role in helping us meet the needs of patients.

In addition, based on its mechanism of action, Otezla might help prevent the respiratory distress seen in late-stage COVID patients. As Dave Reese will explain in a moment, we will be exploring this question in clinical trials imminently. We've long prioritized being a good citizen within the healthcare ecosystem and within the communities where we live and work. (Technical Issues) by COVID-19 has been devastating for many. While we certainly have been impacted by the pandemic at Amgen, we recognize that we're in a fortunate position and we're committed to doing our part to help during this time of need.

Towards that end, Amgen Foundation is supporting COVID-19 in a variety of ways with a focus on communities where we have a significant presence. To give you just one example, we donated testing equipment in Ventura County, our home county that effectively has doubled the testing capacity for COVID-19 here.

Looking forward, we're confident in the future. We were in a strong position heading into the COVID-19 pandemic and we expect to stay strong as we come through the other side of this. We remain focused on delivering sustained long-term growth and we're confident in our outlook for that.

As I've already noted, we have a number of important innovative medicines advancing in our pipeline and the key programs remain on track in the timing perspective. Our integration of Otezla has been seamless. In Japan, we have now successfully completed the integration for Astellas partnership, and we're already well advanced and collaborating effectively with our colleagues at BeiGene in China. All this gives me confidence that we're executing effectively around the world despite the challenges of COVID-19.

Finally (Technical Issues) a fact that will enable us to continue our capital allocation principles, which to remind you are to invest in innovation internally and externally, while returning significant capital to our shareholders. Though the pandemic is still very fluid and to be sure the first few weeks of April have clearly shown some signs of disruption, the combination of our results from the first quarter and our expectation of an improving outlook from global healthcare activity give us confidence that the guidance we provided earlier in the year still incorporates the likely range of outcomes for our business in 2020. Peter will give you more color on this shortly.

Amgen's strength has always come from its people. Like me, they believe in the power of science to make a difference in the world. We often talk about this being a Bio Century, the golden age of innovation for biology. We may have met our challenge of the century in SARS-CoV-2, but I hope however bleak this pandemic may seem at times that all of you share our optimism, this virus will ultimately yield to the relentless efforts of the biopharmaceutical industry to rest them into ground. I'm proud of the team at Amgen for coming together to support each other and all of those who serve during such a challenging time and proud also of the work we are doing with our industry colleagues to tackle the COVID-19 challenge.

With that let me turn over to Dave Reese, who will provide a pipeline update. Dave?

David M. Reese {BIO 19782623 <GO>}

Thanks, Bob, and good afternoon everyone. In light of the evolving COVID-19 epidemic, the structure of today's R&D update will differ from my usual approach. Some of the first quarter highlights can be found within our press release and accompanied presentation, and of course, I'll be happy to address questions on any other aspects of our pipeline following our general comments.

I don't have to tell you that we're in the midst of the biggest public health crisis of our lifetime, which presents unprecedented challenges in patient care and clinical development. Therefore, today my comments will focus primarily on our R&D operations and clinical trial execution in the current environment, where our first principle is to ensure the safety and well-being of patients and healthcare providers taking part in our clinical trials.

With respect to key late stage trials that are scheduled to readout this year, we've been working closely with our collaborators at AstraZeneca and Cytokinetics on the execution of our pivotal studies such as tezepelumab and omecamtiv mecarbil respectively, both of which have completed enrollment. We currently do not expect any significant delays and continue to expect completion of these studies this year.

We believe, we will have high quality data from both of these trials. This is also the case with our potentially pivotal Phase 2 monotherapy study for AMG 510, now known as sotorasib in advanced non-small cell lung cancer, which is also fully enrolled. As I mentioned last quarter, we will be collecting at least six months of response data in these patients and continue to expect these results later this year.

I would note that the Phase 3 trial of Otezla in mild-to-moderate psoriasis also remains on track, and we expect data from that study in the coming weeks. As previously disclosed, we have temporarily paused the enrollment in clinical trials where there is uncertainty around the ability of sites to ensure subject safety or data integrity. Patients who are already enrolled in our studies continue to receive study drug and we remain focused on supporting our clinical investigators to ensure appropriate care of these patients in a safe manner, consistent with clinical site and agency guidelines.

We're actively working with regulators and implemented study procedures as appropriate that are consistent with the recent FDA guidelines, including remote monitoring, virtual follow-up, alternative locations for assessment, and home delivery of investigational product. We continue to make decision study-by-study and site-by-site to minimize the risk to the patients and facilities and to maintain trial integrity.

For example, enrollment continues in certain studies where there is the potential for significant benefit in a seriously life-threatening condition and with site resources, allowing new patients that are safely enrolled and closely monitored. Such trials include but are not certain -- limited to our half-life extended BiTE program targeting BCMA, DLL3 and PSMA and we look forward to sharing data from these studies later this year.

In other studies such as our sotorasib Phase 1 combination study with KEYTRUDA and the Phase 3 confirmatory study where we have paused the enrollment to ensure patient safety, timelines may be impacted and I will provide updates as the situation develops and we gain more clarity.

There is ongoing interest from investigators to provide their patients access to investigational therapies with potential for significant benefit. And we are working to continue to study start up activities for sotorasib and across our entire portfolio to allow rapid site activation. We look forward to resuming enrollment in past studies and initiating subjects enrollment to new studies over the coming weeks and months as soon as they are safe and feasible to do so.

As we look forward to this year's clinical study readout, we will be working with representatives in medical conferences and journals to ensure continued dissemination of important data in the medical community in a peer-reviewed environment as we anticipate that many congresses will be virtual through the end of 2020. In any case, we have provided -- we are committed to providing data updates in a timely manner. We're also continuing to prioritize programs across our pre-clinical and clinical portfolios as you might expect.

For instance, based on the progress of our half-life extended BiTE molecules, we have stopped development of the first generation continuous infusion, PSMA and BCMA BiTE programs.

In research, essential work is continued and we -- and we are beginning to ramp laboratory activities across the organization, as the situation safely permits in various geographies. I'm also pleased to report that our BeiGene collaboration is on track and in this quarter we have begun to transition certain functional activities to BeiGene including non-promotional activities on the three in-line products and some local regulatory responsibilities in China.

I'd like to close by saying a few words about how we are leveraging our expertise in therapeutic antibody development and immunology in the fight against COVID-19. Our recently announced collaboration with Adaptive Biotechnologies to identify and develop neutralizing antibodies to the coronavirus from recovered COVID-19 patients is now actively underway. We view Adaptive's world-class expertise in immune profiling, combined with Amgen's expertise in immunology and antibody engineering and manufacturing has a unique opportunity to contribute to what is an unprecedented industry response to this pandemic.

We are working intensely to identify the highest quality therapeutic candidates as fast as we can, and we'll take advantage of frequent interactions offered by regulatory authorities. In our view, there will likely be more than one generation of antibody therapeutics and our aim is to develop the highest possible quality candidates. In addition to our efforts to develop a therapeutic antibody, we have also been engaged in discussions with multiple groups conducting platform trials in COVID-19 and anticipate

that Otezla will enter the clinic in the coming weeks to be investigated as a potential immunomodulatory treatment in adult patients with the disease.

Finally, we are contributing actively to collaborative efforts to advance therapeutics for COVID-19 including active public-private partnership with the NIH. I want to close by acknowledging our staff, who are working tirelessly and selflessly under these challenging circumstances to deliver for our patients. Their commitment and execution have been exemplary and I can't thank them enough.

I'd now like to turn the things over to Murdo Gordon.

Murdo Gordon {BIO 18450783 <GO>}

Thanks, Dave, and good afternoon everyone. We started the year with strong volume driven growth of 15% on a global basis, with 10% in the US and 32% ex-US. Growth was generated broadly across our portfolio of newer products more than offsetting declines in our mature brands.

Given the unprecedented nature of the COVID-19 pandemic, I want to start by sharing our views on how disruptions in the global healthcare system may impact our business. And then I'll walk through what we're seeing at the product level and what actions we are taking. Like others in our sector, we're seeing varying degrees of impact from COVID-19 across our portfolio as physician, patient interactions are interrupted. These reduced interactions have led to some delays in diagnosis and treatment which in turn reduces new patient starts.

Data from IQVIA suggests that patient office visits have declined by over 50%, although some of this is being offset by Telemedicine and Telehealth services. Data also show that some patients refilled prescriptions early and that there was a modest benefit of approximately $100 million from inventory in the quarter. Finally, increased utilization of patient affordability programs and changes in segment mix due to increased US unemployment could negatively impact US net prices.

Treatments like Prolia that require in-office administration by a healthcare provider have been negatively impacted. On the other hand, the product like Otezla may benefit given that it provides a convenient oral option for patients, compared with injectable or IV Biologics, some of which require monitoring. Despite this disruption, our teams are responding to customer needs via remote interactions. We're identifying innovative solutions to help patients and we're supplying products reliably and consistently.

Now, let me review some product details beginning with Prolia on slide 12. Prolia grew 10% year-over-year from higher volume. Strong demand growth in January and February was consistent with prior years. In March, we began to see a negative impact on Prolia in-office injections, and have since observed a substantial step down in utilization versus prior years.

In more recent weeks, we're beginning to see signs of stabilization and we'll be able to provide more clarity on this when we report our Q2 results in July. The importance of treating osteoporosis in patients who are at high risk of fractures critical. Our teams are working to address continuity of care issues and exploring novel solutions such as alternate sites of care, mobile nurse-administered injections, prescription fills at specialty and retail pharmacies. We're also working with policymakers and advocacy organizations to address treatment challenges in this environment.

Moving to EVENITY, which launched in Japan and the US in the first half of 2019. EVENITY posted a $100 million in sales during the first quarter, driven by continued uptick. In Japan, which represents roughly two-thirds of the EVENITY sales, we've attained share similar to those of established anabolic therapies.

In the US, we saw an acceleration in demand trends with improvements in persistence in Q1 as clinics gained more experience. As patients complete their one-year cycle of therapy with EVENITY, we will work with healthcare providers to help transition these patients to Prolia. EVENITY and Prolia are a complementary set of options to address the 9 million fractures that occur worldwide in postmenopausal osteoporosis patients. And our teams are focused on ensuring these patients are not compromised during this pandemic.

Moving to Repatha. We're off to a strong start in 2020. Our efforts over the past 18 months to improve access and affordability have yielded strong results as Q1 sales grew by 62% year-over-year, driven by 98% volume growth versus the same period last year. New-to-brand prescriptions in the US steadily improved in Q1, growing 51% year-over-year and we held 80% market share exiting the quarter.

As we precised in our last earnings call, Part D contracting to improve access and affordability resulted in a step down in Repatha's net selling price in Q1. We expect net selling price to be relatively stable for the remainder of the year.

On to Aimovig on Slide 15. On a year-over-year basis, net sales grew 20% with underlying volume growth of 46%. Aimovig remains the market leader with 48% total prescription share. To-date, almost 330,000 patients have been prescribed Aimovig by more than 33,000 prescribers. With the recent addition to CVS National Preferred Formulary, we now have access to 93% of covered lives, which led to a 19% growth quarter-over-quarter in new-to-brand prescriptions.

Net price was sequentially lower due to expanded access with CVS and higher co-pay utilization that occurs each year in the first quarter. These factors were partially offset by the proportion of paid prescriptions increasing to almost 90%, up from 81% in Q4 of 2019.

Next to our inflammation portfolio, starting with Otezla. Integration has been seamless evidenced by 23% year-over-year growth driven by volume. These results coupled with planned label expansion, give us confidence in our ability to realize the full global potential of Otezla as an affordable option with a very well defined efficacy and safety

profile. In the current COVID environment, Otezla provides a convenient oral option for patients, it's conducive to Telemedicine and does not require lab monitoring.

Moving to Enbrel, sales were $1.2 billion in Q1 and included a $70 million year-over-year benefit from favorable changes in accounting estimates related to sales deductions. Consistent with prior trends, prescription volumes declined 5% year-over-year. We continue to expect a limited benefit from net selling price in 2020 versus 2019.

In this environment, we're supporting Enbrel's strong continuing base of patients in maintaining their course of therapy through disruptions and out-of-pocket cost barriers. As you know Enbrel has been on the market for over 20 years and does not require routine lab monitoring.

Now to Slide 18. Another contributor to our inflammation franchise is, AMGEVITA, which for three consecutive quarters is the number one adalimumab biosimilar in Europe, recording $86 million of sales in Q1.

Switching to our Hematology and Oncology business. Our innovative portfolio of six brands collectively totaled $1.3 billion in the quarter, growing by 11% year-over-year. Certain products like XGEVA may be impacted in the current environment due to disruptions in physician-patient interactions. Although others including Neulasta's Onpro and our oncology biosimilars MVASI and KANJINTI provide greater value.

Let me highlight some of our larger products. KYPROLIS grew 14% year-over-year, led by a 21% increase in US sales, which was driven by expanded use in second and third line multiple myeloma. Neulasta declined 40% year-over-year. Recall that Q1 of 2019 benefited from a $98 million BARDA order, which did not repeat this quarter. Onpro continues to be the preferred choice and it saw quarter-over-quarter share of 54% despite facing an additional competitor. The revised NCCN guidelines recommend increased use of GCSFs to minimize the risk of febrile neutropenia in cancer patients. Onpro provides a unique value proposition, particularly now as patients can receive their GCSF treatment without having to return to their site of care.

Our two oncology biosimilars MVASI and KANJINTI generated $234 million in sales globally in the first quarter. In the US, they sold a $108 million and $96 million respectively with market shares exiting Q1 at or above 27%. We continue to see encouraging adoption rates in clinics with hospital adoption accelerating. These biosimilars are increasingly valuable given the cost savings they provide.

Switching to Nephrology, starting on Slide 24. Given the serious nature of end stage renal disease, patients require dialysis treatments three days per week. Therefore, we're not seeing a meaningful impact on the use of the Amgen medications in these patients that would attribute to COVID-19.

In Q1, EPOGEN sales declined 29% primarily due to lower net selling price from our contractual commitments with DaVita and approximately $20 million of unfavorable changes in accounting estimates. Sensipar sales declined 42% year-over-year due to the

impact of generic competition. As a reminder supplemental patent protection certificates for cinacalcet have now expired in major EU markets, which could result in a significant decline in ex-US sales in 2020. Parsabiv grew by 39% year-over-year in the first quarter, independent and midsize dialysis providers already utilize Parsabiv for a majority of their calcimimetic patients, while FMC and DaVita continue to increase adoption.

In summary, I'm truly inspired by the entrepreneurial spirit of our employees who are helping patients and healthcare providers in this unprecedented time.

And with that, I would like to turn over to Peter.

Peter Griffith {BIO 4299061 <GO>}

Thank you. Murdo. Good afternoon, everyone. Before reviewing our results and guidance, I would like to take a moment to build on Bob's comments regarding the unprecedented COVID-19 pandemic, and provide additional insight and how we are responding to and navigating through the associated macroeconomic challenges.

First, we confront these challenges from a position of strength. Our fundamentals are strong, with over $8 billion of cash and investments and a business that generated $2 billion of free cash flow in the first quarter, we are in a strong finance (Technical Issues] we remain committed to our capital allocation principles shown on slide 28, which start with investing in internal innovation.

We will patiently evaluate external business development opportunities that clear our hurdle rate and are consistent with our areas of therapeutic focus. Our capital expenditures remain a high priority including our industry-leading environmentally-friendly next generation biomanufacturing facility in Rhode Island.

We will continue to return capital to our shareholders. Our capital allocation principles will continue to build on our efficient capital structure, which results in an optimal weighted average cost of capital. Now, I will briefly walk through our first quarter financial results before discussing our 2020 guidance.

The financial results are shown on Slide 29 of the slide deck. The first quarter marked another period of solid performance, as we grew volumes 15% increased investments in the business and delivered 17% year-over-year non-GAAP EPS growth. Q1 revenues at $6.2 billion increased 11% year-over-year. In the quarter, we saw worldwide product sales increase 12% to $5.9 billion as our portfolio transitioned with strong growth from our newer products outpacing declines in our mature products.

Now onto the rest of the P&L. Total operating expense for the quarter increased 7% year-over-year. For the full year, we now expect total operating expenses to grow in the high single-digit percentage range year-over-year on an absolute basis. On a non-GAAP basis, cost of sales as a percent of product sales decreased by 1.6 percentage points to 13.1%, driven primarily by lower manufacturing costs, partially offset by an increase in milestone

expense. For the full year, we continue to expect cost of sales as a percent of product sales to be generally consistent with 2019.

Research and development expenses of $927 million were 8% higher due to higher spending on Otezla and AMG 510 partially offset by cost recoveries from our collaboration with BeiGene. For the full year, we also expect R&D spend on an absolute basis to increase as we invest in our innovative pipeline and new Otezla indications. With these increases partially offset by R&D recoveries received from our BeiGene collaboration.

SG&A expenses increased 12%, (Technical Issues) Otezla and for the full year, we continue to expect SG&A spend to increase, primarily due to Otezla spend. Our Q1 non-GAAP operating income at $3.2 billion increased 15% from prior year. Non-GAAP operating margin was 53.9% for the quarter compared to 52.4% in Q1 of 2019.

Other income and expenses were a net $335 million expense in Q1. This is unfavorable by $177 million on a year-over-year basis. This year-over-year change was due to lower interest income on cash balances, as well as market fluctuations of publicly traded securities held in our venture partner portfolio.

We anticipate non-GAAP other income and expense to be a net expense, towards the upper end of the $1.2 billion to $1.4 billion range we previously provided. Recall that we will begin reporting under the equity method of accounting, our share of BeiGene's profit or loss beginning in Q2.

The non-GAAP tax rate decreased 1.8 percentage points versus Q1 2019 to 12.8%. Non-GAAP net income was $2.5 billion (Technical Issues) 17% year-over-year for the first quarter supported by a 5% reduction in share count versus Q1, 2019.

Turning next to cash flow and the balance sheet on Slide 30. During Q1 2020, we generated strong cash flow reflecting a diversified portfolio of products coupled with an industry-leading cost structure. Free cash flow was $2.0 billion in Q1 2020 versus $1.7 billion in Q1 2019.

In Q1 2020, we returned a total of $1.9 billion to shareholders through dividend payments totaling over $900 million, and over $900 million to repurchase 4.3 million shares at an average price of $219 per share. For the remainder of the year, we plan to maintain our quarterly dividend of $1.60 per share, and will execute opportunistic share repurchases that will result in an amount at the lower end of our previous guidance of $3 billion to $5 billion for 2020.

Cash and investments totaled $8 billion at the end of Q1 2020, a decrease of $18.3 billion from the end of Q1 2019. This decrease was primarily driven by the Otezla and BeiGene transaction, cash return to shareholders in the form of share repurchases (Technical Issues) as well as net debt repayments partially offset by free cash flow generated during the period.

Additionally, I note in Q2 2020, we plan to make $1.75 billion payment in debt payment -- debt maturity payments. We issued $5 billion of long-term debt in February in order to take advantage of market conditions for refinancing our long-term debt maturities in 2020 and partially those in 2021. We will continue to be opportunistic with strong access to capital markets.

Debt outstanding at the end of the quarter totaled $31.8 billion, and carries a weighted average interest rate of 3 points (Technical Issues). Turning to the outlook for the business for 2020, starting on Slide 31. Our guidance provided in January contemplated a broad range of outcomes. Due to the uncertainty related to the COVID-19 impact, we expect some degree of uncertainty in quarterly revenue and earnings over the year. We currently expect that we will see the greatest impact later in Q2, with stabilization and then partial recovery occurring during the second half of the year.

And now turning to Slide 32. We are reaffirming our guidance with a revenue range of $25.0 billion to $25.6 billion and a non-GAAP EPS range of $14.85 to $15.60. We will be monitoring the businesses, as the dynamics underlying these assumptions evolve across Q2. And we'll review our latest perspectives with you at our next earnings call.

We are now guiding to capital expenditures of $600 million versus our prior guidance of $700 million, reflecting a change in the timing of spend, rather than a change to our investment plan. Additionally, we are reaffirming our non-GAAP tax rate guidance of 13.5% to 14.5% for the full year. This concludes the financial update.

I've been with Amgen a little over six months and it's a privilege to serve patients every day here by supporting and enabling the Amgen difference. And each day during this COVID-19 disruption, I'm reminded that innovation is the miracle drug.

With that, I'll turn it back over to Bob for some closing remarks.

Robert A. Bradway {BIO 1850760 <GO>}

Before my closing remarks, we'll go to Q&A. So Ian, let's open it up for Q&A and remind our callers of the process that we will follow. Thanks.

Questions And Answers

Operator

(Operator instruction). Our first question is from line of Jay Olson with Oppenheimer. Jay your line is open.

A - Robert A. Bradway {BIO 1850760 <GO>}

Hi, thanks for taking the question and thank you for the work that you're doing to fight the COVID-19 pandemic. I wanted to ask you about the non-GAAP operating margin, it ticked up nicely in the first quarter, and I noticed that you lowered the OpEx expected growth

rate slightly. So I was wondering how do you expect the operating margin to evolve over the course of 2020. And do you expect that higher operating margin to be sustainable in a post COVID-19 world? Thank you.

A - Peter Griffith {BIO 4299061 <GO>}

Jay, thank you for the question. It's a good question. As I indicated, we do project that for the full year, our total OpEx will grow in the high single-digit percentage range. We are confident in our cost structure and our productivity work here at Amgen. So I think our operating margin speaks for itself. And we expect it to be an industry leading cost margin going forward in 2020. And of course, we don't give any guidance beyond 2020 on the margins.

A - Robert A. Bradway {BIO 1850760 <GO>}

Just to state the obvious, Jay. We would have liked to spend more on in Q1, but we were getting a little bit disruptive there as you know, at the end of the quarter. So we will see what it's like for the remaining three quarters of the year.

Operator

And our next question is from line of Tim Anderson with Wolfe Research. Tim, your line is open.

Q - Tim Anderson {BIO 3271630 <GO>}

Thank you very much. My question is something that's probably a thorn in your side, which is the ongoing Enbrel patent challenge, and that's one of the bigger events for the company in 2020, with the Appeals Court ruling. And I'm sure you're confident in your positioning on how that will play out, but these things are never certain.

So I'm wondering if you can just help us describe what [ph] plan B would be in the event that Sandoz actually prevails as your largest product, I'm guessing you have some sort of contingency plan in place. I know it's a low probability event, but any perspective would be helpful.

A - Robert A. Bradway {BIO 1850760 <GO>}

Tim, we're not going to go into details on that obviously. We continue to feel confident in the intellectual property around Enbrel. So let's leave it at that for now. Thanks.

Operator

And our next question is from the line of Chris Raymond with Piper Sandler. Chris, your line is open.

Q - Chris Raymond {BIO 4690861 <GO>}

Hey, thanks. So I know you guys have talked about the collaboration with Adaptive in your antibody program, but just there are a lot of folks I think that are working on similar sort of

purpose-built products, Regeneron, Sanofi and others. I wonder if you could give a little bit more color on what differentiates what you guys are doing and maybe also a little more color on timelines in terms of being in the clinic, et cetera. Thanks.

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Chris. Dave Reese here. I'll take that question. Yeah, so as you -- as you know, there are a number of efforts going forward to develop therapeutic antibodies. What we're trying to do, I think that is potentially unique here is, number one, combined, adaptive capabilities in immunoprofiling with our immunology and particularly our genetics work based out of deCODE.

Our goal also is to really identify a very high quality therapeutic candidate, and it's my belief that there may well be more than one generation of antibody therapeutics entering the clinic. So as we think about this, we want to balance speed of development, which of course is important with generating the highest quality candidate. And as work progresses, we are up and running in the laboratory. But we will provide guidance as -- in terms of clinical timelines as that work unfolds. But that collaboration is actively proceeding right now.

A - Murdo Gordon {BIO 18450783 <GO>}

Chris, maybe I could just add a comment about manufacturing. Obviously, (Technical Issues) protein, we have great expertise and manufacturing of scale. And we think the things we can bring to the party here is our ability to supply a vast number of patients with our antibody.

Operator

And our next question is from line of Geoff Meacham with Bank of America. Geoff, your line is open.

Q - Geoff Meacham {BIO 21252662 <GO>}

Good afternoon, guys. Thanks for the question. I guess one for Bob. You got the first full quarter of Otezla and the mix, and now it looks like you have a pretty competitive growth profile in the industry from a top and bottom line perspective. So I know that's obviously fully expected but does either the growth acceleration or the volatility from COVID affects your attitude towards BD. I'm just thinking about maybe a step-up in the number of deals or maybe increasing appetite for larger ones in this environment. Thank you.

A - Robert A. Bradway {BIO 1850760 <GO>}

I think the environment is pretty fluid still, Geoff. So I wouldn't try to -- I'm not sure I'd like to declare an answer to your question at the moment. But other than to reiterate it, and we think we're in a strong position to talk about our balance sheet and to talk about our desire to allocate capital to our internal innovation as well as external innovation. And as you know we're pretty focused on our strategy and we will look to see whether there are things externally that are going to help us strengthen our chosen areas. But maybe the

other thing I would add is just as a way to reiterate my appreciation to my Amgen colleagues is, we had three very significant and successful integrations in the first quarter.

So it was a priority for us as a company to get off to a good start with Otezla and with BeiGene and with our Japan transaction, and we really feel we've done over the first four months of the year. So, I feel good about that.

Operator

And our next question is from the line of Michael Yee with Jefferies. Michael, your line is open.

Q - Michael Yee {BIO 15077976 <GO>}

Thank you for the question, and congrats on all the progress and appreciate the color during this tough time. My question is for David on AMG 510, of course, you didn't mention you have an update at ASCO. Can you just remind us how to think about colorectal cancer as a monotherapy. I guess what was new there. And then excluding lung and colorectal, there is an update there, can you just remind us what would be the relevance there? And then the timing on the combos, which is -- which are not at ASCO, what do you think about there in timing? I appreciate the update.

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Michael. Yeah, series of questions regarding AMG 510 here. We're continuing to enroll monotherapy patients with colorectal cancer. And as I indicated before, we're going to look at those data, I would say over the coming few months to determine whether we feel there is an appropriate monotherapy path forward in colorectal cancer or whether a combination therapy is most appropriate.

With respect to other non-lung cancer, non-colorectal cancer indications that, we will -- we are -- there are other malignancies such as small percentage of pancreatic cancer, appendiceal cancer and the mutual cancer and we won't be able to provide updates on at ASCO on some of those tumors and response data.

And then finally in terms of the combination therapy trial, these are some of the trials that we -- some of them we paused, because they were either just initiating or had just initiated. We're getting ready to ramp back up. So I would expect first data at the early or [ph] later this year or perhaps the very first part of next year on those, but we're confident that we're not experiencing significant disruptions across the program in totality and we're happy. We're quite happy actually with its progress.

Operator

And our next question is from the line of Terence Flynn with Goldman Sachs. Terence, your line is open.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question. Maybe a follow-up from me on AMG 510. I know you guys have guided to the Phase 2 lung cancer data in the middle part of this year. Just wondering now as we're closer to the data, if you could share any perspective on what you view as the efficacy bar here. Is CYRAMZA the right bar? or should we think about higher efficacy here given it's a targeted drug. Thank you.

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Terence. This is Dave. Yeah, in terms of the timing of the date, I'd point out that what we've indicated is that we want at least six months of response data on all patients and given that the last patients were enrolled towards the end of last year, you know that it takes a month or two typically for responses to develop. You can see that, that pushes it into the second half of the year in terms of when we expect the data readout. We're absolutely on track and we're not experiencing any -- I would say substantial hiccups in the Phase 2 monotherapy study.

We do want robust duration of response and progression-free survival data as part of that package and I think those endpoints along with response rate, to address the second part of your question will be an important part of the package in this Phase 2 monotherapy study.

Operator

And our next question is from line of Yaron Werber with Cowen. Yaron, your line is open.

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thanks for taking my question as well. And I have an AMG 510 question as well. The Phase 3, David, the study obviously is fairly sizable, it's of 650 patients head-to-head against docetaxel, and I think it kind of drew some questions as to why was that docetaxel really used as the control and not CYRAMZA in combo and maybe give us a little bit of sense, why is the study so sizable? Is it -- should we read into your expectation on OR? Or is it really about trying to power for survival? Thank you.

A - David M. Reese {BIO 19782623 <GO>}

Yeah. Thanks Yaron for the question. In terms of the comparator arm, this was -- this choice was based on what remains one of the standards of care, docetaxel around the world, discussions with regulatory authorities and investigators. And we feel that that's an appropriate comparator here. The sample size calculations were driven by the desire to be able to robustly test for overall survival. And so the second part of your statement there is correct, that this was powered on overall survival.

Operator

And our next question is from line of Matthew Harrison with Morgan Stanley, Matthew, your line is open.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good evening. Thanks for taking the question. I just wanted to ask a question around stocking dynamics for the quarter. I know you called out a couple of one-time items and what you thought was the benefit from COVID. Could you maybe just put that in context? Obviously, normally in the first quarter, you see a lot of destocking across the product lines.

Did you not see that typical destocking? And so could that be also a potential benefit that's going to come out through the year? Maybe you could just comment on that. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, hi Matthew, it's Murdo. Yeah, as I mentioned, we saw about $100 million of stocking inventory build, I should say in the first quarter which happened across markets, and the only other element that I would maybe compare and contrast to some other companies that are reporting our business given that it's predominantly specialty biologics. I know a fair in line of physician administration products didn't necessarily have the same extent of early prescription pills and patient 90-day pills that would have been an additional pull forward for some other companies as they reported they blend that dynamic with and customer and wholesale inventory build.

So what the $100 million refers to end customer and wholesaler inventory specifically on products like Otezla we may have had some pull-forward from early pills and maybe 90-day scripts and we'll just have to wait and see how that works through in Q2.

Operator

And our next question is from the line of Robyn Karnauskas with SunTrust Robinson. Robyn, your line is open.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi guys. Thank you so much, and great work on running the business in this time. So can I take a broader step back question, I know we've been focused on a lot of specific questions. You guys have had a lot of experience, intended to financial crisis and people switching from a commercial payer to a Medicare or government payer. Help us think about how you manage that? How you get people quickly switch? And how you manage the impact of that?

And then secondly, for Telemedicine, how comfortable are prescribers writing to Evenity? And how do you think that Telemedicine really impact your business? I know that's a new one for you. Thank you.

A - Robert A. Bradway {BIO 1850760 <GO>}

Robyn, before Murdo answers, let me make sure, we heard that you said how comfortable are we writing -- our doctors writing, did you say Evenity's prescriptions on Telemedicine?

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Yeah, yeah. The Telemedicine aspect is new for all of us. We're trying to understand how that will impact businesses and obviously your many products that could be prescribed of Telemedicine. So those are two aspects of -- it would be great.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, Robyn and if I could just clarify further on the first part of your question. Your -- is your question related to opening up government access like we've done over the last little while or is it the transition of people potentially from commercial to a government benefit because of COVID-19?

Q - Robyn Karnauskas {BIO 15238701 <GO>}

It's really transition. So what a lot of people are asking is, what if we transition given a potential, a lot of people at work that have transitioned to a government-based plan. You've been through this before. So you're one of the few companies that can probably tell us how you manage that? And how you run the business and you think the impact might be?

A - Murdo Gordon {BIO 18450783 <GO>}

Okay. No, that's helpful, thanks for the clarification. So let's start with that topic. On the -- first off, our overall Medicaid portion of our business right now is quite low, it's less than 10% of our total revenue. And the majority of our products beyond that are reimbursed through Medicare Part B and D with about 50% of our total business being reimbursed through commercial. So it's that commercial piece as you rightly pointed out that is likely or possible -- a portion of that is likely to transition to a government channel.

Now the thing that's harder to predict is at what rate. So as people who become unemployed and an important distinction is furloughed, they retain benefits for a period of time if they opt into COBRA, and furloughed employees are often still on their self-insured company employee plan, sponsor plan. So there is a time lag that's going to occur before people transition to either a state exchange or a Medicaid benefit. So I think the impact could be a delayed one, more like towards the end of this year and into 2021. And of course trying to pin down the actual numbers of the Americans that are going to end up on unemployment benefits, it's hard to tag right now.

So those are the two things, it's that total bolus and the rate of change. I've heard some commentary and read some things that would appear to indicate people expect that earlier. Our perspective is that some of these patients and people will transition over time and it will more likely be a delayed '20 effect into 2021.

On Telemedicine, I would just say that there is a -- there is a variety of maturity of how Telemedicine is used by therapeutic area. If you think about mental health, and I would argue even in neurology, Telemedicine is already used quite extensively even pre-COVID. And I would say that the uptake for Telemedicine and evaluating someone like a migraine patient is going to be relatively straightforward as it would be perhaps for a dermatology

patient. So in the case of neurology, migraine would be Aimovig, and then for dermatology would be Otezla.

You mentioned Evenity. Of course, Evenity is primarily prescribed post-fracture. So patients are likely to be in a clinic or hospital setting. And so the ability for the physician to evaluate the patient and prescribe Evenity is probably pretty straightforward related to that acute event. But we're watching it closely. We actually because of Aimovig and other brands that -- where Telemedicine was already being used fairly extensively, we've had some experience here that goes back over a year. And we've been scaling our experience there now. So I think Amgen will be on the front foot when it comes to building our capabilities in that area.

Operator

And our next question is from the line of Ronny Gal with Bernstein. Ronny, your line is open.

Q - Ronny Gal {BIO 15022045 <GO>}

Good evening, and let me add my thanks to Jay for the all the work you're doing on COVID-19. Two, if I may. First for David. The PD-1 and you have expanded that vertical a couple of times. You started about 40 patients, now you have about 270 patients. What -- given that you're originally a little bit skeptical at Amgen about PD-1, is this just looking for ways to leverage the same protocol to do more. What does that mean about your ability to bring that product to market and timing?

And then to Murdo, you've done fabulously well with the biosimilars. It might contribute about $320 million this quarter. Now you have sides that's coming into the United States. They've taken a bit more extra price decreases, what is that -- what's your expectation for the rest of the year and if you could also mention what you guys are doing with your Remicade biosimilar kind of an interesting product?

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Ron. This is Dave. I'll start with the PD-1 question for AMG 404. We continue to develop AMG 404 primarily as a combination partner for our pipeline agents. This is a Phase 1 umbrella study and we added cohorts to study additional indications where the tumors in question have well described PD-1 sensitivity. That will limit the need, we hope for single-arm data in future trials and ultimately, we think we will probably need on the order of 200 give or take monotherapy patients to support the standard safety package for AMG 404. So all of that put together, the expansion of the Phase 1 trial allowed us an efficient way to generate appropriate data.

A - Murdo Gordon {BIO 18450783 <GO>}

Yes, and when it comes to our biosimilars business, we are pleased with the run rate over $300 million in the quarter. I would say, I would attribute our success first and foremost to Amgen's reputation as a high quality biologics manufacturer. I think that is something that differentiates us and is perceived well by our customers. Our experience in Europe was a

very positive one. We applied those lessons learned to our US launches of the two oncology biosimilars. And I think it shows you that the biosimilars market is functioning well in the United States. I would also say that the biosimilar business model for Amgen is very much integrated with our innovative products.

So the same people who are defending Neulasta, the same account managers who are defending Neulasta day-in and day-out and making sure that the benefit of OnPro is understood by our customers are the same people who are establishing the uptake curve for MVASI and KANJINTI. So those account relationships that we've cultivated over many, many years in oncology have been extremely valuable. And our relationships at the payer provider level I think have helped us extend that trajectory nicely.

I would also say that our patient services are exemplary, and we have the very same patient services that we have for a product like KYPROLIS or XGEVA we apply to our biosimilars business as well. And then you mentioned Avsola, which is our Remicade biosimilar. We do intend to launch that this year, and that product will help strengthen what is already a strong immunotherapy portfolio for us, and will help us broaden that customer perspective. And again that product will be integrated with our innovative autoimmune portfolio.

A - Arvind Sood {BIO 4246286 <GO>}

Ian, let's take the next question. And it's getting -- as it's getting late on the East Coast, if I can just ask everybody to please limit yourself to one question. Ian, let's go onto the next one.

Operator

Certainly. Our next one is from the line of Evan Seigerman with Credit Suisse. Evan, your line is open.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi guys. Thank you so much for taking the question. And kind of a follow-up from what you were just talking about, Murdo. So how has the pandemic impacted the uptick of biosimilars? Have you seen an acceleration in adoption to save costs? Or if centers really delayed uptake given potentially overwhelmed system? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

So it's a bit early to tell. So take my comments with a very few weeks of experience here, I would say, so far we have not seen a negative effect on our uptake, if anything, we're seeing a steepening of our uptake curve. The one thing I will say that we haven't yet assessed that could happen is the total cycles of bevacizumab or the total cycles of trastuzumab could be impacted. So from a share of molecule perspective, we're very pleased. What we're watching is the total number of infusions of each of the molecules going forward.

Operator

And our next question is from the line of Dane Leone with Raymond James. Dane?

Q - Dane Leone {BIO 15203956 <GO>}

Hi. Thank you for taking the questions and the update. I just wanted to ask a business development question and I'll skip the one here. When you're thinking about ramping up your efforts of KRAS, obviously the initial data set is great for how you're thinking about the target oncology space. Thinking about that and then also thinking about the bolt-on with Otezla that you did to start broadening out, how you think about immunology. Where do you want to go in those respective areas from a biz dev perspective? I mean there is a lot of room you guys still have to work with especially in targeted oncology? Should we be expecting more bolt-on acquisitions within these two areas over the course of 2020?

A - Robert A. Bradway {BIO 1850760 <GO>}

I don't know about the course of 2020, Dane. Those are two areas of keen interest for us for sure, oncology and inflammation. And we'll will continue to look for attractive innovative assets that we think we can add value to. The trick is always to be able to license or acquire molecules at a price that leaves return for our shareholders. And we're pretty comprehensive in the way we assess the marketplace and we will continue to keep an active watch and see whether there are some things that might be a good fit.

Q - Dane Leone {BIO 15203956 <GO>}

Great, thanks.

Operator

And our next question is from the line of Umer Raffat with Evercore ISI. Umer, your line is open. Umer, you may have us on mute.

A - Robert A. Bradway {BIO 1850760 <GO>}

Let's come back to him.

Operator

And moving on to the next question is from Alethia Young with Cantor Fitzgerald. Alethia, your line is open.

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys, thanks for taking my question, and congrats on all the progress. I guess I just wanted to know when you think about the Otezla and some of the benefit you're seeing with the orals, maybe in the light of COVID, do you think that might be a sustainable trend. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, Alethia, just want to clarify. It's Murdo here. You're talking about the natural demand, you're not talking about clinical trial activity with Otezla correct?

Q - Alethia Young {BIO 17451976 <GO>}

No, not clinical trial, commercial activity, please.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, okay. Yeah, we're -- look, we continue to watch the weekly trends. We're listening to what our customers are telling us and we definitely think that we've got a little bit of buffer supporting Otezla right now because it is a convenient oral option. It's got great market access coverage, it's affordable. We are obviously also we mentioned at the end of last year that we were putting in additional primary care effort to broaden that promotional effort behind Otezla and I think that's also helping.

So we're feeling good about it and I think just it's the ideal kind of product for a time like this, where a lot of patients are concerned about visiting a healthcare protection.

Operator

And our next question is from the line of Geoffrey Porges with SVB Leerink. Geoffrey, your line is open.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much. To follow-up, Murdo another question, you highlighted some of the softness that you're seeing in March and then continuing into April for some of the office administered injectables. Could you give us a sense of which products you think most likely will be most significantly affected? I think you particularly highlighted the Prolia visits that might be down as much as 50% to those relevant specialties. Is that the sort of effect that we should be expecting portfolio in Q2?

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, I think what -- thank you, Geoff. I think what I mentioned was that patient visits were down 50%. So Prolia and -- were maybe not as impacted yet on Evenity are definitely the products that will, that we are seeing most impact in our portfolio. If you think about the physician administered products for Amgen in three buckets, we have our bone business, we have our nephrology business, we have our oncology business. Bone is by far the business that is being impacted the most. Obviously is partly to do with the agent vulnerability of patients and we're spending a lot of time working on alternate sites of care, improving continuity of care, setting up mobile programs where nurses can visit patients homes and administer.

And we're working -- we continue to work with the administration, CMS policy advocates to try and improve the buy and bill access to that home injection channel as well. Nephrology is holding up well obviously in end-stage renal disease, these patients have

to have their dialysis as its life-sustaining. So, those volumes are holding up well and the providers there have been very good at collaborating and providing safe isolated sites of care for patients. And then oncology, it's down, but not nearly as much as the bone. So that gives you a relative order of understanding as how we're seeing it.

Operator

And our next question is from line of Cory Kasimov with JPMorgan. Cory your line is open.

Q - Cory Kasimov {BIO 3009346 <GO>}

Great. Good evening, guys, thanks for taking my question. Given the importance of this growth portfolio to the overall business, wanted to better understand the underlying dynamics for Aimovig. We look at I mean despite the leading share position and an increase in paid prescriptions sales, it's seemingly fallen short of expectations for the last few quarters, is this just a function of lower net price with the broader access or is there something else going on that we're all missing?

A - Arvind Sood {BIO 4246286 <GO>}

Yeah. Thanks, Corey. Look, we're very pleased with Aimovig's share performance and we did have to do quite a bit of work over the course of the year to get to that 90% paid level. And now we have 93% of covered lives. So we're pretty pleased about that basis. I think what we're counting on for growth going forward because we expect price to stabilize throughout the course of the balance of the year is we're counting on unlocking additional patient volume. We've got over 4 million potential CGRP patient candidates out their, physicians tend to persist with older oral products and aren't yet adopting CGRP products at the rate that we think that they could and should be to help ease the suffering of chronic migraine sufferer. So that's where we're focused, we're focused on unlocking the future potential volume, now that these products and particularly Aimovig has a very affordable access coverage in the market.

Operator

And it appears that we have Umer Raffat from Evercore ISI back on. Umer, your line is open.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, I just learned how to unmute myself. So thank you so much. Arvind, one question for you from me. I think it will be very helpful for investors to understand if you're optimistic on the durability of response of care at monotherapy, and if you're starting to develop a view whether a MEK or a PD1 is a better combination partner? Thank you so much.

A - Arvind Sood {BIO 4246286 <GO>}

Thank you. Omer for the question. Yeah, I mean I think duration of response is one of the critical questions and that's why I indicated we're building the Phase 2 trial. I think is going to give us the definitive answer there, that will and we wish to have enough follow-up to very robustly address both duration of response and progression-free survival. In

terms of the combination, I think it's perhaps a little too early to pick favorites. We are looking at a number of combinations, which is typical for oncology programs, all of those are based on an underlying biological rationale. And as I indicated, we'll be generating data in that program in combinations over the course of this year.

Operator

And next we have a question line of Michael Schmidt with Guggenheim. Michael, your line is open.

Q - Michael Schmidt {BIO 3870043 <GO>}

Hey, guys, good evening and thanks for taking my question. I had a high-level question on the biosimilar business which has been going really well for Amgen. I'm just wondering as we see sort of the biosimilar market mature longer term and as we see potentially more product launch within these markets, I guess, what is your view on the long-term price erosion relative to brand and how should we think about potentially of slower relative to the manufacturing and development costs in the biosimilar area? Thank you.

A - Robert A. Bradway {BIO 1850760 <GO>}

Yeah. Thanks, Michael. The one thing I mentioned earlier in response to the question on biosimilar was the Amgen experience in knowing how to make biologics at scale in a very efficient way. So we have really good margins on this business. And I think going by our experience in Europe where I would argue that the price degradation has probably been faster than it will be in the US even with multiple competitors, we've been able to compete effectively for volume and we've been able to retain a very profitable business there.

We obviously don't have a lot of analogs in the US to understand the rate of change. So I'm going to hold back from speculating on what the future will hold. But there are clear things here that the more competitors you have compressed in the early phase of a biosimilar launch pattern, the more likely there is to be some precipitous price erosion. We're fortunate that we were early in the US with both MVASI and KANJINTI and able to establish a very strong foothold in the market. I also repeat it, I said it earlier, but I do think that the biosimilar market is alive and well in the US and functioning as you would hope free markets would.

Operator

And our next question is from the line of Carter Gould with Barclays. Carter, your line is open.

Q - Carter Gould {BIO 21330584 <GO>}

Thanks for fitting me and I guess may be a bigger picture question around sort of the lasting impact of Covid when you guys think around either shift to manufacturing strategy, location, bigger picture questions on footprint. And I guess, as well as commercialization

models, I guess just really kind of bigger picture question when we return to normal will that look different to sort of the sort of your infrastructure and business model is how you had set it up historically? Thank you.

A - Arvind Sood {BIO 4246286 <GO>}

Yeah, that's a really interesting question. Carter and one that I think we'll get a lot of attention once things settle down a little bit, it's still awfully fluid to be trying to predict how the experience of COVID-19 will affect our industry, our business model. But we'd be happy to engage with you on that topic at greater lines again when the dust is settled a little bit. But fundamentally for us, our supply chain is in great shape. We unlike some of our peers in the industry predominantly manufacture in the US obviously (technical difficulty) the people who work for us they are US citizens. And so we have the benefit of the vast majority, nearly all of our manufacturing is done in the US. So that supply chain question is a little bit less relevant for us than some of our industry peers.

But I do think that this isn't going to be the last viral challenge that we face as a society. And I think we'll all be trying to improve our business continuity planning and thinking when we come out of this to make sure that we're in a stronger position as possible to avoid interruptions from events like this. But I think there will be a lot of learning across the whole economy including the biotech economy. So look forward to talking you about that at the right time.

Operator

And next we have a question from the line of Mohit Bansal with Citi. Mohit, your line is open.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thanks for taking my question and congrats on all the progress. I have a quick question regarding your IL-2 mutein program. What is your level level of excitement around this program, seems like you have two fully enrolled trials at this point. Should we expect to see any data from this program later this year? Thank you.

A - David M. Reese {BIO 19782623 <GO>}

Thanks, Mohit. Dave here. Yes, so we remain keenly interested in the 595 IL-2 mutein we're enrolling trials going forward and would expect data over the course of the year or perhaps early next year. Some of those trials we did temporarily pause because of the reluctance of investigators to start patients on the new immunomodulatory agents in the course of the epidemic. But we remain quite interested in that program and we'll provide guidance as to when we're going to get data readouts as we move forward.

Operator

And next we have a question from the line of Kennen MacKay with RBC Capital Markets. Kennen your line is open.

Q - Kennen MacKay {BIO 18821382 <GO>}

Hi, thanks for taking the question, maybe for Peter or Bob, actually even love to hear Dr perspective. I was wondering, where are you seeing the most opportunity for M&A right now and really where your focus there. And Dave I had hoped to include you in that question really just to get your perspective on where some of the most interesting biology and chemistry is taking place now and what Bob has referred to so eloquently as the golden age of biotechnology. Thanks so much.

A - Robert A. Bradway {BIO 1850760 <GO>}

Well Dave since I've talked a little bit about M&A and Business Development already on the call. Why don't we let you take a crack at this. So what areas what mechanisms and most intriguing to you in your R&D colleagues to mode.

Q - Kennen MacKay {BIO 18821382 <GO>}

Yeah, I think it is a golden age and I would approach it from two perspectives. There are new platforms and our Head of Research rate to Shea's published very a great article in nature a week or to ago. I'd encourage all of you to read about what we're calling induced proximity platform. This is a new suite of technologies that we think and open up much of the unfavorable space. So that sort of business development remains of great interest to us.

And then as we've said before, I think there is a ferment of activity across the therapeutic areas of great interest to us, and that will continue to be a focus going forward.

Operator

And next we have a question from the line of Salim Syed with Mizuho. Salim your line is open.

Q - Salim Syed {BIO 16887281 <GO>}

Great, thanks so much for the question, guys. Bob. Maybe just one for you and is a high level one given your discussions with folks in Washington, obviously the rhetoric in biotech and pharma as well has been pretty negative over the last few years, especially around drug pricing et cetera. And I'm wondering with given this COVID-19, has that changed the rhetoric at all in your view. And is there anything sustainably positive that can carry on post COVID in terms of rhetoric coming out of Washington, in your view. Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Well, I think everybody recognizes that we're going to need science and innovation to lead us out of this challenge that we find ourselves in globally. So importance of innovation and a little bit of humility perhaps on all camps about how hard it is to have the right innovation available for the world at the right time. So the good news is that the government, the innovators, academia, everybody working together at a speed and a scale that I've never seen in my career.

So I think that's a good sign and hopefully we'll be able to look back on this one day and say that it worked. We've got a special ecosystem, in particular in this country and hopefully we'll be able to look back and say when we faced the biggest challenge of our lifetimes the industry came through and delivered what we needed. And if we're able to do that I think it inevitably will help remind everybody that we haven't generated all the innovation we need, as a society, there is still lots of areas of unmet medical need.

And again, the more we can do to address it the better. But the question of drug pricing is not going to go away, but hopefully there'll be some respect for how profoundly important innovation is.

Q - Salim Syed {BIO 16887281 <GO>}

And let's take one last question, if there is a quick one, after which I'll ask Bob to make some concluding comments.

Operator

Very well. Our final question is line of Jim Birchenough with Wells Fargo Securities. Jim your line is open.

Q - Jim Birchenough {BIO 5068439 <GO>}

Good afternoon, it's (inaudible) for Jim and thanks Sophie much for squeezing us in, you had mentioned earlier in your prepared comments about Otezla, the trial of Otezla in Covid. Can you just elaborate on that and is that in the acute setting or perhaps is there an opportunity for patients that have ongoing organ dysfunction, after they leave the hospital maybe due to inflammation. Thanks.

A - David M. Reese {BIO 19782623 <GO>}

Thanks. James is Dave. Yeah, we think it's actually -- there will be utility in studying Otezla in a variety of settings ranging from for example hospitalized patients but those that are not yet in the ICU to attempt to prevent progression to more serious disease, as well as, those with more serious disease. And so again we're in active discussions or have committed to platform trials, the one real guiding principle we have here is that we want these to be rigorous studies to provide the highest quality answers.

Q - Jim Birchenough {BIO 5068439 <GO>}

Okay. Let me just wrap up recognizing that it is on pushing on 7 o'clock on the East Coast. Again, let me reiterate our appreciation for you joining the call. I hope what you take away from the call is that we delivered a solid quarter one, we feel we're executing business well. Our objective will be to remain an effective steward of the business through the short-term and we want to be a leading corporate through this challenging period as well.

And we will remain focused on delivering long-term growth by advancing innovation in those areas that you're familiar with at Amgen. So thank you all keep safe. Look forward to catching up with you on the next quarterly call.

A - Arvind Sood {BIO 4246286 <GO>}

Thanks everybody. Client [ph] from the IR team will be around for some time. So feel free to reach out to us. Thanks again.

Operator

Ladies and gentlemen, we thank you greatly for joining us for Amgen's First Quarter 2020 Financial Results Conference Call. This does conclude the call. You may now disconnect