Q2 2020 Earnings Call

Company Participants

- Arvind Sood, Vice President of Investor Relations
- Bob Bradway, Chief Executive Officer
- David Reese, EVP and Head of R&D
- Murdo Gordon, Executive Vice President, Global Commercial Operations
- Peter Griffith, Executive Vice President and Chief Financial Officer

Other Participants

- Alethia Young, Analyst
- Analyst
- Carter Gould, Analyst
- Chris Raymond, Analyst
- Cory Kasimov, Analyst
- Dane Leone, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, 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
- Umer Raffat, Analyst
- Yaron Werber, Analyst

Presentation

Operator

My name is Erika. And I will be your conference facilitator today for Amgen's Second 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 speakers' prepared remarks. In order to ensure that everyone has a

chance to participate, we would like to request that you limit yourself to asking one question during the Q&A session. (Operator Instructions).

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

Arvind Sood {BIO 4246286 <GO>}

Thank you, Erika. Good afternoon everybody and welcome to our Q2 call. This call is going to feel a bit different than our previous earnings calls, because we are making some changes. As a matter of fact, in response to feedback from many of you that are prepared comments are too long, we are going to limit our prepared comments to around 20 minutes. We'll also limit the duration of the call to one hour. Now that doesn't mean that we are scaling back on disclosure. You'll notice, our press release has been enriched to provide explanations that were previously included in our prepared comments. We think this approach will free up time for Q&A. But to make sure that everyone has an opportunity to ask a question, we are still going to request that you stick to asking only one question.

The slides have been posted, but will not match up to our -- to our prepared comments, given the gravity. Just a quick reminder that we'll use non-GAAP financial measures in our presentation and some of the statements will be forward-looking. Our 10-K and other filings identify factors that could cause our actual results to differ materially.

So with that, I would like to turn the call over to Bob.

Bob Bradway {BIO 1850760 <GO>}

Okay. Thank you, Arvind and thank you everyone for joining today's call. As we look back at the first six months of the year and project forward to the second half, I'm very aware that we're still in the midst of a really significant public health challenge and deep economic downturn. In that context, our results, which includes 6% revenues growth and driven by 13% volume growth, these are strong results and they reflect the resilience of our people, strength of our operating systems and our success in continuing to supply every patient, every time with the medicines they need. We remain confident in the long-term growth potential of innovative medicines like Otezla, Repatha, Prolia, Evenity and Aimovig as well as our expanding portfolio of marketed biosimilars.

Even in the second quarter when we felt the depths of the pandemic, we delivered. Murdo will have more to say about that later and also about how we're navigating commercially through what remains a very dynamic week-by-week situation, especially in the US and other parts of the world. As we find new ways to meet the needs of current patients, we're excited about the potential of the medicines in our pipeline to enable us to serve many more patients in the future. We expect readouts in the second half of the year for sotorasib which of course is our AMG 510 in non-small cell lung cancer, tezepelumab in severe asthma and omecamtiv mecarbil in heart failure. Encouragingly, we've restarted many of the earlier stage clinical trials that we put on hold due to COVID-

19 at the end of the first quarter and beginning of the second. We're also exploring Otezla as a potential treatment for patients with COVID-19, you'll hear Dave say more about that in a moment.

In an environment of ongoing uncertainty, our strong financial position provides us with competitive flexibility and as Peter will discuss in a moment, our financial strength enables us to continue to invest in long-term growth of our business internally and externally while also returning capital to our shareholders. We demonstrated tight control of expenses in the first half of the year. With health care systems operating more normally now, we expect increased expenses including for activities that were curtailed in parts of the first and second quarters. We're in a strong position heading into the second half of the year. I just want to take a moment to thank the Amgen staff around the world, for their steadfast support of our mission. I also want to express our profound appreciation for all our partners in the health care community for the support that they have shown to the patients that we're trying to serve together.

I look forward to answering your questions later in our call. But right now, let me turn it over to Murdo.

Murdo Gordon {BIO 18450783 <GO>}

Thank you, Bob. We continue to focus on growing volume across our diverse portfolio, while expanding our business geographically. Despite the challenges introduced by COVID-19, we executed effectively in Q2, growing year-over-year global revenues by 6%, with 13% from volume. Our US business grew 7% with 14% from volume and our ex-US business grew volume by 11% posting nearly $1.5 billion in sales. As expected, during Q2 we experienced varying degrees of impact from COVID-19 across our portfolio. Exiting Q1 and through the first part of Q2, we saw interruptions to physician-patient interactions that led to delays in diagnosis and treatment. During the quarter, certain professional medical societies such as NCCN and others introduced treatment guidelines to assist in decision making during the pandemic. Implementation of those guidelines had varying degrees of impact on prescribing for some of our products.

For example, Prolia which addresses an older, more vulnerable patient population and requires in-office administration, experienced greater negative impact early in the quarter. In the case of Nplate, we saw transition to competing oral alternatives as patients to limit their visits to doctors' offices. XGEVA was also impacted by fewer patient visits and NCCN's recent recommendation to prioritize primary cancer treatments over bone targeting agents. In contrast, Neulasta OnPro benefited during the quarter as it provides a convenient solution to help patients avoid additional visits to their site of care post chemotherapy. As physicians and patients learned more about ways to reduce the risk of COVID infections and as local conditions improved in many countries and states, we saw some recovery during the second half of the quarter.

Let me just spend a few minutes discussing steps we've taken to provide continuity of care for patients during the pandemic. In bone health, with Prolia, we implemented programs to address issues such as identifying alternate sites of care, mobile nurse administered injections and prescription fills at specialty and retail pharmacies. Given

Prolia's 6 month dosing schedule, we're keeping a close eye on further disruptions for the balance of 2020 and into 2021. With Evenity, we continue to see this product as a complementary growth opportunity with its unique bone building profile and usage in high risk, post fracture patients.

Within cardiovascular, total Repatha prescriptions grew quarter-over-quarter, in part because of access and affordability improvements. We experienced the reduction in new prescriptions in April due to COVID-19, that saw improvements later in the quarter. While we're pleased with the new patient growth in Repatha, we're disappointed by CVS's decision to remove Repatha from it's national formulary as of July 1st, which will negatively impact total prescription growth in the third quarter. However, even with this formulary change, we continue to have segment leading coverage in the PCSK9 class with 75% of lives covered. And given the significant unmet medical need in treating high risk cardiovascular patients, we remain very confident in our ability to grow Repatha.

Moving to inflammation portfolio, Otezla TRx growth remained strong in the quarter. Otezla grew in new to brand prescriptions and maintained a leading NBRx share, despite a decline in NBRx volume for the overall psoriasis market due to COVID-19. Otezla has proved to be a convenient option for patients due in part to its oral administration and lack of required lab monitoring. Otezla performance is tracking ahead of our original expectations in part due to exceptional integration. With Enbrel, the pace of growth in the RA market slowed this quarter, causing a greater decline in overall market unit volume than past quarters. Consistent with prior results, we anticipate volume and net price trends for Enbrel to continue through 2020. Enbrel is a cornerstone of our inflammation therapeutic area behind which we continue to invest, especially given the reaffirmation of Enbrel's intellectual property. We also continue to find promotional synergies across our inflammation portfolio of Otezla, Enbrel, Amgevita and recently launched Avsola, our biosimilar to infliximab.

Moving to our biosimilar products, they generated $357 million in sales in Q2. As a reminder, these products are promoted by the same teams as our branded products making for an efficient commercial model. As we talk with customers they increasingly recognize the value proposition of Amgen's biosimilars given their high quality, reliable supply and cost savings they provide. In late Q1 and early Q2, social distancing measures also led to medical distancing. Looking ahead, we see a different pattern in the second half of 2020. While social distancing remains a critical behavior to minimize the risk of COVID infection, we see providers and payers encouraging patients to stay in touch with their doctors and to continue to seek medical care, either by telemedicine or through in person appointments. While certain parts of the US and other countries have observed an increase in COVID-19 infections, our conversation with customers indicates that they are better prepared to handle spikes in cases, as compared to four months ago. We continue to be vigilant and watch the spread of the virus as additional patient care disruptions could occur.

I am very appreciative of the hard work of Amgen employees through these challenging times. We remain focused on ensuring continuity of care for patients, including executing on investments in the second half of 2020 to drive growth of our marketed products, continue our geographic expansion and prepare for potential new product launches.

And with that, I'll turn it over to Dave Reese.

David Reese {BIO 19782623 <GO>}

Thanks Murdo. Good afternoon everyone. I'll begin with an update on our clinical trial execution, as we look forward to important data sets in the second half of 2020. Enrollment in our clinical studies has rebounded in recent weeks and we have resumed enrollment to most of the studies that we paused due to COVID-19. Going forward, we expect to make additional investments in the second half of the year as enrollment increases in our clinical studies and work in our research labs approaches pre-COVID levels. We are also putting in place strategies to mitigate the uncertainties in clinical research created by any potential regional outbreaks of COVID-19.

Importantly, our pivotal studies for sotorasib, tezepelumab and omecamtiv mecarbil remain on track and we continue to expect high quality data sets from these trials later in the year. We have also initiated new trials including the sotorasib Phase III lung cancer study and several sotorasib Phase I combination cohorts. Finally, we continue to make progress with our half-life extended BiTE programs and as previously communicated anticipate sharing initial data for AMG 701 targeting BCMA, AMG 757 targeting DLL3 at meetings in the second half of 2020. Initial data from the AMG 160 program targeting prostate specific membrane antigen or PSMA will be presented at the virtual ESMO Meeting in September. We will be presenting an update on our sotorasib Phase I non-small cell lung cancer cohort including initial biomarker data at ESMO as well.

In our mid-stage pipeline, based on encouraging Phase I data in patients with elevated Lp(a) AMG 890, our short interfering RNA or SI RNA has now entered Phase II development. In inflammation, with AstraZeneca, we made a strategic decision to discontinue the Phase II trial of tezepelumab in atopic dermatitis after reviewing the 16-week top-line data. No new safety signals were observed and this decision has no impact on the ongoing studies in asthma and COPD.

Let me conclude by saying a few words about our efforts against COVID-19. We are investigating Otezla in multiple platform trials as a potential immunomodulatory treatment in patients hospitalized with viral infection and the first of these studies should be announced in the coming days. In our pursuit -- pursuit of therapeutic antibodies, we are taking an orthogonal approach by focusing our efforts on the development of antibodies against targets other than the SARS-CoV-2 receptor binding domain, the RBD, the goal here being to develop an antibody complementary to the first generation therapies. I'll be happy to discuss these or any other topics further in the Q&A session.

Before I hand off to Peter, I'd like to thank all of our staff for continuing to deliver for patients during a difficult and important time. Peter?

Peter Griffith {BIO 4299061 <GO>}

Thank you, Dave. Good afternoon. I hope everyone is healthy and safe. Let's turn to the business. Our confidence in the growth potential of our business remains strong. This is

exemplified by our solid execution in the second quarter. You will find our detailed Q2 results in the press release. Let me provide some summary comments on how I view the quarter. On a year-over-year basis, we delivered 6% revenue growth and 7% non-GAAP EPS growth during the second quarter, in a challenging environment. We are particularly pleased with revenue growth driven largely by unit volume increases in Otezla, biosimilars, Evenity and Repatha. Operating expenses increased 2% year-over-year as we continue to invest to drive growth, while recognizing COVID-19 related expense slowdowns. These slowdowns were pronounced in the second quarter, including a slowing of clinical trial activity. However, we exited the second quarter with an acceleration of activity as most trials were initiating clinical sites and enrolling patients. Overall, we expect to increase investment in the second half of the year.

We have a strong balance sheet and cash position. This position was further strengthened in the second quarter with free cash flow of $2.7 billion and our debt issuance of $4 billion at attractive rates. Our capital allocation principles and plans remain unchanged and uninterrupted. Investment in both internal and external innovation remains the cornerstone of our long-term growth. Earlier this month, we announced an additional $421 million of investment in BeiGene reflecting our confidence in our ongoing collaboration with them. Further underscoring our confidence in generating free cash flow, we continue to return capital to shareholders through both growing dividends and opportunistic share repurchases.

Let me now share some thoughts on our outlook going forward. We experienced a negative impact from COVID-19 on our sales early in the second quarter but began to see a general recovery in the second half of the quarter. The more recent resurgence of COVID-19 infections in parts of the United States and certain other countries create significant uncertainty, both in the magnitude and the specific timing of the recovery. This could cause fluctuation in our quarterly revenues and earnings over the duration of the pandemic. Despite this uncertainty, we are reaffirming our revenue guidance of $25.0 billion to $25.6 billion. We are updating our non-GAAP earnings per share guidance to $15.10 to $15.75 versus prior guidance of $14.85 to $15.60, this reflects our confidence in our underlying business continuing to deliver for patients. For the full year, we continue to expect total non-GAAP operating expenses to grow in the high single-digit percentage range year-over-year with a breakdown as follows.

Cost of sales as a percent of product sales to be generally consistent with 2019. In R&D, we plan to increase investments in the second half of the year, including in our innovative pipeline and as clinical trial and lab activity accelerate. SG&A spend is projected to increase primarily due to Otezla, geographic expansion and launch preparations for our late-stage pipeline. I would reemphasize, that we expect operating expenses to meaningfully increase in the second half of the year as the recovery continues. This increase reflects, first, investments in our pipeline as well as launch preparation and secondly, the typical historical spend pattern for our business. We anticipate non-GAAP other income and expense to be a net expense of about $1.4 billion. We continue to expect share repurchases at an amount at the lower end of our previously disclosed range of $3 billion to $5 billion. And I too would like to thank all of my colleagues around the world for their commitment to the Amgen difference to patients.

This concludes the financial update. I'll turn it back to Bob to get to our Q&A.

Bob Bradway {BIO 1850760 <GO>}

Okay. Erica, can you remind our callers of the procedures for asking their questions?

Questions And Answers

Operator

(Operator Instructions). And your first question is from Evan Seigerman with Credit Suisse.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi guys. Thank you so much for taking the questions. And I appreciate the new format of the call. So, I'm looking at -- I'm curious on the tezepelumab Phase II Atopic Dermatitis data, did you see any signal in this trial? And more importantly, is there any read through to the Phase III asthma trial expected later this year?

A - David Reese {BIO 19782623 <GO>}

Thanks. Evan. This is Dave. I'll take that question. While there was some evidence of activity on some disease measures, we just have top line data right now. We've got a number of additional analysis, including biomarker analysis to do. Importantly, I really don't think there's much read through at all to asthma and in fact the best insights that we have into the activity of the drug and asthma are the large Phase II study that we previously conducted in asthma across the range of patients with both eosinophil high and eosinophil low forms of the disease. We're on track as I mentioned for the read out of those data and this doesn't really change our point of view on asthma.

Q - Evan Seigerman {BIO 18922817 <GO>}

Okay, great. Thank you.

Operator

Your next question is from Yaron Werber with Cowen.

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thanks for taking my question. I have a -- maybe a quick question on biosimilars and again you are continuing to really capture a lot of share, you're sort of in the 30's already with MVASI and KANJINTI. You've had some destocking and now it sounds like you obviously are continuing to expect some competition coming in. So I want to know, give us a sense, kind of, if you can, where are you sitting with inventories and and how much competition or how impactful of a competition you think will be, given that you're capturing share and how quickly would Avsola really be a meaningful contributor? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Thanks, Yaron, it's Murdo. We are very pleased with the performance of the biosimilar portfolio and specifically the two that you highlighted, MVASI and KANJINTI, which quite frankly in the period of time has been disrupted by COVID, I think providers are looking for a lot of places where they can extract more value in the healthcare system. So we've been pleased with the uptake. As you mentioned, we're in the high 30's with MVASI, mid 30's with KANJINTI and we don't see those trends slowing right now given competition. So that's the first comment I would make. And, overall inventories, there has been no real build there over the last few weeks. So we continue to see normal inventory levels in the biosimilars market. I would say, to your point on competitive dynamics overall, as more entrants come into the market, I would say we're less challenged on share but you may see some net price effects of multiple competitors entering.

A - Bob Bradway {BIO 1850760 <GO>}

Murdo, do you want to touch on Avsola, which was one of the other questions Yaron asked?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the prompt, Bob. Yes, we're, we're pleased. We just recently launched Avsola at the beginning of July, our biosimilar to infliximab. It's early days, so I don't really have any performance metrics to provide with you. It is a nice addition to our strong inflammation portfolio with Enbrel, Otezla, Avsola and soon, some other biosimilars as well as hopefully tezepelumab. So, really strengthening our portfolio overall. We are a little late on this one. So, we're going to see how we do in the market versus the existing competitors, but we have a strong team there and just like we did with oncology, where we use our innovative field force who have existing relationships with providers to commercialize our biosimilars, we're doing the same thing in inflammation.

A - Peter Griffith {BIO 4299061 <GO>}

Erika, lets take the next question please.

Operator

Yes. Your next question is from Jay Olson with Oppenheimer.

Q - Jay Olson {BIO 18027199 <GO>}

Hi, thanks for taking my question and congratulations on an impressive quarter during difficult time. I'm curious about the comments you made regarding mobile administration of Prolia. Is that a temporary strategy to navigate the pandemic or is it something you consider more of a permanent arrangement and if so, would you also consider providing home infusion for other Amgen drugs besides Prolia?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question, Jay. Yeah the Prolia story is one that I'm really thankful for. That team mobilized very quickly around the world, wasn't just in the US. Prolia is in many

markets actually a hospital administered products and if I can use Prolia as an example, we actually were able to do home delivery of Prolia for Italian patients. If you recall is the spike, that they had with COVID in Northern Italy. In the US, we worked closely actually with CMS and even the FDA to ensure that we were appropriately opening up alternate sites of care for Prolia patients and we were successful in securing this mobile nurse platform that you alluded to, we also actually opened up the possibility of home infusion or injection in this case with Prolia and potentially even self administration, we developed with input from the FDA, a self-administration kit.

I would say this way, I would say the vast majority of Prolia administrations is still -- are still in-office and continue to be as long as we have relatively open access to physician practices. And physicians have evolved and are adapting to COVID by helping create safe waiting rooms and safe care environment for patients. However, should there be additional spikes in COVID or additional disruption to that patient care, we believe we have opened up other channels that we feel good about in helping patients have continuity of care. And, as to the long-term possibility of this, I think, we see a lot of innovations during COVID that could persist. There are definitely some reimbursement mechanisms with Prolia being a Part B product that make that a little more difficult, but with time and experience, we will know more on how to continue to make Prolia available to patients.

Q - Jay Olson {BIO 18027199 <GO>}

Thank you.

Operator

Your next question is from Terence Flynn with Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, great, thanks for taking the question. Dave was just wondering, as you think about your BiTE platform here, is your confidence level in the platform, the same in terms of the heme indications versus the solid tumor indications? Just wanted to kind of get a sense from you. I know you've made some comments in the before about solid tumor activity, but just curious on kind of how you view that lately. And then can you just remind us of the design of the 160 Phase I study that's going to be at ESMO. And maybe what you're hoping to see to advance into Phase II. Thank you.

A - David Reese {BIO 19782623 <GO>}

Yeah, thanks for the question. As I mentioned, we're going to be presenting at ESMO, the 160 data. We've got two of the BiTE programs moving along in solid tumors, IL-1 and the program targeting DLL3 in small cell lung cancer. Both of those are in dose escalation. So you're going to see the initial dose escalation from 160 at ESMO. I would say we're seeing interesting hints of activity, you'll get a look at those data as we move forward. It's still early days and we're still dose ranging. But I think we remain confident in the half-life extended BiTE platform, and we're looking forward to pushing those studies through dose escalation.

Operator

Your next question is from Geoff Meacham with Bank of America.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey guys, thanks for taking the question. Bob, I want to get your thoughts on the drug pricing and other executive orders. I didn't hear much about it in the prepared remarks and so the question is, what do you expect implementation in its current form and as written, where would you imagine would be the greatest exposure relative to the Amgen portfolio? Thank you.

A - Bob Bradway {BIO 1850760 <GO>}

Jeff, I would just say it's early days still. We're looking forward to seeing the actual language behind these executive orders and we're pleased that one of the executive orders addresses the rebate mechanism and we're very focused on, as you know, our view is a nation needs more innovation, not less. And the nation needs to have less innovations sitting stuck on pharmacy shelves, making its way to patients and one way to do that is to try to bring down the out-pocket cost for in particular seniors at the pharmacy. And we think the rebates rule the executive order as we understand it anyway, opens the door for that. So that feels constructive.

Obviously there's a lot of focus as well, Jeff, on this most favored nation or IPI like executive order. But as far as I'm aware of the language on that is not available yet and obviously for us and I think for all the innovators in our industry, the idea of importing prices from socialized medicine countries where there are all kinds of other access problems for innovative medicines like like ours and like those which US citizens have access to, we think is problematic. And the good news for seniors in the United States is, virtually all the innovative cancer medicines that you ask us about and that we're so excited about are available to our citizens and it's a very different picture in other parts of the world, including other parts of the world that -- that that order might reference. So we will watch with concern, but we think there are better ways to address the issue and than that in that approach. So, stay tuned. I'm sure there will be more information on it at this time passes.

Q - Geoff Meacham {BIO 21252662 <GO>}

Okay, thank you.

Operator

Your next question is from Chris Raymond with Piper Sandler.

Q - Chris Raymond {BIO 4690861 <GO>}

Hey, thank you. Just with regard to Aimovig, some of our checks we've done recently indicate there is a pretty decent level of receptivity to oral CGRPs in the prevention setting once once those options are labeled. Maybe, Murdo, maybe just sort of talk about your

view of sort of the longevity of Sub-Q CGRP's in general and maybe Aimovig in particular. You've been when there is an oral option available in that setting. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question, Chris. Yeah, the overall, we have to just reflect on the huge unmet need with migraine here. We are barely penetrating roughly a 4 million incident patient population where, there is a significant amount of usage of older medications that just do not provide the migraine relief that Aimovig can and so far, we're pleased with the evolution of penetrating that unmet need with Aimovig and we're definitely very pleased with the impact we've had on patients' lives.

What we're seeing so far with the oral agents is really, they're used more as, add-on treatment options given their current indications and I think that's actually helping further strengthen Aimovig's perception in clinical experience for patients from neurologists. It will be interesting to see what the data look like on the prevention side and what labeling looks like as well. But overall, I think there is a lot of room for more patients to benefit from a CGRP based therapy, and we think we've got the one of the best if not the best given the convenient once a month injection, the really strong coverage that we now have across the US in terms of insured benefit and great patient support programming to help patients possibly even titrate up in their dosing on Aimovig.

So I think a lot of, a lot of growth, yet to be realized. Even with additional entrants in the market.

Q - Chris Raymond {BIO 4690861 <GO>}

Thank you very much.

A - David Reese {BIO 19782623 <GO>}

Yeah, -- Chris, this is Dave. I would just add that obviously we'll be looking at long-term safety with the small molecules, when you get to chronic administration and we're very happy with the long-term safety profile now extending 4 years in some patients with Aimovig.

Operator

Your next question is from Ronny Gal with Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Good morning. Question is for David. First, if you don't mind clarifying, you kind of mentioned that tezepelumab data in Atopic Dermatitis, you haven't mentioned safety side in the in the Phase II in Asthma, you did see a case in Julian bar and I guess, stroke and there is always a concern of anaphylaxis in this population. I was wondering if you could just clarify if we are seeing this signal repeating themselves in the in the Atopic Dermatitis trial. And then, on the neutralizing antibody strategy, is the strategy that you're having to find and antibodies, which are complementary to spike proteins, is that coming instead of

the previous strategy was to look for the high specificity antibody or is this an addition additional strategy?

A - David Reese {BIO 19782623 <GO>}

Yeah, thanks, Ronny. So, in regard to the teze data, I would say, there were no concerning safety signals at all in the Phase II Atopic Dermatitis trial. The Phase III trial, as a standard has an independent data monitoring committee that of course periodically evaluate safety and they have always indicated the trial should proceed as planned and we fully expect that that will happen to completion over the coming few months. In terms of our COVID-19 therapeutic antibody strategy, we, as we have looked at the rapid evolution of the field, most of the antibodies, as I'm sure you're aware that have gone into the clinic, target the RBD, Receptor Binding Domain of the spike protein. Our technical assessment of those antibodies is that some of them appear to be quite good. And our belief is that we could potentially add value here to the therapeutic armamentarium by developing an antibody targeting another epitope non-overlapping and that could potentially be added to an antibody or a cocktail from that first generation. So that is the strategy, we were open to that from the start and we are now focusing on that, I would say, as we watch the evolution of the field.

Q - Analyst

Care to share with us, who's antibody you are you particularly impressed with?

A - David Reese {BIO 19782623 <GO>}

I'm not going to comment on that one, I'll leave you to assess that.

A - Arvind Sood {BIO 4246286 <GO>}

Erika, let's take the next question.

Operator

Your next question is from Matthew Harrison with Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good afternoon. Thanks for taking the question. Dave, I was hoping to ask about the IL-2 mutein program. It seems like you made a decision not to move ahead in RA. But there are obviously some GI indications that you and other companies are studying, can you just talk a little bit about your excitement or lack thereof around around those other indications and any data you got from RA, which may influence the profile in those other indication. Thanks.

A - David Reese {BIO 19782623 <GO>}

Yeah, Matt, thanks for the question. You know, we remain quite interested in this molecule, which again to remind everyone, is designed to enhance the number and function of T regulatory cells and restore some of the dysregulation of the insystem that

occurs in certain autoimmune diseases. We knew from the start that it's a high bar in rheumatoid arthritis giving existing therapies based on the emerging data elected not to go forward in that indication. I think, there are a variety of other autoimmune diseases, where this is of interest, and we're continuing to push that program forward as we move towards additional trials, of course, we will share that with you. And we've got ongoing studies in diseases like lupus, where there remains significant unmet medical need.

Operator

Your next question is from Michael Yee with Jefferies.

Q - Michael Yee {BIO 15077976 <GO>}

Hey there, thanks for the question. Question for David on omecamtiv mecarbil, ofcourse a big Phase III readout and has a unique mechanism and Allergan science, could you just put into context for us what maybe one or two things you specifically like from the prior data and what degree of confidence you have given a high bar for CV outcome study, clinical meaningful magnitude of benefit, maybe just talk a little bit about that and how you handicap that, appreciate it.

A - David Reese {BIO 19782623 <GO>}

Yes. Thanks, Mike. As you mentioned, there is -- It's a novel mechanism action. It's the first drug that directly affects contractility of myocardial cells and that's of course one of the primary dysfunctions in advanced heart failure. So, that's obviously our priority, one of the things that we like about the molecule. In addition, I think the Phase II data, what caught our eye was the fact that there was internal consistency when you looked across physiologic measures, the various physiologic outcome measures that are used in mid-stage heart failure programs as well as our various biomarkers and to see that sort of internal consistency is another thing that gives you confidence. But I would point out that we're now doing the definitive experiment, a Phase III trial in over 8,000 patients. It's well powered and there will be sufficient follow up. And so, I think we're going to know the answer is to the utility of omecamtiv mecarbil in advanced heart failure by the end of the year.

Operator

Your next question is from Robyn Karnauskas with SunTrust.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi, thanks for taking my question and love the new format. And so I guess two quick ones. What are the trends that you're seeing in the doctor's office as far as ease of reimbursement, given the economic climate. Are you having to give more free drug. And second question, given the environment, but spending more in the back half of the year. And what about your exchanges or a new thought and update us on your appetite for M&A or business development. Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Okay. Robyn, why don't I start with if --,I'll start with the first part of your question and turn it over to Bob for your second part of your question.

Overall, we are actually pretty pleased with what we're seeing particularly in the latter part of the second quarter, in patients accessing reimbursement for their medications. We do have generous programs that we provide. But given the fairly significant expansion in Repatha, Aimovig and Evenity coverage with a permanent J code, we really have seen less need for those programs, currently. Now that could change in the longer term as some of the patients who are maybe currently furloughed could become displaced or laid off or as patients who may be securing COBRA could end up lapsing. Also, many patients end up going off of their own benefits to a spousal benefit. So there is multiple layers of how people who are losing their insurance coverage, might be able to bridge through different mechanisms. We're also hopeful and maybe even optimistic that some additional stimulus would be provided so that patients can seek continuity of their health care coverage. But overall, I would say, so far so good, despite significant disruption obviously in our economy.

A - Bob Bradway {BIO 1850760 <GO>}

And on business development, Robyn, I wouldn't point to any changes in our approach, we've addressed this, I think pretty consistently on prior calls. We're looking for licensing or acquisition opportunities in the areas of our focus. So, will continue. I think in particular, scouring the licensee landscape at the moment. So keep you posted as opportunities develop.

A - Arvind Sood {BIO 4246286 <GO>}

Erika, let's take the next question. And just a reminder to our participants, if you can please limit yourself to one question. Erika, go ahead.

Operator

Your next question is from Geoffrey Porges with SVP Leerink.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you. Thank you very much for taking the question and congratulations on continued the business in trying circumstances. Just to follow up on the other question on the omecamtiv, so could you give us a sense of, it was very well powered study, so what sort of hazard ratio are you aiming for to achieve statistical significance and then more importantly perhaps what sort of hazard ratio of benefit do you think is clinically significant, given quite a few other products that are advancing in that setting right now?

A - David Reese {BIO 19782623 <GO>}

Geoff, thanks for the question. What I would say is that the study is powered to detect what we would consider clinically meaningful difference in outcome. The primary endpoint as a standard for these sorts of trials is a composite heart failure events and cardiovascular death on the order of 15% or so improvement on those measures is the

sorts of things that cardiologist will typically look for and considered clinically meaningful and the study has been designed to detect those sorts of differences.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Great, thank you.

Operator

Your next question is from Umer Raffat with Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my questions. I just wanted to focus on KRAS for a second. A, maybe gauge your expectations on durability of response, how you would prepare the Street heading into your data. And B, if you could catch us up on whether there is any early evidence emerging on your BID dosing. And if you're seeing possible efficacy differentiation with the higher AUC at BID? Thank you.

A - Bob Bradway {BIO 1850760 <GO>}

Thanks, Umer. In terms of duration of response, still early as I mentioned, we're going to have an update on Phase I data at ESMO in roughly 6 or 7 weeks seen in that by the time we have those datasets, we will get some look at duration. In BID dosing, we continue to examine. I would expect it's going to be later in the year or first part of the next year, until we would have enough data to thoroughly examine both safety and then whether there is any sort of efficacy difference between monotherapy and BID dosing. I would reiterate that based on everything we've seen, we remain comfortable with the monotherapy dose that we've chosen to go forward with in terms of KRAS inhibition in certainly in lung cancer. That is our primary focus right now.

Q - Umer Raffat {BIO 16743519 <GO>}

Thank you.

Operator

Your next question is from Alethia Young with Cantor Fitzgerald.

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys, thanks for taking my question and congrats on the progress during the quarter. Another one on omecamtiv, I know there is a roughly about 3 million people with heart failure with reduced injection fraction, but I was hoping Murdo maybe you could drill that down a little bit and help us think about maybe kind of an initial population based on how the study is designed. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yes, thanks Alethia. I would say this and Dave's already touched on it. Given that this is a slightly sicker population than some of the other recent heart failure trials, our focus is really in the institutional setting. We have made investments over the course of last year and this year, to expand our cardiovascular hospital presence. We've established a cardiovascular account management team who will focus really on the more, the more severe hospital frequent flyer, if you will, heart failure patients who really need some symptomatic improvement and need some functional improvements, so that they can reduce the amount of hospitalization, that they have. We also think that's where quite frankly the greatest value in treating heart failure can exist in the health care system. So hopefully, we have a successful trial in our hands, because we still see a really good opportunity for that type of patient.

A - Bob Bradway {BIO 1850760 <GO>}

And I would add Alethia, that the trial includes initiation of therapy in both hospitalized patients and non-hospitalized patients. So as Murdo mentioned, it is a little sicker population than some of the other trials that have read out recently and heart failure is typically the leading or top handful of causes of hospitalization in most countries now, it's almost always the leading cause of re-hospitalization within 30 days, which has huge economic implications. And so as Murdo mentioned, these factors really have informed our thinking about how the drug might be positioned going forward.

Operator

Your next question is from Cory Kasimov with JPMorgan.

Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good afternoon guys. Thanks for taking the question. This one is probably for Murdo. I'm curious if you anticipate a longer-term tailwind for Neulasta OnPro that might extend beyond COVID-19 given that more providers may see the value of the product and that may have previously. Just curious if you're able to gather any feedback from the field on this front during the pandemic.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks, Cory. The experienced so far, I mean there is really there's two drivers of that tailwind you alluded to. One is, the overall utilization of long-acting filgrastim in general has gone up, and then of course the innovation that is Onpro which allows patients to have less frequent visits to their site of care has driven some share preference for Onpro. I think we'll be able to hold quite a bit of that improvement in our share, but I'm also hoping that oncologists remain vigilant and continue to increase their usage of long-acting filgrastim in general, consistent with the NCCN guidelines. Clearly as long as COVID is out there, people should be using care strategies to minimize patients exposure, particularly compromised patients exposure to risk, and of course for Onpro minimizing their exposure to the site of care where they may pick up an infection. So overall, I think we're pretty enthusiastic about what we're seeing with Neulasta and with Onpro specifically.

Q - Cory Kasimov {BIO 3009346 <GO>}

Okay. I appreciate it.

Operator

Your next question is from Mohit Bansal with Citigroup.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thanks for taking my question and congrats on the progress. One quick one on Aimovig. One of the common feedback we get from doctors is that many of these patients migraine patients get treated by primary-care physicians and not just by a headache specialist and that may be the reason why the penetration to be slow for these agents. To that end, how do you see clients that use CGRP's expanding to primary care. Is it even possible and what could a Company like Amgen could do to make it possible? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Yes thanks Mohit. We do have experience with primary care physician promotion and we do have primary care physicians in our target audience. And there are those that specialize in treating migraines, that become good at it. And I would say that their openness to using Aimovig is actually quite good and quite high. I think one point that I would I would make that's that's adjacent to what you're describing is, we definitely saw in COVID and even post-COVID, some bottlenecking on the part of the neurologist and to some extent these headache clinics in getting caught up with patient care after the March-April period of COVID disruption. And so, I think we continue to watch that closely. We're seeing good improvements, but this is a stretched specialty neurologists take care of a lot of different conditions as you know, and the more we can expand care into primary care community-based treatment, the better, I think it will be for the growth of the category. So I would align with your observation that we need to expand the prescribing population of physicians for CGRP and I actually see that that's what's happening in our data.

Q - Mohit Bansal {BIO 18070890 <GO>}

Thank you.

Operator

Your next question is from Carter Gould with Barclays.

Q - Carter Gould {BIO 21330584 <GO>}

Thank you. Good afternoon, guys. I have a question for Peter. I was hoping he could walk through the cost of goods progression in the quarter. I appreciate the full-year guidance. But in the quarter, I mean volume was up mid-teens, biosimilars were up meaningfully and I believe you have a meaningful royalty on that and yet, non-GAAP COGS was only up 3%, is this strictly sort of a COVID-19 related ability that sort of downshift or is there

some other nuance I'm missing or does it speak to some sort of broader COGS story? Thank you.

A - Peter Griffith {BIO 4299061 <GO>}

Thank you, Carter. Yeah, on cost of goods sold, it was just the product mix in the first in the second quarter rather, and so we would expect that as we said, to be consistent with 2019 on an overall basis for the year.

Operator

Your next question is from Salim Syed with Mizuho Securities.

Q - Salim Syed {BIO 16887281 <GO>}

Great, thanks so much for the question, guys also throw in my -- thanks for being a leader in the industry here in shortening the prepared remarks hopefully others can follow suit, as well. I just had one question on omecamtiv, maybe for for David. David, it sounds like you're pretty bold up on this trial working and heading the 15% bogey that you mentioned. I just want to know if there was one thing that you had to pick in the trial design, whether it's in the sicker patients you mentioned or maybe the slight proponent elevation that we saw in COSMIC, if there was one reason why this trial failed and didn't hit that 15% bogey. I'm curious, what you believe that reason would be?

A - David Reese {BIO 19782623 <GO>}

Yeah, thanks Salim. It's hard to speculate on a specific reason. Look, advanced heart failure is high risk by its nature, and we fully recognize that, we think we've done methodologically a very good trial. But at this point, it is up to the molecule in mother nature and we're going to know that answer in a few months.

Q - Salim Syed {BIO 16887281 <GO>}

Okay, all right, thank you.

Operator

Your next question is from Dane Leone with Raymond James.

Q - Dane Leone {BIO 15203956 <GO>}

Hi, thank you for taking the questions. Congrats on navigating the difficult macro environment. So my one question, I just wanted to focus on Otezla, clearly the results in the mild, moderate psoriasis setting were good. You're building up an effort to go to market in that setting. The question we get is, just how do you actually tackle that market from where the drug is being used now and specifically in mechanistically. How are you going to open up the formularies to actually really unlock to more mild patients phenotype versus more of the moderate where you already do you have penetrations now. I guess one, on the label, how will it really read differently and open up and then

two, how are you going to work with payers and how is that going to change the formulary status?

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks for the question, Dane. Overall we see, there is a very large population of mild to moderate patients out there, but we're really focused on those patients that tend to have larger surface area of the skin involved in their psoriasis where they are really finding the topical treatments incompatible with the nature of their disease and looking for something better like an oral option. And I think given the strength of the results in the clinical trial, we feel that we would be able to target and motivate that population of patients to seek an alternative to topical treatments. Much the way Otezla is currently used today which is post topical, pre biologic, we think it's really a logical expansion of our current positioning. From our interactions with prescribers, we've, we've been encouraged by their enthusiasm for what Otezla may offer these individuals, these patients. The other thing I would say is we did at the end of last year, initiate a primary care promotional effort on Otezla, something that our legacy Celgene colleagues couldn't do or had not done and we were able to try that. We actually saw a good promotional response there. So, we have the ability, given the scale of our primary care field force to add Otezla to the mix there. I think that will help grow our commercial presence. We also are cross training all of our Enbrel field force on Otezla to ensure that we have maximal presence for hopefully an approved indication in not too distant future.

With respect to access, which you mentioned specifically, because again, because of the very good cost benefit of Otezla compared to particularly to biologic options, we've actually got very good coverage in this patient population today, not mild to moderate, but in the moderate to severe patient population today that we think we will be able to expand without too much gross to net erosion. So we're feeling we're feeling pretty good about this growth opportunity. I'm pleased with how Otezla has performed since we integrated into our portfolio. It is performing ahead of our expectations in TRx and that's with some nominal COVID pandemic impact on the overall dermatology category. So, so far so good.

A - Peter Griffith {BIO 4299061 <GO>}

Hey, Erika, we have 4 minutes remaining, let's take one last question after which, Bob is going to make some concluding comments.

Operator

Yes. Your final question is from Michael Schmidt with Guggenheim securities.

Q - Michael Schmidt {BIO 3870043 <GO>}

Hey guys, good afternoon and thanks for squeezing me in. I had a follow-up on the care us program, store to asset obviously being also evaluated and multiple combinations with other agents. How do you see those various combinations position relative to each other. For example, if there is indication overlap such as an lung cancer potentially and secondly, I guess what do we need to see from that KEYTRUDA combination in lung

cancer, which I believe has most advanced and development to advance that particular combination into the next development phase?

A - David Reese {BIO 19782623 <GO>}

Yeah, thanks for the question. The combinations as you indicate would potentially cover a range of indications or diseases, as well as different lines of therapy or there may be partial overlap, as these datasets emerge, of course, we would go, we will evaluate them and determine where we think that the most promise lies, I think it's too early, it's early days and too early to call forces there, the KEYTRUDA combination started first, but there are half dozen in the clinic now and as we move along in the coming months, we'll give guidance and we'll look forward to sharing those data. We know there are not in their stuff for this program and for the entire field as this program moves forward, It continues to move quite quickly. Bob?

Q - Michael Schmidt {BIO 3870043 <GO>}

Great, thanks. Appreciate it.

A - Bob Bradway {BIO 1850760 <GO>}

All right everyone, we're going to wrap up so that we can close here at the top of the hour as promised. But let me just simply thank you for your ongoing interest and support of our Company. I know we're all operating in unprecedented times here, but we feel like we're in a strong position, operating the Company well and particularly grateful that our staff worldwide are as engaged as they are in our mission even in this challenging time we find ourselves in. So, thank you again for your ongoing support and we will be available to answer your questions if you have any following the call. We look forward to connecting with you after the third quarter.

A - Murdo Gordon {BIO 18450783 <GO>}

Thank you everybody.

Operator

Ladies and gentlemen, this concludes Amgen's second quarter 2020 financial results conference call. You may now disconnect.
