Q3 2020 Earnings Call

Company Participants

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

Other Participants

- Alethia Young, Analyst
- Chris Raymond, Analyst
- Colin Bristow, Analyst
- Cory Kasimov, Analyst
- Evan Seigerman, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennan MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Mohit Bansal, Analyst
- Robyn Karnauskas, Analyst
- Ronny Gal, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst

Presentation

Operator

My name is April and I will be your conference facilitator today for Amgen's third 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 now begin.

Arvind Sood {BIO 4246286 <GO>}

Okay, thank you, April. Good afternoon, everybody. I together with several members of our leadership team that you will hear from today, would like to welcome you to our Q3 call. The format of our Q2 call was very well received, so we'll stick to keeping our prepared comments to a minimum and limit the overall duration of the call to one hour. The slides have been posted. Just a quick reminder that we use non-GAAP financial measures in our presentation and some of the statements will be forward-looking statements. Our 10-K and subsequent filings identify factors that could cause our actual results to differ materially.

So with that, I would like to turn the call over to our Chairman and CEO, Bob Bradway. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay, thank you for joining today's call. I'll take a few moments to discuss our performance in the third quarter and then share some thoughts on the overall operating environment in a COVID context.

We delivered another strong quarter, and you can see that in our revenue growth of 12%. And in addition, once again this quarter, our revenue growth exceeded expense growth, enabling us to report earnings per share growth well ahead of revenues. Putting the results in a broader context, our double-digit increase in revenues was driven by the continued volume driven growth of many of our innovative products, the strong uptake of our high-quality biosimilars and the relative stability of our base business, which is proving resilient in the face of increased competition. We expect these three factors to be key for our long-term success.

Turning to COVID-19, clearly the pandemic remains an important factor affecting performance for Amgen and for our industry. You'll recall that Amgen grew revenues by 11% in the first quarter of the year, with the first 10 weeks of performance largely unaffected by the pandemic. In the second quarter, when conditions were at their worst, revenues grew by 6%. Our performance in the third quarter reflects an encouraging recovery from the depths of the pandemic and was largely consistent with what we anticipated for you in our remarks at the time of our second quarter call. As regards to the fourth quarter, we see the current resurgence in cases as a potential headwind for our business, and we are closely monitoring this to see what the impact may be for the rest of the year and if there might be any spillover into 2021.

We don't expect anything like what we saw earlier in the year, as global healthcare systems know much more about how to treat COVID-19 and are better prepared to do so than they were earlier in the year. However, on the margin, we're not ruling out that there will be some impact and we tried to incorporate this into our planning assumptions for

the fourth quarter and into the beginning of next year. Overall, I remain optimistic that innovation from the biopharma industry will break the back of this pandemic, with vaccines antibodies and other therapeutics that are being developed with unprecedented speed and collaboration. One thing this pandemic has exposed is the importance of innovation, and that of course is at the core of our strategy and it's reflected in the first-in-class molecules that are advancing rapidly in our pipeline.

We're pleased, of course, with the Phase II results of our first-in-class molecule Sotorasib and we expect to see top line Phase 3 data for Tezepelumab, a potential first-in-class treatment for severe asthma by year end. We're also making good progress with several of our half-life extended BiTE molecules particularly in solid tumors like prostate and small-cell lung cancer. All the work that we do is taking place at a time when more is expected of companies than ever before. We understand these expectations and are committed to good corporate citizenship and sustainable operations.

Before I turn things over to the rest of the team, let me thank our staff members around the world for their unwavering commitment to serving patients during this challenging time. Their resilience, creativity and ability to execute give me great confidence in our long-term future. Dave?

David M. Reese {BIO 19782623 <GO>}

Thanks Bob. I'll begin with Sotorasib, our first-in-class KRAS G12C inhibitor. Based on the data we have accumulated and the evolution of the field, we are extremely optimistic about the potential of Sotorasib and will continue to aggressively advance the development program. Earlier this month, we reported positive top line results from our Phase II monotherapy study in advanced non-small cell lung cancer, demonstrating an objective response rate consistent with our Phase I data at 960 milligrams and promising results on other measures of efficacy, including duration of response, with more than half of the responders still on treatment at the data cut off. Safety and tolerability were similar to previously reported data for this population and have been remarkably consistent across the 160 patients treated with our Phase II dose.

Our Phase I and Phase II data are based on protocol specified intent to treat criteria as is our practice and the scans to assess efficacy parameters in Phase II have been evaluated by independent central review. We look forward to presenting the Phase II results at the World Congress on Lung Cancer taking place in January.

We also reviewed with interest a data presentation made a few days ago. Based on our assessment of available efficacy and safety data, including durability measures, we remain extremely confident in our molecule. To date we have treated over 550 patients with Sotorasib and we are looking forward to discussions with the FDA and other regulatory agencies to determine the best path forward as monotherapy in patients with advanced lung cancer. We couldn't be more enthusiastic about our position as we move towards establishing Sotorasib as a KRAS G12C foundational therapy.

We also remain optimistic about our BiTE platform. We now have evidence of clinical activity in solid tumors, including recently presented prostate cancer data from AMG 160 which targets prostate specific membrane antigen. The benefit risk profile AMG 160 has continued to improve with additional dose optimization. AMG 757 is our half-life extended BiTE targeting DLL 3, which is a very attractive target due to its differential expression in small-cell lung cancers, and we look forward to presenting initial data at the Society for Immunotherapy of Cancer Annual Meeting next month.

Small cell lung cancer is a large unmet medical need globally and yet treatment options have not advanced significantly in decades. We will also investigate AMG 757 for the treatment of neuroendocrine tumors. We expect to present data from AMG 701 targeting BCMA for multiple myeloma later in the year as well. And before leaving the BiTE platform, I wanted to mention a Phase II publication in the New England Journal of Medicine that reported deep responses and a tolerable safety profile for Dasatinib induction followed by BLINCYTO consolidation in adults with Philadelphia chromosome positive ALL. 60%[ph] of patients achieved a molecular response and disease free survival was 88% at 18 months, highlighting the potential of a chemotherapy free regimen. If these results are confirmed in larger trials, this could lead to a potential paradigm shift in the treatment of this disease.

In cardiovascular disease, we recently released the top line results from our Omecamtiv mecarbil Phase III outcome study and the results will be presented at the American Heart Association Scientific Sessions in November. In inflammation, along with AstraZeneca, we look forward to the top line results of the pivotal Tezepelumab Phase III study, Navigator, in patients with severe uncontrolled asthma, which remains on track. We also expect the results from the oral corticosteroids sparing Phase III study source by the end of the year, which should complement the pivotal data.

I'm happy to announce that we will be advancing our third inflammation program into Phase II development next year with AMG 592 now named Efavaleukin alfa or IL-2 mutein for Systemic Lupus Erythematosus. The trial was selected for inclusion in the FDA's complex innovative trial designs pilot program, which supports the development and regulatory review of novel clinical trial designs for new therapies.

In closing, I would like to thank all of the Amgen teams for executing at such a high level during the ongoing pandemic. Murdo?

Murdo Gordon {BIO 18450783 <GO>}

Thanks, Dave. We've seen volumes continue to improve from the initial stages of the pandemic, with Q3 global revenues growing 12% year-over-year driven by 18% volume growth. During Q3, physician-patient interactions increased to near pre-COVID levels. Across the industry in the U.S. total prescriptions are still down approximately 2% and physician visits, either in person or remote are down approximately 10% versus the pre-COVID baseline. While trends improved during the quarter, we are seeing infection rates rise in many parts of the world, which may bring additional quarter-to-quarter variability.

Let me spend a few minutes to discuss our Q3 performance and outline our expectations for the remainder of 2020. In bone health, our efforts are focused on ensuring patient continuity. We grew Prolia volume by 10% year-over-year, even though osteoporosis diagnosis rates have returned to just 70% of pre-COVID levels in the U.S. COVID has also resulted in a change in historical quarterly trends for Prolia. Prior to the pandemic, the first and third quarters each year had lower sales than the second and fourth quarters. However, given the impact of the pandemic in the second quarter and the six-month dosing regimen of Prolia, we would expect year-over-year growth rates in the fourth quarter to be lower than pre-COVID growth trends. With the current rise in COVID infection rates in the U.S. and Europe, there could be additional delays in patients receiving their Prolia treatment in Q4.

EVENITY sales in the U.S. grew quarter-over-quarter driven by 30% volume growth. This growth was offset by lower sales in Japan, which were partially related to timing of purchases by our partner Astellas. We believe EVENITY's unique bone-building abilities will continue to drive growth in our business as physicians appreciate its benefit risk profile in treating their post fracture patients. Repatha sales increased 22% year-over-year, driven by 60% volume growth and is a segment leader globally. We remain confident in our ability to grow Repatha, and given the significant unmet medical need in treating high risk cardiovascular patients, our comprehensive patient payor[ph] coverage, the convenient self administration and the established outcomes data in the label.

Moving on to Parsabiv which is an attractive treatment for secondary HPT, supported by the convenience of its IV administration. In January 2021, reimbursement for Parsabiv will move into the dialysis bundle payment system. We've already begun to see some negative impact on Parsabiv utilization in the U.S. and we would expect this impact to continue in Q4.

Transitioning to our Inflammation portfolio, total prescriptions for Otezla in the U.S. grew 11% year-over-year. Underlying volume trends remained strong. Sales were negatively impacted by lower inventory levels versus last year. We're confident that Otezla will continue its double-digit year-over-year volume growth based on its well-established safety and efficacy profile, convenient oral dosage, broad payor coverage and the lack of lab monitoring requirements.

Enbrel remains the cornerstone of our Inflammation franchise and we continue to invest in Enbrel, along with our broader inflammation portfolio including Otezla, AMGEVITA and recently launched AVSOLA. Enbrel was impacted by slowing growth in rheumatology prescribing in Q3 related to COVID and experienced some share loss in the quarter while maintaining price stability year-on-year. Continued softness in rheumatology prescribing related to rising COVID infections could further impact Enbrel in the fourth quarter.

Our Q3 Biosimilar revenues were $480 million, supported by share growth by MVASI and KANJINTI. We've achieved leading biosimilar shares for AMGEVITA in Europe and for MVASI and KANJINTI in the U.S. Our highly efficient operating model and full complement of patient services provide an important advantage as we face additional biosimilar competitors heading into 2021.

In Oncology, Neulasta Onpro remains the preferred long-acting GCSF with 55% share of volume in the quarter. Neulasta sales decreased 22% year-over-year, driven by declines in volume and net selling price. Competitive activity in long-acting filgrastim is impacting average selling price. The most recent published average selling price for Neulasta in the U.S. declined 19% year-over-year and 6% quarter-over-quarter.

Overall, I'm very pleased with our Q3 performance. We remain vigilant as the pandemic continues to create uncertainty and potential disruptions in the healthcare marketplace. Amgen employees around the world are focused on insuring continuity of care for our patients, and we will continue investing to drive growth of our innovative products, advance our geographic expansion and prepare for potential new product launches.

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

Peter H. Griffith {BIO 4299061 <GO>}

Thank you, Murdo. Consistent with the first half of the year, we executed effectively during the third quarter, delivering 12% revenue and 19% non-GAAP EPS year-over-year growth. As you heard Murdo say, revenue growth was driven by volume increases of 18% consistent with our focus on volume-driven growth. Third-quarter non-GAAP operating expenses increased 10% year-over-year and 9% quarter-over-quarter, as we accelerated our investments to drive growth and advance the pipeline.

Although activity levels during Q3 were still partially impacted by COVID-19, most trials continue to enroll patients. Customer facing commercial activity levels increased and launch preparations were in process. We see activity levels increasing in the fourth quarter of the year, resulting in increased investments. We have financial flexibility with $12.4 billion in cash and investments on our balance sheet, and continue to generate stable free cash flow with $3.2 billion in the quarter. Additionally, our third quarter dividend was $1.60 per share, an increase of 10% over last year. Our capital allocation principles and plans remain unchanged and uninterrupted.

Let me now share some thoughts on our 2020 outlook going forward. We are narrowing our revenue guidance to $25.1 billion to $25.5 billion from $25.0 billion to $25.6 billion. The range reflects the uncertainty created by the recent resurgence of COVID-19 infections globally which Bob discussed in his remarks. And as you just heard Murdo say, our products, including Prolia, for the most at risk COVID patients are most susceptible to the accelerated rate of infection. The lower end of our range takes into account a more accelerated impact from COVID globally.

We are raising our non-GAAP earnings per share guidance to $15.80 per share to $16.15 per share versus our prior guidance of $15.10 per share to $15.75 per share. We continue to believe that we could experience fluctuations in our quarterly revenues and earnings over the duration of the pandemic. As we shared during our Q2 call, we expect full-year total non-GAAP operating expenses to grow in the high single-digit percentage range year-over-year on an absolute basis. We expect fourth quarter non-GAAP operating expenses to grow at about 20% on a quarter-over-quarter basis.

Now let me share a bit more detail on our non-GAAP expectations for the full year 2020. Cost of sales as a percent of product sales will be generally consistent with 2019. We plan to increase R&D investments in the fourth quarter of the year, as clinical trial and laboratory activities continue to recover from COVID related slowdowns. SG&A spend is projected to increase due to investments in Otezla and other growth brands, geographic expansion and launch preparations.

We anticipate other income and expense to be a net expense of about $1.3 billion, which includes more than $130 million of benefit from mark-to-market gains on our equity investment portfolio in Q3. We are updating non-GAAP tax rate guidance to 13% to 14%, versus prior guidance of 13.5% to 14.5%. Our expectations for share repurchases are unchanged. At the lower end of our previously disclosed range of $3 billion to $5 billion. Finally, recall that Q4 of 2020 will be comparing against a partial quarter of Otezla sales and expenses in Q4 2019.

So as we approach the end of 2020. We are pleased with our progress and execution this year, including the successful integration of Otezla, collaboration with BeiGene and transition from Astellas in Japan. As is customary, we will provide full 2021 guidance on our January call.

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

Robert A. Bradway {BIO 1850760 <GO>}

Okay, April, why don't we open up the lines for questions and perhaps you could start us by reminding our callers of the procedures for asking A question.

Questions And Answers

Operator

Yes, sir. (Operator Instructions). And your first question comes from the line of Michael Yee from Jefferies.

Q - Michael Yee {BIO 15077976 <GO>}

Hey guys, thanks for the update. Really appreciate it. I had a question on Tezepelumab, of course a really important readout coming soon and it's an important drug. Just wanted to understand David's perspective on the importance of the low eosinophil group can in the context of the overall data and how important that is to hit there and how that would change the overall profile or -- and outlook for that drug? Thanks.

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

Thanks, Mike. Yeah, and of course we are greatly looking forward to that readout as well. What I can say is that the trial is very well powered to look at outcomes on the primary endpoint here as annualized exacerbation rates the standard endpoint for asthma studies across the different subgroups including the low eosinophil population. So we feel very

comfortable that this will be a definitive test of Tezepelumab across the entire range of patients with severe asthma.

A - Arvind Sood {BIO 4246286 <GO>}

April, can we have the next caller, please?

Operator

We have the next question comes from the line of Matthew Harrison from Morgan Stanley.

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Good afternoon. Thanks for taking the question and thanks for the update. I guess another question for Dave. Could you maybe just comment, I know you commented on your opening remarks here on G12C. I guess the question here is as we think about moving the response rate higher in terms of the combination studies that you have ongoing, what's your relative confidence around those studies either improving response rates or improving durability? And how do you think about your ability to progress them rapidly now that you have a good sense of the monotherapy activity of the compound? Thanks.

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

Yeah. Thanks, Matt. That's certainly the combination studies are an important topic, they're moving forward quite briskly. We have I think seven cohorts open now, three or four more are coming very soon. So we feel we are testing in a range of indications. The biologically plausible and clinically relevant combinations will have data next year on a number of these. And to your point, the goal always in combination therapy beyond monotherapy is to enhance efficacy and potentially in terms of response rates, but also durability if you are cutting off avenues of tumor resistance or escape, and that's certainly our goal. We're very much guided by the biology here, and as you look at those cohorts that are coming up I think you'll see that that's the case.

Operator

And next question comes from the line of Yaron Werber from Cowen.

Q - Yaron Werber {BIO 19486720 <GO>}

Yes, hi. Great, thanks for taking my question. David, I'm just going to maybe keep you on the spot on Sotorasib. Some of the data or comments that we heard this week is that a competing product was well tolerated at the high dose with an EGFR inhibitor and pembro. If I remember correctly at ESMO, I think you're investigator said something along the lines, and correct me if I'm wrong, that it -- with your product with PD-1 there was tolerability, there was -- but it was addressed with dose reduction, something along those lines. If you don't mind maybe exactly correct what he said.

And then secondly on Tezepelumab, our understanding is that the way the study is designed, it's actually incorporating the low eosinophil dose into one of the analysis in the primary endpoint as a sub-analysis. And so if you hit that, does that mean you get a broad label? Thank you.

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

Yeah, sure. So let me take those in order. In terms of the combinations, and one thing I would caution everyone is let's not over read anything into cohorts of three or four patients, whether that's our trials or anyone else's trials. We're moving forward. We've been -- what we have is a foundation of tolerability in monotherapy, which is the critical thing to build on in combinations. And I think this was put into some perspective by an editorial in The New England Journal of Medicine that accompanied the publication of our Phase I trial a few weeks ago and I'd refer you to that.

And certainly it's very common in combination therapy development in oncology to look at all sorts of dosing and scheduling regimens, and we fully intend to do that and [ph]our priori[ph] we would intend on doing that. And with regards to the analysis in Tezepelumab, yeah, that's correct. The analysis is powered and geared across the entire population then with also look at the low eosinophil population. So your suppositions there are correct.

Operator

And your next question comes from the line of Jay Olson from Oppenheimer.

Q - Jay Olson {BIO 18027199 <GO>}

Oh hey, congrats on the quarter and thank you for taking the question. I just wanted to follow up on the comments around KRAS G12C. The competing program that that future data over the weekend did report QT prolongation, including some cases of, grade 3, 4, is this a class effect and have you seen any cases of QT prolongation with Sotorasib? And how important is this cardiovascular safety findings in this patient population? Thank you.

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

Yeah, well, I can't speak to directly to others data and of course, I'll allow them to do that. I will say that we've, as I mentioned, treated over 550 patients. There is no evidence whatsoever of a QT signal to date and we remain quite pleased with the overall tolerability of Sotorasib.

Operator

Your next question comes from the line of Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Great, thanks for taking my questions. Maybe I was just wondering if, as you think about capital allocation, if the Omecamtiv setback maybe changes anything on that front,

particularly, how you think about the cardiology opportunity for the Company? And then a question for Peter. I was just wondering if you could give us a preliminary view of 2021 expenses just relative to this year? Just wondering if you're wrapping up a number of late-stage programs now. why spend would grow next year. Thank you.

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

Okay, Terence. This is Bob, why don't I take the first part of your question. The answer is -- the short answer is no. The Omecamtiv results don't change our thinking on capital allocation. We continue to look for business development opportunities and continue to look for internal programs in cardiovascular disease. As you know, we're moving rapidly with our Phase II program directed against LPs little As. So we're excited to have some advanced studies going for that molecule, and we'll continue to look for ways to invest in that franchise. Cardiovascular disease as you know, the leading killer of people on the planet. We continue to think what we need in that field is more innovation, not less. So will continued looking for that.

A - Peter H. Griffith {BIO 4299061 <GO>}

Terence, it's Peter. Thank you for your question. A good question. As you know, we will guide on 2021 when we get to January. But I do want to just say we always intend on continuing to be a top-performing biopharma firm looking at various financial metrics, always operating margin right there. So look, we're going to remain flexible and adaptable as attractive opportunities arise, and with the underlying objective to grow our after-tax cash flows. So that's where we sit right now on expenses. We wanted to be clear on the fourth quarter and how that's going to sequence in which is really on a normal historical basis, just at the upper end of it a OpEx basis. So with that, I'll turn it over to the next question.

Operator

The next question is from the line of Evan Seigerman from Credit Suisse.

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi, guys. Thank you so much for taking the question. Actually one for Murdo on some of the dynamics in the Biosimilar business. So you're talking about pricing headwinds as volumes increase. Are you seeing this more in the inflammation space or this is -- is this in oncology? And can you provide some color as to how accounts generally I guess in the U.S. are using biosimilars? Is it more just totally forgetting the brand and going all to the biosimilar or do you see some sort of a mix? Thank you so much.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks. Evan. Yeah, we're -- look, we're really pleased with what we've been able to do with our Biosimilars business in the quarter. We were -- the team has done a really nice job this year despite COVID in establishing strong penetration into the U.S. oncology market within MVASI our Avastin biosimilar and KANJINTI our Herceptin biosimilar. I would say with respect to the dynamic in the market, a lot of people question whether or not we had an efficient functioning biosimilar market in the U.S. because I think they were

over interpreting some of the early biosimilar launches. And I think what you can see now is that we have an efficient market, that when there are -- when there is a clear value on the table healthcare systems, providers and payers are able to capitalize on it. And that's what's driving of course the uptake of our biosimilars.

I also think that the experience we've had in defending against biosimilar erosion on products like Neulasta has positioned us well to understand how accounts are looking to purchase biosimilars. So when we launched our own, we were able to take some advantage of that. And I would say that of the accounts that have opened up biosimilar usage generally initially we thought they might be using biosimilars for new patients going forward, but we've actually seen them use our biosimilars both for new patients and switching patients who are mid-course of treatment to biosimilars as well.

So I'd say that the penetration at an account level has been deeper than we originally anticipated. And I think by now there is fairly broad adoption in the U.S. at the 340 B level, the non-340 B level and of course within the clinics. Now that's oncology. It's a little different in inflammation depending on the biosimilar itself whether it's a -- an infused biosimilar or whether it's a self-injected or self-administered biosimilar. And I think need to watch that carefully because the two are not analogous. So I would treat each business segment as its own example and not draw comparisons from one to the other.

Q - Evan Seigerman {BIO 18922817 <GO>}

Thank you so much.

A - Arvind Sood {BIO 4246286 <GO>}

April, go ahead. April, are you there?

Operator

Sorry. One moment.

A - Arvind Sood {BIO 4246286 <GO>}

April, what's happening?

Operator

All right. And your next question. Sorry about that is from the line of Chris Raymond from Piper Sandler.

Q - Chris Raymond {BIO 4690861 <GO>}

Thanks for taking the question. Yeah, I was wondering if I could maybe ask on Sotorasib again and take the conversation back there. So I heard, David, your commentary on hopes on the response rate in combo. But I think you guys are also working on a BID dose. And if memory serves, I think we were -- maybe we were expecting to see something by year end or at least in the coming months. So I wonder if you could talk

about your hopes with respect to that, potential as a monotherapy BID? And then also on the same topic, can you just confirm, does Sotorasib have CNS activity? Can you give us a indication on that one? Thanks.

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

Yeah. Thanks, Chris. Both important questions. It's standard in any new molecule as part of the clinical pharmacology program to examine different schedules. So we continue to do that with twice daily dosing. But one thing I'd urge everyone to do is go back to basic pharmacokinetics here as we think about this field and what are the reasons to go to split dosing. Well there are really two reasons. One, if you need split dosing in order to achieve target coverage. Or two, if you need to split the dose because of tolerability issues. And with Sotorasib, we're very convinced that we are getting target coverage throughout the dosing interval with our once-daily dosing, and of course we've got very nice tolerability at once daily dosing. And so that's really -- if -- this is I think basic pharmacology and pharmacokinetics and the science underlying that that has driven our clinical choices.

In terms of CNS penetration, we did mention at ESMO we have a couple patients with -- one or two patients with CNS metastases who clearly had responses. So the question with small molecules or in CNS responses in general is always is that due to true penetration or because there is typically a highly disrupted blood brain barrier in that setting you almost always get some exposure to drug.

The third potential explanation, which we continue to explore is that it's a secondary immune activation that could potentially trigger activity in the central nervous system. We are exploring this question explicitly in a cohort that we're just opening for patients with brain metastases. And so I think in through next year, we'll have a good sense of potential activity in the central nervous system.

Q - Chris Raymond {BIO 4690861 <GO>}

Thank you.

Operator

And your next question comes from the line of Geoffrey Porges from SVP Leerink. Please go ahead.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Hey. Thank you for the question. This is Andrew on for Geoff. So I have a question regarding to Tezepelumab's read outs. So if the study is successful, how might it be commercialized given the conflict that your Partner has with (inaudible) for the same indication? Thank you.

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

Yeah. Thank you. I'll jump in on that one. We've obviously been very transparent with our Partners on how we can commercialize Tezepelumab. I have to say with the many years of

experience that AstraZeneca has in this therapeutic area, we continue to believe they're outstanding partner. We've worked through all the details of commercialization. AstraZeneca will indeed be putting up dedicated resources for the promotion of Tezepelumab. So think about different sales reps literally in the market promoting the two different products.

We will be handling many elements of the commercial process in the U.S. For example, we'll be lead on the market access negotiations and relationships, while AstraZeneca will lead on consumer marketing and professional marketing. So I think we've really put the best of the best together here and I continue to have a lot of confidence in the emphasis that our Partner is placing on this really exciting molecule, both for the launch and also just strategic lifecycle management ideas that they have as well.

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you.

A - Arvind Sood {BIO 4246286 <GO>}

Move on to the next question.

Operator

And your next question comes from the line of Ronny Gal from Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Good afternoon and thank you for taking my call. You've done really well with biosimilars. You're closing in on about $2 billion run rate from about $1 billion last year, I'm wondering about the balance for next year, you were seeing significant competition coming in on both the Avastin and Herceptin biosimilars. You're launching to yourself in rituximab and infliximab, but the dynamics seem to be potentially tougher. If we're going to think about the next 12 months, should we -- can we expect the same kind of growth rate or is this asking for too much? And then separately, Murdo, I was wondering if you can comment on Repatha outlook and how do you think about the competition with an RNA-based physician office based molecule?

A - Peter H. Griffith {BIO 4299061 <GO>}

Okay, thank you. And overall, I think the biosimilars business, as I said, has evolved really nicely and we've penetrated quite well. If I look at the oncology products in the U.S. running at 44% share currently on our Avastin biosimilar. I do think, as you see additional competitors come in the average selling price will come down. So that's a reality that competition brings and it's related to my comment earlier about this being an efficient marketplace. I do think there is an appreciation though for what we've done at Amgen which is to have a very effective provider-focused commercial presence the same people that are talking to accounts about our innovative portfolio are talking to those same customers about our biosimilars.

So all of our services that we normally have on an innovative product are available on biosimilars, and that includes patient services for things like reimbursement or co-pay assistance and I think that differentiates us. So I would anticipate us being able to continue to capture good volume albeit at some price erosion as we go into the new year. But as I said, we're at 44% share of of the total bevacizumab market and slightly less than that of the trastuzumab market. So there's still a lot of headroom for growth. And I think on the inflammation side, the dynamics are a little bit different depending on whether it's a product like our Remicade biosimilar (inaudible) or whether we're looking at a product like our Rituxan biosimilar. So I think we have to watch how we draw parallels on expectations. Overall, we made a big commitment to biosimilars. So we'll continue to advance new products through the clinic and into the market and we compete effectively across Europe and we're competing nicely so far in the U.S.

Just transitioning to Repatha. Look we've done I think an excellent job of converting to an affordable price of Repatha. We've got about 80% access coverage across Medicaid and commercial and we're seeing really nice volume growth with 60% in the quarter, and I think we're also seeing some nice evolution outside of the U.S. where Repatha continues to gain share.

The product -- really with Repatha, we are scratching the surface of those that need this. There is a lot of high-risk coronary event patients who require more aggressive with a lipid lowering therapy. And in light of COVID, I actually think that Repatha is a unique solution. It's a self-administered product with excellent coverage and well demonstrated efficacy and safety profile and we have event reduction data in the label. So I think compared to a product that might require patients to travel to a physician office for administration in light of COVID, that's going to be a tougher task for another product to come in. So, I feel good about where we are and I feel good about our growth prospects going forward.

Operator

Your next question comes from the line of Colin Bristow from UBS.

Q - Colin Bristow {BIO 17216671 <GO>}

Good afternoon and thanks for taking the questions. So another one on Sotorasib. I'm just curious like you have more data on this asset now, what's your current thinking around the potential to advance this to early or I guess first line therapy in light of the strong data we've seen some higher agents in the G12C patients? Thanks.

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

Yeah. No. Thanks, Colin, and great question. And of course as is typical in oncology development programs, you start in later lines of therapy where patients don't have much in the way of treatment options, but certainly moving into earlier lines of therapy will be part of the development program as we move forward. I would also point out that an important part of the program in later lines is the head to head Phase III trial against docetaxel chemotherapy. That is very important outside of the U.S. In some jurisdictions for regulatory approval, but also in many jurisdictions for our reimbursement. And so I

wouldn't also overlook the potential of that. This is a global development program and that's another important piece. Thank you.

A - Arvind Sood {BIO 4246286 <GO>}

April?

Operator

And the next question comes from the line of Mohit Bansal from Citibank.

Q - Mohit Bansal {BIO 18070890 <GO>}

Great, thanks for taking my question. Maybe one question on Tezepelumab and asthma. So as the data are coming up, how important do you think is to show the benefit in low U.S. patients in case if it doesn't work, do you think you're partner may not be interested in commercializing this product given that they already have a product for high EOS patients and they may have two competing for (inaudible)? Thank you.

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

Yeah, well, let me start and then I'll hand things off to Murdo. As we discussed, the primary endpoint is powered across the entire population and also the analysis plan allows a look in the low eosinophil group. In our Phase II data, which is currently our best predictor we showed relatively comparable efficacy regardless of eosinophil status and it certainly would be our hope that we're able to replicate that in Phase III. In terms of commercialization, let me ask Murdo to weigh in.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. As I mentioned before, there is a strategic commitment here from our partners for Teze. They've been very supportive constructive and helpful as we've worked through the development plan and now we look beyond to the commercialization and potential lifecycle management ideas and I think that there is a strong press from AstraZeneca to continue to really think about all of the patients that we can benefit with development of Teze. I would just say that there is a large market opportunity here in severe asthma. Having alternative mechanisms in the market and is a good thing and I think that there's plenty of room for us to launch effectively there and I'm pretty sure that's how of our Partners at AstraZeneca see it.

A - Arvind Sood {BIO 4246286 <GO>}

Okay, thank you. The next question.

Operator

And your next question comes from the line of Geoff Meacham from Bank of America.

Q - Geoff Meacham {BIO 21252662 <GO>}

Afternoon, guys. Thanks so much for the question. Murdo, I feel like I ask this one a lot, but on Aimovig, what do you think it will take for this product to really break out? I get it,li's growing on units. But for a new product, it looks range bound. Is there a meaningful negotiation with -- renegotiation with payers like you guys did with Repatha that's going to be required or what do you think it could take? Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, thanks, Geoff. Let's narrow or reframe the question. I don't think it's a payer issue. I think we've negotiated very good access for Aimovig. It's covered broadly with very little in the way of utilization management criteria. Physician requests are being filled very well. Our percentage of paid patients is very high now. We're in the high 80% range for patients. So it's not a -- an access restriction that's reducing the uptick of the class. There are really two things. One, is obvious, it's COVID. We are down substantially in new patients per week because of COVID and a lot of migraine sufferers unfortunately are just not seeking care. And neurology as as a prescribing specialty is down more than some others like cardiology recovered nicely in the quarter. Neurology is still down in terms of total prescribing. And that's the COVID impact.

And then there's another I think opportunity which we are focused on and that is to have both neurologists and patients moving quicker through older, less-effective preventative agents and to try biologic CGRPs like Aimovig, and that's really where our focus is for growth. We've seen movement there and it was going well, but we've got -- we've still got a lot of work to do, as you point out.

But we've got a large volume of patients, over $4 million. I think we're 15% penetrated into that patient population. So there is really no doubt in my mind that it will move. I also think, by the way the oral CGRPs are helping here with the promotional effort, communication of patients, awareness building of the benefits of the category. So they're acute promotion is also helping in the preventive space. But yeah, we are focused on that. I think we've done all the right things on the communications front to payers. Now we are focused on patients and patient -- providers and patients.

Operator

And your next question comes from the line of Kennen MacKay from RBC Capital.

Q - Kennan MacKay

Hi, thanks for taking a question and congrats on the quarter. Wondering or hoping rather that you could set the record straight for plagued[ph] with Omecamtiv mecarbil? Are there plans to pursue a regulatory filing for the insurance and if so, what is the gating factor? Thank you.

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

Thanks, Kennan. I'll take that. With Omecamtiv we issued the top line results. We've got data coming out with the American Heart Association in just a couple weeks, and I think in the wake of that we will be discussing next steps.

A - Arvind Sood {BIO 4246286 <GO>}

Okay, April. Let's take the next question please.

Operator

And your next question comes from the line of Umer Raffat from Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my question. I had two here, if I may. First, I know there's a lot of focus on the duration of response data as it's evolving in your Phase I and Phase II trial with KRAS. But my question is, as we think about one step out in a possible first-line setting, possibly as a PD-1 combination, we know what KEYTRUDA does as a first-line regimen on a duration of treatment and duration of response. I'm curious, what's your expectation that KEYTRUDA paired with a targeted therapy, how much improvement can we see realistically? That would be very helpful. Number one.

And also on that same note, as we head into the colorectal data in the first half knowing that there were I think 3 out of 25 responses in colorectal previously, what are your expectations on what we need to see to be more constructive on colorectal? Thank you.

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

Yeah, thanks, Umer. So, in terms of duration of response in and moving in earlier lines of therapy, it's very clear what the checkpoint inhibitors do. Typically you're going to look for 25%, 30%improvements on these sorts of efficacy measures to get into the clinically meaningful range. So as we're designing programs, those are the sorts of targets that we would generally look at.

In colorectal cancer, as I've mentioned before, we fully enrolled the Phase II trial data. Next year that will inform a potential monotherapy path forward. I would want to see response rates perhaps a little better than we've observed now for monotherapy, but that'll be a discussion with folks in the field. And here, I would say there is also just a huge amount of emphasis on combination therapy to both enhance the response rate and then of course to generate duration of response. As I mentioned earlier, we've got a number of combination trials, either up and running or about to launch and some of them are directed specifically for colorectal cancer. So we're really looking forward to generating those data. But I think that's the state of play right now.

Q - Umer Raffat {BIO 16743519 <GO>}

Thank you very much.

Operator

And your next question comes from the line of Alethia Young from Cantor Fitzgerald.

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys, thanks for taking my question and congrats on the quarter and the progress. Can you just talk a little bit about Otezla and what you've seen in light of maybe COVID-19? Would it be an oral? And I know is more kind of marketing, I guess on the television. Just wanted to get your outlook on price and volume over the next 12 months. Thanks.

A - Peter H. Griffith {BIO 4299061 <GO>}

Yeah. Thanks, Alethia. So we've been pleased with Otezla. We continue see all of our integration activities of bringing that product and being smooth uneventful, largely now under the management of Amgen employees around the world. And the field force continues to really do an outstanding job of making sure dermatologists understand the benefits of Otezla in the treatment of psoriasis and psoriatic arthritis. I think what we've seen in the quarter is a return to customer activity, largely about 90% of pre-COVID levels. The majority of those customer interactions are in the virtual realm, about 60% of those.

I think overall, we're pleased with the growth in volume in the quarter. We did see some one-time events, accounting adjustments. We had a favorable accounting adjustment in 2019 in Q3 and an unfavorable accounting adjustment in Q3 this year, creating an unfavorable compare quarter-over-quarter from prior year. And we are also seeing a bit of softness in the dermatology prescribing volume year-on-year on the basis of COVID. But I think the differentiation of having an oral versus biologics versus topicals in psoriasis is really helping us hold up well, and we continue to feel confident about our double-digit growth going forward. We've also held price nicely as we go into 2021. That's a good effect of having a differentiated product.

And then overall, I think as we look at sources of growth throughout the world, our international expansion plans have been going well. We secured reimbursement in Australia. Our Japanese business really is doing well and we're looking at reimbursement and market authorization in other markets. So, overall, it's been a really good growth story for us and we continue to feel good about the future. And then we will wait patiently to see if we're able to secure a mild to moderate indication next year because I think that's a patient population that could really benefit from the convenience of an oral and the safety profile that we've established of Otezla versus say more potent orals or even biologics.

Operator

Your next question comes from the line of Cory Kasimov from JPMorgan.

Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good afternoon, guys. Thanks for taking the question. Wanted to follow up on Otezla and ask about your baseline assumptions for tick 2 just given the proximity of that data in psoriasis? Those results are roughly are consistent with the Phase II data that's been published. How do you think about this potentially slotting into the market and the potential impact it may or may not have on the future trajectory of Otezla? And can you remind us whether the double-digit CAGR expectation you put out there for Otezla contemplates U.S. competition? Thanks a lot.

A - Peter H. Griffith {BIO 4299061 <GO>}

Yes. So I'll answer your second part of your question first Cory. The double-digit growth assumptions that we put out there did indeed assume the launch of other orals into the U.S. in a relatively similar timeframe as to what's been publicly disclosed. I think overall, as I was saying earlier, we feel really good about the position of Otezla in the market. It's a widely reimbursed product with really good market access, an affordable products from a patient perspective, a very safe product from an overall profile perspective, and I just think that new entrants into the category will not necessarily differentiate on efficacy or on safety right out of the gate.

I think it's going to take some time before dermatologists who are quite frankly leery of potent biologics or other products that might have efficacy, but that might travel with some safety concerns and that's not the case with Otezla. So this familiarity with Otezla, the unique positioning of it being the first product they go to post topical and pre-biologic, I think is going to hold up really well and we continue to invest heavily. Somebody mentioned they noticed more television advertising. We have ramped up DTC given COVID is somewhat disrupting patient behavior. And also in light of COVID, there are a lot of products in this category that require lab monitoring and Otezla doesn't. So a really good profile and I think one that will hold up well despite competition.

A - Arvind Sood {BIO 4246286 <GO>}

April is getting to the top of the hour. So let's take one more question, after which, Bob will make some closing comments.

Operator

And your last question will come from the line of Robyn Karnauskas from Truist Securities.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Great. Thanks for squeezing me in. I'll say on Otezla. So I know that the current topicals are not ideal with the side effect profile. Wondered if you could comment on the recent data for topinerov[ph] with a pathey[ph] score that looked on par with Otezla? And my specific question is more what percentage of Otezla use is with low surface involvement patients? And do you see these new topicals that are coming out potentially disruptive on a share or price basis? Thanks.

A - Peter H. Griffith {BIO 4299061 <GO>}

Yeah, thanks, Robyn. We really see these as unique segments of the market. The topical segment doesn't necessarily compete with the oral segment and we do see -- right now, we do see some low surface area usage. But I think as we look at our mild to moderate indication in the future,.I think there would be more potential overlap with say -- let's say more effective topicals for low surface areas and orals, but it's really -- it's not impeding our ability to grow and I don't see them as overlapping sectors. I think when patients say they want the convenience of an oral, it's a very clear choice to go to Otezla.

A - Arvind Sood {BIO 4246286 <GO>}

Bob, would you like to make any closing remarks?

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

Sure, just briefly. With nine or so weeks left in the year, we're encouraged that we continue to execute well. I think you see that in the numbers and in the progress we're making in our market shares and in our pipeline. But we know that this is a year unlike any other, so where we're trying to be prudent. As we look at the balance of the year and the beginning of next year, particularly as regards to the risk posed --the risks posed by COVID-19. So appreciate your joining our call. We'll look forward to seeing you or speaking to you in the New Year. And in the meantime, Arvind and his team are here for any questions that you might have. Thank you.

A - Arvind Sood {BIO 4246286 <GO>}

Thank you, everybody.

Operator

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