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# Q2 2021 Earnings Call

## Company Participants

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

## Other Participants

- Alethia Young, Analyst
- Allie Revlon, Analyst
- Andrew Galler, Analyst
- Brian Skorney, Analyst
- Carter Gould, Analyst
- Cory Kasimov, Analyst
- Dane Leone, Analyst
- Geoff Meacham, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Schmidt, Analyst
- Michael Yee, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Unidentified Participant, Analyst

## Presentation

### Operator

My name is Erica, and I will be your conference facilitator today for Amgen's Second Quarter 2021 Financial Results Conference Call. All lines have been placed on mute to prevent any background noise. There will be a question-and-answer session at the conclusion of the last speaker's prepared remarks. 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>}

Erica, thank you. Good afternoon everybody, welcome to our Q2 call. I think the three key themes for this quarter are great execution in a challenging environment, pipeline advancement and smart and strategic business development. Lots to cover, so let's jump right in. Slides are up, quick reminder that we'll use non-GAAP financial measures in our presentation and some of the statements will be forward-looking statements. Our SEC 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 Arvind and hello everyone, and thank you for joining our call. Through the first six months of the year, Amgen has continued to execute well, driving demand for our current products globally, while also paving the way for growth from future products. Total revenues in the second quarter increased 5% over the prior year and 11% over the prior quarter. We achieved this growth despite the lingering effects of COVID-19 and increased competition in many of our therapeutic categories.

We continue to see strong volume-driven growth from Repatha, Otezla, Prolia and EVENITY and a number of our oncology medicines as well, all of which address significant health challenges.

We also saw strong growth in the quarter from our biosimilars supporting our commitment to deliver value to healthcare systems around the world. We generated volume growth of 22% outside the United States and we're particularly encouraged by our progress in the Asia Pacific region where two notable approvals in the second quarter should provide additional growth moving forward. In China, our partner BeiGene secured approval for KYPROLIS which joins BLINCYTO and XGEVA in our oncology collaboration there and in Japan, the approval of Aimovig for migraine marks another important milestone for us in that market.

In the US, we're excited by the strong launch of LUMAKRAS which is providing hope to lung cancer patients in need of new treatment options. We are very pleased with the enthusiasm LUMAKRAS has generated in the oncology community. We're also excited that the FDA granted priority review to tezepelumab further confirming our belief that it offers significant advantages over currently available treatment alternatives for people with severe asthma, a debilitating disease that affects millions worldwide. We've long sought to complement our internal innovation efforts with the best available external innovation and in the first half of this year, we've executed on several compelling business development transactions, which fits squarely in our stated areas of interest. The

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acquisition of Five Prime Therapeutics and our partnership with Kyowa Kirin, for example, have added two potential first-in-class Phase III ready assets in cancer and inflammation to therapeutic categories where there remains high unmet need.

The acquisition of Teneobio, which Dave will address in a moment, will significantly strengthen our protein engineering capabilities across therapeutic areas. Our strong balance sheet and cash flows will enable us to take advantage of additional business development opportunities like these as they arise.

All the work we do is focused on advancing our mission to serve patients and to do so in a way that helps to address the many challenges facing society. You may have seen our recently announced plans to invest approximately $1 billion to build two new manufacturing facilities, one in North Carolina and the other in Ohio to meet the demand for our medicines.

Both facilities will utilize cutting-edge technologies to be much more efficient and environmentally friendly than traditional plants supporting our goal of achieving carbon neutrality by 2027. Both plants will also draw from very diverse talent pools as we, along with a number of other large companies that are part of the OneTen coalition, look to collectively hire one million Black Americans into well-paying jobs over the next 10 years. You can learn more about our commitment to good corporate citizenship by reading our ESG report, which can be found in the responsibility section of amgen.com.

Finally, before I turn things over to Murdo, let me thank my Amgen colleagues for their continued commitment to serving patients around the world and delivering strong performance across all aspects of our business. Murdo, over to you.

## **Murdo Gordon** {BIO 18450783 <GO>}

Thank you, Bob. Second-quarter product sales increased 3% year-over-year, volumes increased 8% driven by double-digit growth across a number of our products including Prolia, Repatha and our biosimilar products, MVASI and KANJINTI.

Our ex-US business grew 18%, with volume growth of 22% year-over-year. We continue to see gradual recovery from the impacts of the COVID-19 pandemic in Q2 when compared to Q1 2021. Patient visits and lab test procedure trends continue to improve, but remain below pre-COVID-19 levels.

We remain focused on customer execution. Overall, US field activity improved quarter over quarter reaching 80% of pre-COVID levels. Face-to-face customer interactions are increasing and accounted for 60% of activity during the second quarter. Over the course of the pandemic, the cumulative decline in diagnoses has suppressed the volume of new patients starting treatment, which we expect will continue to impact our business during the second half of the year.

Now, let me review some product details beginning with our innovative portfolio. In bone health, Prolia increased 24% year-over-year, driven primarily by volume growth. In the

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second quarter, osteoporosis diagnosis rates remained at approximately 90% of pre-pandemic levels. We remain focused on driving patient growth and are optimistic about Prolia strength in the second half of the year. EVENITY sales increased 30% year-over-year driven by 32% volume growth. In the US, sales nearly doubled year-over-year as we saw an acceleration in demand trends driven by new and continuing patients. We believe EVENITY's unique bone-building attributes will continue to drive revenue growth.

Moving to Repatha, which has reached more than one million patients since launch. Repatha sales increased 43% year-over-year driven by 49% volume growth and we maintain US and global share leadership in the PCSK9 class. In the US, total volumes grew 37% year-over-year and outside the US, volumes grew 66% year-over-year.

Volume growth in the quarter was partially offset by lower net selling price, resulting from an increase in Medicare Part D patients receiving Repatha and answering the coverage gap. Looking forward, we expect some ongoing reduction in global net selling price on a sequential basis.

Overall, we're confident in our ability to grow Repatha to help more patients at risk of developing a heart attack or stroke. Now onto Aimovig, which grew 24% quarter-over-quarter. On a year-over-year basis, net sales declined 16%, volumes grew 11% but were more than offset by lower net selling price and unfavorable changes to estimated sales deductions.

In the US, Aimovig TRx volume grew 7% year-on-year and the brand maintained total prescription share leadership among subcutaneous CGRPs. Looking ahead, we see continued rebate pressure as oral CGRPs compete per share in the market. To date more than half a million patients worldwide have been prescribed Aimovig and we believe Aimovig has significant potential to help many more patients suffering from chronic migraine given the clinical data that will be published soon showing Aimovig superiority versus topiramate.

Moving to our inflammation portfolio, Otezla sales were $534 million in the quarter with 5% volume growth more than offset by unfavorable changes to estimated sales deductions and lower net selling price. In the US, Otezla maintained first-line share leadership in psoriasis. New-to-brand prescription volumes grew 10% year-over-year, even as patient visits to dermatologist remained 15% below pre-pandemic levels.

The number of new patients who started treatment with Otezla in Q2 was near pre-pandemic levels but those gains were largely offset by a lower percentage of 90-day prescription fills and lower prescription refill rates for Otezla.

We expect that pandemic recovery in the dermatology segment will progress over the coming quarters. Looking forward, we're preparing for the anticipated approval of the mild-to-moderate psoriasis indication in the US later this year and for the launch of Otezla in China. Enbrel sales decreased 8% year-over-year primarily driven by lower net selling price and unfavorable changes to estimated sales deductions. On a year-over-year basis, volumes declined 1% supported by Enbrel's long track record of the efficacy and safety.

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Turning to biosimilars, Q2 sales were $567 million, driven by strong volume growth, which was partially offset by declines in net selling price. We continue to hold leading biosimilar shares in Europe for AMGEVITA and in the US for MVASI and KANJINTI. For the remainder of the year, we expect worldwide biosimilar volume growth to be offset by declines in net selling price due to increased competition.

Longer-term growth for biosimilars will come from expansion of existing products in new markets and launches of additional biosimilar molecules such as AMGEVITA in the US and biosimilars for SOLIRIS, STELARA and EYLEA. In oncology, Neulasta Onpro remains the preferred long-acting GCSF with 52% volume share in the quarter. Sales declined 18% year-over-year driven by lower net selling price and lower volume. This was partially offset by a $75 million year-over-year benefit from favorable changes in reimbursement mix. Neulasta's US average selling price declined 35% year-over-year and 12% quarter-over-quarter.

We expect this trend will continue throughout 2021 driven by intensifying competition. KYPROLIS sales increased 11% year-over-year primarily driven by volume growth and net selling price. Moving forward, we expect growth from KYPROLIS use in combination with CD38 antibodies including DARZALEX and SARCLISA.

I'd like to take this opportunity to comment on our recent (inaudible), which is off to a strong start with unaided brand awareness, increasing 20 points since launch. KRAS testing in patients with metastatic non-small cell lung cancer now stands at 70% and 46 of the top 50 testing labs now identify KRAS G12C as actionable in their lab reports.

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We're very pleased with the positive reaction from the oncology community and we'll be working closely with them to ensure access for patients who can benefit from this breakthrough medicine. Overall, I'm pleased with our Q2 execution given the sustained impact of COVID-19 on our business.

We will closely monitor the course of the pandemic and its impact on patient and physician behavior during the second half of the year. Maintain our focus on execution to ensure our medicines continue to reach the patients they can benefit. With that, I will turn it over to Dave.

## **David M. Reese** {BIO 19782623 <GO>}

Thanks Murdo and good afternoon everyone. We made several important advances in R&D last quarter. I will begin with our acquisition of Teneobio which will strengthen Amgen's leadership in developing engineered protein-based medicines to treat patients with serious illnesses. There are three important components to the acquisition.

First, Teneobio's core antibody technology will enable the development of multi-specific biologics directed against targets in a wide range of diseases across our key therapeutic areas. Teneobio's antibody platform offers capabilities complementary to our XenoMouse.

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It is genetically modified to express human IgG molecules comprising only a heavy chain. A small single chain antigen binding BH domains from these molecules are soluble and stable and can be easily strung together like beads on a string to generate multi-specific molecules.

In addition, Teneobio also brings a novel lower affinity CD3 engaging technology that complements our BiTE platform. The availability of a second CD3 engager will allow us to broaden our bispecific's capabilities and enable customization of the T-cell engaging domain depending on the disease and target.

Finally, we are acquiring clinical and preclinical oncology programs directed against high-value targets of interest, which we specifically selected based on our own discovery efforts and target validation.

These include a Phase 1 bispecific antibody for prostate cancer that complements acapatamab, AMG 160 also targeting PSMA and AMG 509 targeting STEAP1 which was recently granted Fast Track designation by the FDA.

Turning to oncology, we continue to advance LUMAKRAS registration around the globe with regulatory reviews and progress in multiple jurisdictions including Europe and Japan. Feedback from the medical community on the LUMAKRAS launch in the US has been overwhelmingly positive and I have heard personally from oncologists who are excited to have LUMAKRAS available and are heavily screening their patients for KRAS G12C mutations.

I'm pleased to report that more than 2000 patients have received LUMAKRAS across more than 1000 sites and 900 investigators or treating physicians, including to our global early access programs.

In the LUMAKRAS development program, we continue to advance our broad-based combination efforts. Initial data from our Vectibix combination in colorectal cancer had been accepted for presentation at ESMO in September and the MEK and oral EGFR combination abstracts will be submitted to a medical meeting in the fourth quarter.

To expand our LUMAKRAS experience with SHP2 inhibition along with our ongoing collaboration with Revolution Medicines, we have also entered into a collaboration with Novartis for SHP2 combination trial.

Updates from our monotherapy non-small cell lung cancer study including additional biomarker analyses as well as data in patients with stable brain metastases have been accepted for presentation at the World Congress on Lung cancer. Recall that we are also investigating LUMAKRAS in patients with active brain metastases. We also plan on initiating a Phase 2, first-line non-small cell lung cancer study in patients with PD-L1 negative and or STK11 mutant tumors in the third quarter.

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In the bemarituzumab program, we are having good discussions with regulators on the Phase 3 gastric cancer development path and plan to initiate a registrational program by year end. This will include two Phase 3 trials, one investigating utility of bemarituzumab in combination with chemotherapy and the other evaluating the addition of bemarituzumab to chemotherapy and a checkpoint inhibitor.

We are also planning a potentially pivotal Phase 2 study with Tarlatamab AMG 757 or half-life extended BiTE molecule targeting DLL3 for small cell lung cancer and we look forward to discussing next steps with regulators in the coming weeks.

I'm also pleased to report that we have completed enrollment in the castrate-resistant prostate cancer expansion cohort for Acapatamab or AMG 160.

In inflammation, continuing our leadership in dermatology, we are working closely with Kyowa Kirin to advance AMG 451, also known as KHK4083, a first-in-class OX40 antibody into Phase 3 for atopic dermatitis. We look forward to the presentation of the Phase 2 Atopic Dermatitis data at the Annual Meeting of the European Academy of Dermatology and Venereology at the end of September as well as initiating discussions with regulators on our Phase 3 development plans in the coming months.

In addition, the FDA accepted the Otezla supplemental filing for mild-to-moderate psoriasis. Finally, we and our partners, AstraZeneca, we're very pleased that the FDA granted tezepelumab priority review for the treatment of asthma reflecting significant unmet medical need. In closing, I would like to thank the entire organization for continuing to advance important medicines for our patients. Peter?

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## **Peter Griffith** {BIO 4299061 <GO>}

Thank you, Dave, and good day everyone. I will briefly walk through our second quarter financial results before discussing 2021 guidance. The second quarter marked another period of solid performance as we grew volumes 8%, increased investment in both internal and external innovation and delivered 4% year-over-year non-GAAP EPS growth. As stated earlier, Q2 revenues at $6.5 billion increased 5% year-over-year.

Other revenues at $412 million increased 38% year-over-year primarily driven by shipments of the COVID-19 antibody therapy to Lilly. We continue to expect full year 2021 other revenues to be in the range of $1.4 billion to $1.5 billion.

Second quarter total non-GAAP operating expenses increased 15% year-over-year as we continue to make investments to drive growth and maximize shareholder value. We expect full-year operating expenses including approximately $200 million of operating expenses related to the Rodeo, Five Prime and Teneobio acquisitions and also to the Kyowa Kirin collaboration on an absolute basis to increase about 6% to 7% over last year, while delivering a full-year operating margin of roughly 50%.

On a non-GAAP basis, cost of sales as a percent of product sales increased 4.1 percentage points on a year-over-year basis to 16.9% driven primarily by product mix including

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COVID-19 antibody shipments to Lilly as well as profit share and royalties. For the full year, we continue to expect cost of sales as a percent of product sales to be 16% to 17%.

Our cost of sales has increased as products with royalties and profit share payments have increased. As a reminder, a few of our products subject to royalties are Aimovig and biosimilars such as MVASI, RIABNI and KANJINTI, though subject to profit-sharing arrangements are EVENITY and tezepelumab upon approval and launch. Non-GAAP R&D spend increased 11% year-over-year due to investments in bema acquired in Q2 as part of the Five Prime acquisition and increased investments in discovery research. For the full year, we continue to expect non-GAAP R&D spend will increase as we progress our innovative early-stage and late-stage pipeline programs. For the full year, we expect non-GAAP SG&A spend to decline.

Non-GAAP other income and expenses were favorable by $146 million on a year-over-year basis due primarily to our portion of BeiGene's results which we record one quarter in arrears.

Q1 BeiGene results reflect the upfront payment BeiGene received in connection with the collaboration agreement. We expect our Q3 and Q4 non-GAAP other income and expense to be more in range with our Q1 and expect full year net expense in the range of $1.3 billion to $1.5 billion.

Now turning to the outlook for the business for 2021, we are excited by our pipeline. This innovation is augmented and balanced by the business development that we have announced this year. Based on underlying market dynamics and our investment plans, we are reaffirming our 2021 revenue guidance range of $25.8 billion to $26.6 billion and our non-GAAP EPS guidance range of $16 to $17, notwithstanding absorbing the roughly $200 million of operating expenses mentioned above related to business development activities including Five Prime, Rodeo, Teneobio and the Kyowa Kirin collaboration.

These ranges reflect uncertainty continuing in the second half of the year related to emerging variants. Patient visits and lab test procedure trends in the United States continue to improve, but still remain below pre-COVID-19 levels.

Our non-GAAP tax rate guidance remains unchanged at 13.5% to 14.5%. Our capital expenditure guidance remains unchanged at $900 million and our capital expenditures continue to reflect our investments in our manufacturing and related facilities including improving their environmental footprints, investments in digital technologies throughout our business and increasing ESG investments.

We expect share repurchases for 2021 to be in the upper range of $3 billion to $5 billion. This concludes the financial update. I'll turn it over to Bob for Q&A.

## **Robert A. Bradway** {BIO 1850760 <GO>}

Okay, Erica, let's open the lines for questions. Maybe you could remind our callers the procedure and are better for them to ask one question so that we have the opportunity to

get to everybody who has a desire to ask a question of us and I feel sure our callers would like to know that it's Arvind's birthday today, so bear that in mind when you ask questions of us here this afternoon.

Okay Erica, open them up.

# Questions And Answers

## Operator

(Operator Instructions) Your first question is from Yaron Werber with Cowen and Company.

## Q - Unidentified Participant

Hi, this is (inaudible) for Yaron, thanks for taking my question and congratulations on the quarter. My question is focused on the LUMAKRAS study in first line lung cancer in patients with low PD-L1 and-or STK11, could you just kind of talk about the, I guess, your benchmarks for historical comparisons in the STK11 and G12C co-mutants what you would use as you referenced there and any updates on your discussions with regulators in the past you mentioned that there could be a need for head-to-head studies in the future and what those could look like and what the comparison arms would be? Thank you.

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

Yeah, thanks, Dave. Yes. So, as we mentioned, as you pointed out, this study in first-line non-small cell lung cancer will be conducted in patients who are either PD-L1 negative or STK11 mutant. These are populations of patients of course who -- of patients who don't typically benefit from checkpoint inhibitors where there is really we think a lot of residual unmet medical need, in fact STK11 mutational status may help confer resistance to checkpoint inhibition, so that is the population that we're targeting. Whether this can be potentially registration enabling or not, I think it's too early to speculate. The FDA has generally been clear that in first line lung cancer, they wish to see randomized trials.

So one would have to anticipate having a pretty spectacular efficacy readout to lead to registration based on a single-arm Phase 2 trial. Obviously, if we saw compelling data, we would have the appropriate conversations going forward.

## Operator

(Multiple Speakers) Your next question is from Umer Raffat with Evercore ISI.

## Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys, thanks for taking my question. I just really wanted to focus on Arvind's age today?

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

You and me both 30 (Multiple Speakers).

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## Q - Umer Raffat {BIO 16743519 <GO>}

Congratulations, my question today was on KRAS and really around whether there is any, A, if you could just remind us what the plan for the interim is for the ongoing Phase 3 study, as well as whether there is any primary analysis limited to PD-L1 negative stuff that in particular, I'm quite intrigued that the first line Phase 2 trial is limited to PD-L1 negative or STK11. Thank you very much.

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

Yeah, in terms of the Phase 3 trial, I think the best way to think about that, Umer, is that we expect data in the first half of next year and given the general rapidity of progression of patients historically in second and third line lung cancer to standard therapy, the utility of an interim analysis may not be particularly useful, meaning the primary analysis often falls very quickly after an interim analysis.

So of course we'll take a look at that as to get a better sense in the second half of the year of the event rates but I would really point to the primary analysis in the first half of next year as the major event and then in first-line as I said, we think that there is significant unmet medical need in the PD-L1 negative, STK11 mutant and-or STK11 mutant population given the relative refractoriness of those tumors to currently available treatments and so we're very much looking forward to getting that study launch shortly and seeing the data readout will provide guidance on timelines as soon as enrollment is really underway.

## Q - Umer Raffat {BIO 16743519 <GO>}

Thank you.

## Operator

Your next question is from Jay Olson with Oppenheimer.

## Q - Jay Olson {BIO 18027199 <GO>}

Oh. Hey, happy birthday Arvind, and thank you so much for taking the questions. I'm curious about the combination data of LUMAKRAS with Vectibix, will that be in colorectal cancer only or should we expect to see combination data in non-small cell lung cancer and related to that, can you comment on the potential for that combination data to drive incremental use of Vectibix? Thank you.

## A - Arvind Sood {BIO 4246286 <GO>}

Thanks, Jay, given the regimen that we're studying you can expect that most of the patients that have been enrolled on that particular combination of LUMAKRAS and Vectibix will have colorectal cancer given the backbone of Vectibix here, although the trial is open across malignancies for treating physicians to enroll patients if they feel that regimen may be appropriate in terms of driving uptake of Vectibix, I don't want to speculate on that.

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Our job here is really to generate these combination data and see if, we think we can really drive things forward particularly in colorectal cancer.

## Operator

Your next question is from Salim Syed with Mizuho.

## Q - Salim Syed {BIO 16887281 <GO>}

Great, thanks so much for the question, guys, and I'll add my happy birthday Arvind. Me and you are both 30. So I just wanted to focus on the tax position, if I can, so it seems like this Notice of Deficiency was not just for one year, but it was for three years 2010, 2011 and 2012, so I'm just curious if there is a pattern here and how you guys are doing the accounting and is triggering these Notice of Deficiencies and I guess the underlying question here, should we be expecting Notice of deficiency or ease for 2013 through 2020 and then, just curious what the interest rate is that the IRS would impose here? Thank you.

## A - Peter Griffith {BIO 4299061 <GO>}

Salim, thank you. It's Peter and on your question around the IRS matters the dispute. Look, these notices are related to transfer pricing dispute with the IRS regarding the allocation of the profits between the US and the territory of Puerto Rico. So you can see we have a difference of opinion on the value of the significant risk and the complexity we undertake with activities performed at our Puerto Rico facility. We strongly believe the IRS's position is without merit and we have appropriate tax reserves and this dispute will take several years to resolve.

I would like to know Salim that Puerto Rico is our flagship manufacturing facility responsible for the majority of Amgen's global manufacturing. We're proud of our Puerto Rico operations, very proud of them and our colleagues there. We've had a major manufacturing presence in Puerto Rico for about 30 years. We have more than 2200 highly skilled colleagues in Puerto Rico, and who produce very sophisticated biologic medicines for patients all over the world with serious diseases.

We've invested nearly $4 billion to expand and modernize those facilities in Puerto Rico. And we're proud to be consistently recognized as one of the Island's best and most responsible employers. So on the matter of interest rate, I'll have to refer you to the IRS for that, but that's the IRS matter in brief.

## Q - Salim Syed {BIO 16887281 <GO>}

Okay, thanks so much.

## Operator

Your next question is from Terence Flynn with Goldman Sachs.

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## Q - Terence Flynn {BIO 15030404 <GO>}

Great, thanks so much for taking the question. Maybe another one for Peter, I was just wondering if you can comment on margins longer term. I noticed you called out that royalty and profit splits are going to be increasing here given some of the newer products you're launching, but how should we think about that 50% operating margin this year and the cadence on the forward? Thank you.

## A - Peter Griffith {BIO 4299061 <GO>}

Terence, thank you. And as always, we don't give long-term margin guidance, but what I -- and I'd really like to say our North Star around this, we always pause and think about our objective is to grow our after-tax cash flows for the enterprise versus targeting specific operating margin or OpEx growth rates. So we're going to continue to make prudent investments that lead to that objective.

So I would just note, we're continuing to invest in internal, external innovation, you've seen the fruits of that in the second quarter with the launches of new products, broader digitalization efforts. Secondly, we highlighted our expectation that R&D expenses are going to grow year-over-year as we increase our spend on AMG 160 and AMG 757 and dose expansion, we're going to rapidly advance those assets in prostate and small-cell lung cancer. We have three biosimilars in Phase 3, three inflam assets in Phase 2.

And third, I'll just note Terence that we're absorbing the upfront costs related to the acquisition of Rodeo as well as the cost of the Five Prime acquisition, our recent collaboration with Kyowa Kirin and our recently announced acquisition of Teneobio which we do expect to close in the second half of 2021. We also plan to rapidly progress these Phase 3 ready molecules and development bema and KHK4083. We began seeing higher manufacturing costs in Q2. Those were related to the Lilly COVID antibody efforts that adds to the OpEx built for the rest of year two.

But on a year-over-year basis, remember we're comparing as depressed spend in Q2 and Q3 2020 due to COVID. So at the end of the day, there is any number of financial metrics that we expect to be measured on by our investors and the analysts and we take pride in knowing that we want to end up really in the top of the group in terms of our operating efficiency. So that's very important to us, so you can rest assured that we'll continue to stay focused on that.

## Operator

Our 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 wondering if you could just comment on the IL-2 mutein, I know we're going to see some of the data here for SLE towards the end of the year, but it looks like you've started a Phase 2 and you're also looking at UC, just maybe broadly on the profile and what you think you need to generate Phase 2B to have that be a competitive asset?

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

Yes. Thanks, Matt. I'm glad you brought up AMG 592, our IL-2 mutein. Just to remind everyone, this is a molecule designed to enhance the number and function of T regulatory cells, some of the key modulatory cells in the immune system in many autoimmune diseases, the T regulatory access is out of black.

As you mentioned, we anticipate sharing Phase 1B data in lupus at a medical meeting towards the end of the year and we'll look forward to being able to share those data with you. In addition, a Phase 2 trial in lupus is actively enrolling now. And then finally, as you mentioned, Matt, we are launching a study in ulcerative colitis, another autoimmune disorder in which there is quite a bit of evidence of dysregulation of the T-reg access. So I think it's really the Phase 2 readouts here that will be critical as we accrue those data and as always we'll look to make sure that we are adding something to what is standardly available. In lupus, there remains very large residual unmet medical need, there was an approval within the last day or two of course, but only the second drug in 40 years and a very large patient population there is still requiring active medicines of ulcerative colitis, particularly for long-term remission, is also an area with substantial unmet medical need. So it's full speed ahead in the IL-2 mutein program, and we'll look forward to sharing these data with you.

## Operator

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

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

Afternoon guys, thanks for the question. And happy birthday Arvind. Commercial question on Otezla for Murdo. So when you look at the growth in the first half of this year, how much of a factor was COVID versus say competition or pricing? And do you think any of these headwinds could impact the upcoming launch when you look at the mild-to-moderate disease patient population? Thank you.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yes. Thanks, Geoff. I would say throughout the course of last year, we saw a slowdown in the number of bio-naive psoriasis patients moving into the market based on COVID disruption to patient visits and given that Otezla is an early option in the treatment of psoriasis, we were impacted by that, I would say more than the biologics, which tend to gain growth from Otezla and from each other. So that slowed down in the new patient diagnoses last year compounds into our growth rate this year.

The good news on the quarter is we saw new patient trends tick up. So we did see 10% growth in new patient, prescribed new-to-brand prescriptions in the quarter. However, this was somewhat offset by an increase in the number of patients that switched away from Otezla to another treatment and we think that that was pent-up treatment decision making that didn't happen because patients weren't going to see their dermatologist last year. There were some price reductions mostly related to our co-pay programs, but that's usually a good indication of new patients starting.

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So overall I would say it's primarily COVID impact. With respect to other products coming in, I'm not sure how to answer that. What I can say is, we continue to like our share position, share has held in the share of bio-naive psoriasis patients and we continue to feel optimistic about the growth of Otezla given the pending indication in mild-to-moderate patients, which should come, hopefully by the end of this year. Teams continue to execute well. Our field execution as I mentioned in my opening remarks is improving and we're very focused on making sure we continue to grow Otezla with the long haul.

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

Great, thank you.

## Operator

Your next question is from Ronny Gal with Bernstein.

## Q - Ronny Gal {BIO 15022045 <GO>}

Good afternoon and thank you for taking my question. Let's start with the immunology team here. You guys are developing both STELARA and Humira for 2023, 2024 biosimilars and given you're going to be in both sides of the innovator biosimilar world, I was wondering if you had a thought about kind of like the long-term trajectory of the pricing in the immunology market that is without giving specific numbers, kind of so we begin to see something along the lines of what we see with diabetes with an ongoing gradual price decreases, so like how do you think about this market longer term?

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## A - Arvind Sood {BIO 4246286 <GO>}

Great, Murdo, you want to respond to Ronny?

## A - Murdo Gordon {BIO 18450783 <GO>}

Sure. Thanks for the question, Ronny. I'm hesitant to go out too far. What we are seeing of course in inflammation right now is a lot of new entrants, a lot of new mechanisms and a lot of competition which is increasing the gross to nets that new entrants have to pay to secure access. We're also seeing increased management by the large national PBMs of national formularies as to which mechanisms get placed in a preferred status versus being held in reserve after patients fail in earlier lines of therapy.

So if we take rheumatoid arthritis as an example, I do see TNS continuing to entrench themselves in that first line position and novel mechanisms are likely to be in second and perhaps even third line after patients have failed to have resolution of their RA symptoms or improve the progression of their disease. In the biosimilar dynamics, I think we're seeing now the increase in interest from both payers and PBMs and providers given some of the trends that we're seeing with the early biosimilars in the inflammation category and I do think that interest and biosimilars will increase and I think that biosimilar penetration of parent molecule or originator molecule will accelerate with new entrants.

So we're expecting that to be the condition on the ground by the time we launch Amgevita in the US, but overall I would just come back to the strength that we have as a company given our portfolio of innovator, an originator molecules enhanced with the presence of our biosimilar portfolio and I think that affords us an opportunity to serve many patients across a host of autoimmune diseases, as well as serve providers, payers and PBMs with a lot of value to deliver to the healthcare system.

FINAL

## Operator

Your next question is from Geoffrey Porges with SVB Leerink.

## Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much for taking the question. I'll continue with the biosimilar brands, specifically on denosumab, what are you thinking in terms of the first biosimilar coming in for denosumab and then, would you expect the erosion trajectory for branded Prolia and XGEVA to be similar to, for example, Neulasta or to the erosion of the oncology biologics or would you expect it to be more gradual or fast, I am just wondering what you think the trajectory will look like?

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

Thanks, Geoffery for the question. I would say it's again hard to project into the future as to how healthcare systems, payers and providers will change in their adoption of biosimilars, but I think given that denosumab is a Part B product, the oncology biosimilar curves would be a close approximation (inaudible).

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## Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you.

## Operator

Your next question is from Michael Yee with Jefferies.

## Q - Michael Yee {BIO 15077976 <GO>}

Hi guys, thanks for the question. We had a two part for David on KRAS, you have upcoming data for MEK plus or minus EGFR, just wanted to understand in the context for how to interpret that data, what is good data and is the goal to significantly increase response rate in PFS beyond LUMAKRAS alone maybe just help us right size, how to think about that study and you also announced that you expanded a combination with the Novartis SHP2, is that just diversifying and spreading it around or how to think about SHP2 if you have done a second collaboration there? Thank you.

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

Thanks, Michael, let me start with the second part first. You're exactly right that simply diversifying our experience, we're moving forward, as I noted with both revolution

medicines combination as well as this new collaboration with Novartis when we'll look forward to both datasets.

In terms of the MEK or EGFR combination, so as I've said before in terms of response rate. It's going to vary by line of therapy and indication in terms of what sort of increments that you want to see, but generally 10%, 20%, 30% are relative improvement in response rates and progression-free survival, certainly beyond first line is typically what we would want to see and those are the rough sort of benchmarks that we'll use. Now, these first cohorts of course the critical thing upfront to safety in determining appropriate doses and then moving into expansion cohorts for efficacy. Thanks again.

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## Q - Michael Yee {BIO 15077976 <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 happy birthday to one of the best in the IR game, here's to you Arvind.

## A - Arvind Sood {BIO 4246286 <GO>}

Thank you Alethia.

## Q - Alethia Young {BIO 17451976 <GO>}

I wanted to get a little bit of flavor on the Repatha and I know you're seeing very nice volume growth but like continued kind of pricing pressure or discounting pressure, do you think we're kind of hitting a stabilization but I know you talked about little bit of sequential deceleration but if you can give us some flavor on how to think about when that might start to right size and stabilize and see real growth from the volume that you're generating?

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

Thanks for Alethia. We are quite happy with the performance of Repatha and if you know to really treat how a large number of patients we reached a million patients now with Repatha, so quite a milestone. The overall dynamic that is dragging price down is really a US Part D patient dynamic as patients enter into the coverage gap or as we sometimes refer to the donut hole and as we expand our percentage or share of business in the Part D or Medicare Part D business and segment of the market, we will see some negative price drag quarter over quarter, now that it's not going to be as precipitous as the price changes that we've made historically, so our volume is outpacing that and we will see that drop to the net sales line.

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So overall good evolution, we're also seeing nice growth on Repatha ex-US where price is relatively stable year-on-year, so that part of the mix is helping bolster price evolution over time as well, but some slight drag will continue but again, it's a good sign, because it means we're expanding that Medicare pool of patients much more rapidly than we did historically.

## Q - Alethia Young {BIO 17451976 <GO>}

Great, thank you.

## Operator

Your next question is from Kennen MacKay with RBC Capital Markets.

## Q - Kennen MacKay {BIO 18821382 <GO>}

Hey, thanks for taking the question. Maybe just would love to get a perspective on which combinations you're most excited about currently for LUMAKRAS whether it's more in line with previously with the oral and antibody MEK inhibitors to the mTOR inhibitor maybe or with the Novartis collaboration, does the SHP2 now takes the top seat and then just one quick question on the biosimilar pipeline, when do you see as the earliest that you might be able to launch your biosimilar EYLEA, a ABP 938. Thanks so much and congrats on the birthday, Arvind.

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

Yeah, maybe I'll start with the question on combinations. Of course the ones we like the best are the ones that work and that's what we're testing right now. It would actually -- all of these combinations have been selected for one or another reason or both one and most importantly biologic plausibility, so reason to believe in either additive or synergistic effects and then two, if combining molecules are part of a background regimen and so we think we're really covering the waterfront in terms of indications of interest with relevant combinations here and at this point, I think it's really empirical matter of generating the data in the course, we will share that as we've outlined.

## A - Murdo Gordon {BIO 18450783 <GO>}

And Kennen and we haven't announced our timing on EYLEA but we are moving quickly in the enrollment of that program and we anticipate being early in the sequence of launches for that product.

## Q - Kennen MacKay {BIO 18821382 <GO>}

Fair enough. Thanks Murdo, thank you very much.

## Operator

Our next question is from Carter Gould with Barclays.

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## Q - Carter Gould {BIO 21330584 <GO>}

Thank you, good afternoon, I'll pass on my happy birthday wishes to Arvind too. I wanted to ask on your OX40 program. I know it's moving into Phase 3 next year, just wanted to see any further color on the population or dosing you're looking to move forward with in the Phase 3 and if the lingering uncertainty over the JAKs is in any way changed or evolved your underlying assumptions around that market would be helpful? Thank you.

FINAL

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

Thanks, Carter. We're very enthusiastic about this molecule, atopic dermatitis is a disease of widespread prevalence actually global populations. Despite existing therapies, we think there is a very large amount of residual that medical need patients often cycle through therapies given the novel mechanism of action you're targeting the OX40 pathway. We think there is quite a big opportunity to have a real impact in this field, as I mentioned we will be presenting the Phase 2B data at the end of September at one of the major European Dermatology meetings and I think there, you know, you'll get a sense of our thoughts on dosing and what things may look like going forward. And of course, as we have discussions with regulators, we will outline our plans on the Phase 3 program, which will in all likelihood be a suite of studies.

Let me ask Murdo to comment a little further here.

## A - Murdo Gordon {BIO 18450783 <GO>}

Yes, and Carter, we obviously pay close attention to the JAK safety concerns as raised on the Xeljanz data and applied some reduction in JAK penetration assumptions to the AD market when we were evaluating the attractiveness of the OX40 asset. And I think that was one of the drivers here, the biologics still have a large role to play. We think initially the OX40 asset will establish perhaps a second line opportunity in the market and we can expand from there, but the portion of the market that we think will be addressed by JAKs is probably smaller than was once considered.

## Operator

Your next question is from Cory Kasimov with JPMorgan.

## Q - Cory Kasimov {BIO 3009346 <GO>}

Hey, good afternoon guys. Thanks for taking my question. And most importantly, happy birthday to Arvind. Wanted to go back to the line of questioning around the LUMAKRAS combination work and ask specifically about what you're doing with PD1s at this point when you expect to have an update there and is it really still just about trying to figure out the dosing currently before you move forward? Thank you.

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

Yes. Thanks, Cory. As we've discussed before, we're looking at both direct combinations in sequential therapy here, so I think you can see -- you can expect to see data from both of those, some time through the first half of next year or so as we accumulate enough

data to define what the relevant (inaudible) forward is with checkpoint inhibitors. So more to come there, but we continue to actively work on these development programs.

## Q - Cory Kasimov {BIO 3009346 <GO>}

Okay. Thank you, David.

## Operator

Your next question is from Chris Raymond with Piper Sandler.

## Q - Allie Revlon

Hi, this is Allie Revlon for Chris this afternoon. Thanks for taking our question. Just on PD, you have had a lot of activity in the oncology and inflammation space. Just any color on how you're prioritizing other areas of interest on the development side versus opportunity to bolster some of your more legacy commercial franchises like renal and then maybe more specifically on renal, how are you thinking about your longer-term strategy or prioritization for investing in the franchise, be it through internal or external innovation. Thanks.

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

Yeah so, Allie, I'll just repeat what I've said many times before, which is that our business development efforts are focused in the areas where we have ongoing strong research presence and-or commercial presence. So you're right, we've been active in oncology and in immunology area, we continue to look for opportunities in both those spaces as well as in general medicine and to the extent that we see things that we think we're going to add value to nephrology or bone health or in the migraine area, we will look there as well. So we have active efforts underway and we look again across the marketplace actively with a focus on how we can earn a return for our shareholders from the assets that we might license to acquire.

Sorry just quickly, I don't think I addressed your nephrology question. We don't have as much active research in nephrology and bone at the moment and because we haven't seen internally opportunities to advance novel therapies there and we think the medicines we have are addressing the needs in the marketplace very effectively, but that's the extent that there are things outside of Amgen that fit well with our 30 years of leadership, for example, in nephrology or with our global leadership in bone that we pay close attention to that as well.

## Operator

Your next question is from Dane Leone with Raymond James.

## Q - Dane Leone {BIO 15203956 <GO>}

Hi, thank you for taking the questions. And my congratulations to Arvind. Hope you have a fun birthday tonight after the call. So I'll keep it brief. My question is on tarlatamab,

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question for me here is, what you guys thinking to see as you're planning for this Phase 2 study, obviously initial data seemed encouraging from the first 52 patients you had earlier this year, but where do you want to think about positioning this drug in the different lines of small cell lung cancer now, and what have you, maybe, seen as the dose escalation studies progressed since maybe we've seen in the last data update that has you thinking about a pivotal study now. Thank you.

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

Yes, thanks Dane, I think to take the last part of your question, what we've seen or ongoing response rate consistent with the data that you saw from the later cohorts that we presented month or two ago. And in addition, we've actually been impressed with duration of response. Most of these patients are third line plus, which as you know is a very aggressive disease in small cell lung cancer and durable responses here are vanishingly rare. So that I think is in addition, what really gives us encouragement here.

As we discussed, potential registrational path with the FDA in the coming weeks, I think we'll focus on the patient population. But I think the initial foray is likely to be those later lines of therapy. We are moving forward in our development program now and are actively investigating earlier lines of therapy as well that is clearly the end game that we're pointing for with tarlatamab and given this sort of activity that we're seeing in the clinic right now.

## Q - Dane Leone {BIO 15203956 <GO>}

Thank you.

## Operator

Your next question is from Michael Schmidt with Guggenheim.

## Q - Michael Schmidt {BIO 3870043 <GO>}

Hi guys. I have one more on LUMAKRAS. Thanks for taking my question and Arvind congrats will be as well. So I guess it should hypothetically -- should be efficacy, safety profile of the LUMAKRAS PD-1 inhibitor combinations turn out to be insufficient which I guess could be possible. What are other likely avenues to possibly enable access to a broad first line KRAS non-small cell lung cancer indication? Should we think about potential chemo combinations or are there others that are logical come to mind? Thanks so much.

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

Yeah. Thanks, Michael. I think you're exactly right, with these chemotherapy combinations, number one and then going into biomarker selected populations as we've discussed in terms of our planned upcoming first line, which we'll be launching shortly. And so, should checkpoint inhibitor combinations not be feasible. I would expect that we would piece together other routes to first-line to find patients who are most likely to benefit.

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## Q - Michael Schmidt {BIO 3870043 <GO>}

Great, thanks.

## A - Peter Griffith {BIO 4299061 <GO>}

Eric, as we're pushing up against the top of the (inaudible) why don't we take our final two questions.

## Operator

Your next question is from Brian Skorney with Baird.

## Q - Brian Skorney {BIO 15993204 <GO>}

Hey, good afternoon everyone and thanks for taking my question. And happy birthday Arvind. Digging a little more on the disclosed Notice of Deficiency that I think last year you also received modified RAR related to 2013 through 2015 and are also under investigation for 2016 through 2018 by the IRS and It just seems like there is all related to issues around profit allocation in Puerto Rico. So I was wondering if you just kind of walk through the next steps in terms of the tax court petition -- can the petition to be heard in tax court fail and if it does go to court and decision goes against you, does that sort of established precedence for the other years as well and based on the IRS calculation methodology for 2010 for 2012, have you run that same calculation to establish what an upper bound of liability for 2013 through now would be?

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

Brian, thanks for the question. Look, we filed a petition with the US Tax Court in this case, could take several years to resolve. The IRS is also proposing significant adjustments to 2013 to 2015 related to the similar issues as you know. We disagree, strongly disagree with the proposed adjustments. We're pursuing resolution with the IRS administrative appeals offs on that. The IRS as you noted they are currently auditing years 2016 through 2018. So yes, we're sure they'll take the same position for the other periods under audit. We believe that we have adequate reserves for that.

## Q - Brian Skorney {BIO 15993204 <GO>}

Great, thank you.

## A - Peter Griffith {BIO 4299061 <GO>}

And let's go to the final question.

## Operator

Your final question is from Tim Anderson with Wolfe Research.

## Q - Andrew Galler {BIO 19444177 <GO>}

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Yes. This is Andrew Galler on for Tim. I just wanted to ask one question on teze. So given your partner, AstraZeneca officially discontinued atopic dermatitis last week, do you have any impact on your competitive positioning, especially in eosinophilic asthma duty given the high coincidence of these atopic conditions?

## A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, I mean I think the short answer there is no and we remain extremely bullish about tezepelumab given its activity across a range of patients with asthma regardless of eosinophil count. As we mentioned, we were granted priority review by the FDA clearly an acknowledgment of the potential fit of this medicine with a large residual unmet medical need.

So you know that doesn't really give us positive all, Tim.

## A - Peter Griffith {BIO 4299061 <GO>}

Okay, Erica let me just thank our callers for joining the call today. We're excited about the second half of the year, lot going on here and so we look forward to having the opportunity to gather with you in October and update you on the next quarter. I appreciate your interest in Amgen. Thank you.

## A - Arvind Sood {BIO 4246286 <GO>}

Thanks everybody.

## Operator

And this concludes Amgen's second quarter 2021 financial results conference call. You may now disconnect.

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