



## **AMGEN TRANSCRIPT OF FOURTH QUARTER AND FULL YEAR 2022 EARNINGS WEBCAST**

**January 31, 2023**

### **Operator**

My name is Jason, and I will be the conference facilitator today for Amgen's Fourth Quarter / Full Year 2022 Financial Results Conference Call. I would now like to introduce Mr. Arvind Sood, Vice President of Investor Relations. Mr. Sood, you may now begin.

### **Arvind Sood Vice President, Investor Relations**

Okay. Thank you, Jason. Good afternoon, everyone, and welcome to our call to discuss the results for Q4 and full-year 2022. 2022 was once again a year exemplified by great execution despite some of the macro challenges. Our Chairman and CEO, Bob Bradway, will make some opening comments, followed by prepared comments from other members of our senior leadership team.

You should have received a link to our slides that we have posted. Through the course of our discussion, we will make some forward-looking statements and use non-GAAP financial measures to describe our performance, and just a reminder that actual results can vary materially. So, with that, I would like to turn the call over to Bob.

### **Robert Bradway Chairman and Chief Executive Officer**

Okay. Thank you, Arvind, and hello, everyone, and thank you for joining our call. So, beginning the year feeling confident about the long-term growth outlook for our business, and let me offer 5 reasons why. First, we have a number of innovative volume-driven products that still have plenty of room to run, and we saw that in 2022. Repatha, Prolia and EVENITY each generated double-digit sales and volume growth in the fourth quarter and for the full year. We expect continued growth from these products in 2023 and beyond with Repatha, in particular, helped by important new data from the FOURIER open-label extension study and new prescribing guidelines.

OTEZLA delivered 7% volume growth in both the fourth quarter and the full year, benefiting from a label expansion that gives us the opportunity to reach millions of new patients in the U.S. with mild to moderate psoriasis. LUMAKRAS and TEZSPIRE collectively contributed more than \$450 million in full year sales, and we're pursuing additional indications for both products. We're especially pleased to see

TEZSPIRE being utilized by patients across all types of severe asthma. Murdo will share more about the performance of our in-line products in a moment.

Second, we moved 6 first-in-class molecules into Phase 3 or potentially registration-enabling trials in 2022, including Olpasiran for LP(a), rocatinlimab for atopic dermatitis, TEZSPIRE in eosinophilic esophagitis, and of course, bemarituzimab, tarlatamab and BLINCYTO for cancer. We've also begun enrolling patients in a Phase 2 trial for AMG 133. Based on early data, this molecule, with its unique mechanism of action, looks like it may have an attractive profile for the treatment of obesity. And more on our pipeline from Dave Reese in a moment.

Third, we have an industry-leading biosimilars business that will contribute to our growth over time. In 2022, we delivered positive Phase 3 data for our biosimilar candidates to EYLEA, SOLIRIS and STELARA, positioning us to be in the first wave of these launches, which we know is critical to success. We're also less than 24 hours into the launch of AMJEVITA in the U.S., and AMGEVITA is the leading biosimilar to HUMIRA internationally. And with a 5-month lead over the next entrant, we're well positioned for success in the U.S. All told, we have six more biosimilar launches planned in the U.S. and markets around the world between now and the end of the decade, making this another source of long-term growth for us.

Fourth, we've often said that we would look to licensing and acquisitions in our stated areas of strategic interest. And that's what we've done, building on our decades of experience in inflammation with 2 significant transactions that will strengthen our presence in this space. Through the acquisition of ChemoCentryx, we added TAVNEOS, a first-in-class treatment for ANCA-associated vasculitis, and we're off to a strong start there. Our announced acquisition of Horizon Therapeutics will add several additional first-in-class early in life cycle biologic medicines, including TEPEZZA, KRYSTEXXA and UPLIZNA that will add to our growth profile through 2030 and beyond. We're working our way through the regulatory review processes for that deal and are confident that the deal poses no anticompetitive matters. And we have received a second request from the U.S. FTC, and we'll work with them to answer their questions while remaining optimistic that we can complete the deal in the first half of year.

Finally, we've stayed true to our capital allocation priorities, investing in our business to drive long-term growth while also returning capital to our shareholders through share repurchases and a growing dividend. You'll hear more from Peter on this shortly. And everything we achieved last year and everything we will achieve going forward is due to the hard work and commitment of our people. They're passionate about our mission to serve patients. They're clear on how their work contributes to our success, and they're ready to seize the opportunities and meet the challenges that await us. I'm grateful to all of them. I look forward to your questions a little later on, but now let me turn the call over to Murdo.

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Thanks, Bob. 2022 was another year of strong execution of our mission to bring innovative products to the millions of patients in the world who suffer from grievous illness. The evolution of our portfolio continued, driven by record sales for 16 brands. We saw strong volume gains across our general medicine and hematology-oncology growth brands. Our inflammation therapeutic area expanded with the launch of TEZSPIRE and the acquisition of TAVNEOS, 2 first-in-class medicines that treat serious disease.

In addition, our announced acquisition of Horizon Therapeutics will add several important medicines to our portfolio. In total, volume growth for 2022 was 9% with 7% growth in the U.S. and 14% growth ex U.S. as we continue to deliver on our international growth strategy. Excluding the impact of foreign exchange, full year global product sales grew 4% as our volume increases were offset by a 5% decline in net selling price, including the 2% negative foreign exchange impact, product sales increased 2% year-over-year.

In the quarter, we also saw strong volume growth with a 10% increase year-on-year.

Starting with our general medicine business, which includes Prolia, EVENITY, Repatha and Aimovig, overall revenue for these four products grew 21% year-over-year for the fourth quarter and 18% for the full year, driven by 19% and 21% volume growth, respectively. In bone health, Prolia sales grew 14% year-over-year for the fourth quarter, driven primarily by 11% volume growth. EVENITY, which complements Prolia in our bone portfolio, had record sales of \$225 million for the quarter, driven by strong volume growth across markets. Repatha sales increased 22% year-over-year for the fourth quarter with volume growth of 31%, partially offset by lower net selling price. In the U.S., we generated volume growth of 32% for the fourth quarter, aided by broad adoption of Repatha by cardiologists and increasing adoption by primary care providers. We saw declining net selling prices in the U.S. as we offered higher rebates to support broad Medicare Part D and commercial patient access. Looking ahead to 2023, we expect less year-over-year U.S. price erosion than we saw in 2022.

Outside the U.S., fourth quarter sales of Repatha grew 36% year-over-year, driven by 31% volume growth. Globally, Repatha has treated over 1.5 million patients since launch. Repatha's strong prescribing history in cardiology and expanding use in the primary care setting position us well to bring Repatha to more patients globally. With the FOURIER long-term follow-up data, in addition to evolving and more aggressive treatment guidelines, there's a clear rationale that lowering LDL cholesterol as much and as early as possible with Repatha will reduce cardiovascular risk for patients around the world.

Transitioning to our inflammation portfolio. Otezla sales decreased 2% year-over-year for the quarter and increased 2% for the full year. We saw 7% volume growth in both periods. This was offset by lower net selling price, stemming from enhancements to our co-pay and patient assistance programs to support new patients starting treatment as well as additional rebates to improve the quality of coverage. During the fourth quarter, our U.S. Otezla business was impacted by new patient demand from free drug programs by newly launched topical and systemic competition. We expect that impact to continue in Q1 of 2023.

We also expect to see the typical pattern of lower sales in the first quarter relative to subsequent quarters due primarily to the effect of insurance reverifications, co-pays and deductibles for patients. The combined effect could lead to first quarter Otezla sales being similar to or below those from Q1 of 2022. Longer term, we continue to see strong growth potential for Otezla, given its established safety profile, strong payer coverage with limited prior authorization requirements and ease of administration. Otezla remains the only approved oral systemic therapy with a broad indication and is well positioned to help the 4 million U.S. patients with mild to moderate psoriasis, 1.5 million of whom have psoriasis that cannot be optimally addressed by a topical and can benefit from a first-line systemic treatment like Otezla.

ENBREL sales decreased 1% year-over-year for the fourth quarter, driven by declines in volume and net selling price, partially offset by higher year-end inventory levels. ENBREL remains an important product for patients due to its long track record of efficacy and safety. TEZSPIRE continues its strong launch with \$79 million in sales in the fourth quarter and \$170 million for the full year. Allergists and pulmonologists have prescribed TEZSPIRE across a broad range of patients with severe uncontrolled asthma. We're also seeing initiation of TEZSPIRE in both biologic-naive and previously treated patients. Physicians acknowledge TEZSPIRE unique differentiated profile and has broad potential to treat the 2.5 million patients worldwide with severe uncontrolled asthma without any phenotypic and biomarker limitations. We're now preparing for the anticipated U.S. approval of the prefilled pen in the first quarter, which will offer patients the convenient option to administer TEZSPIRE at home.

Sales of TAVNEOS were \$21 million in the fourth quarter. Our integration of ChemoCentryx is proceeding smoothly, confirming our belief that Amgen's deep experience in inflammation and nephrology and substantial market presence will allow us to bring TAVNEOS to more patients with ANCA-associated vasculitis.

We're also excited about our announced acquisition of Horizon Therapeutics. Our combined portfolio, which will include TEPEZZA, KRYSTEXXA and UPLIZNA will address serious inflammatory diseases and improve the lives of many patients. Amgen's commercial capabilities and global presence in approximately 100 markets will allow our combined team to deliver important therapies that will make a meaningful difference for more patients globally.

Today, we announced the launch of AMJEVITA, the first U.S. biosimilar to HUMIRA, a medicine used by more than 1 million patients living with serious inflammatory diseases. With our track record of developing and manufacturing biologics and decades of experience in inflammation, Amgen is uniquely equipped to supply patients with this biosimilar medicine. AMJEVITA is the first significant U.S. biosimilar in pharmacy benefit space, and we expect gradual uptake in the coming months as this market evolves.

Moving to our hematology and oncology business, which includes LUMAKRAS, KYPROLIS, XGEVA, Vectibix, Nplate and BLINCYTO. These six innovative products grew 14% year-over-year with 17% volume growth for the quarter. Full year sales grew 13%, driven by volume gains. KYPROLIS sales grew 14% in the fourth quarter. Nplate sales in the fourth quarter included \$207 million related to a onetime order from the U.S. government. Given the strong performance of our hem/onc portfolio in 2022 and the recent positive data on both BLINCYTO and Vectibix, I look forward to the future growth potential of this portfolio.

LUMAKRAS reported \$71 million in sales in the fourth quarter and \$285 million for the full year. Quarter-over-quarter sales declined 5% with 12% volume growth, more than offset by a lower net selling price driven by a \$12 million unfavorable price adjustment resulting from a reimbursement approval decision in France and unfavorable changes to estimated sales deductions. Outside the U.S., LUMAKRAS has now been approved in over 45 countries. We've launched LUMAKRAS in 30 markets and are rapidly pursuing reimbursement in the remaining countries. As we've noted before, the market for LUMAKRAS focused on the 7,000 U.S. and 20,000 ex U.S. patients in the second-line setting. Longer-term, we expect LUMAKRAS growth to come from moving into earlier lines of therapy and expanding into additional tumor types.

Sales of our oncology biosimilars declined 40% year-over-year for the for the fourth quarter and 30% full year, driven by lower price. While our biosimilars for MVASI and KANJINTI both hold leading shares, we expect continued net selling price deterioration and accelerating volume declines, driven by increased competition. The most recently published average selling price in the U.S. declined 38% year-over-year for MVASI and 51% for KANJINTI. Over time, we expect long-term growth in our biosimilars business to be driven by the addition of new molecules and additional launches.

And as we start the New Year, I'm inspired by the hard work of the thousands of Amgen employees around the world who wake up every day to serve our patients. Our expanding international presence and diverse portfolio of products, further strengthened by the integration of ChemoCentryx and the announced acquisition of Horizon, position us well to serve many more patients globally. And with that, I'll turn it to Dave.

**David Reese**  
**Executive Vice President, Research and Development**

Thanks, Murdo. Good afternoon, everyone. For research and development, last year was one of high-quality execution and on-time delivery of results as we continued to progress our innovative pipeline. In general medicine, we strengthened our cardiovascular franchise and emerging portfolio of obesity assets, 2 areas of significant unmet need, affecting millions of patients globally.

Repatha, of course, is the cornerstone of these efforts. And last November at AHA, we presented FOURIER open-label extension data. These data were recognized by the American College of Cardiology expert consensus decision pathway, which indicated there appears to be no LDL cholesterol level below which benefit ceases. Additionally, LDL cholesterol recommendations were updated to reflect a reduction in target LDL levels in highest-risk patients from 70 to 55 milligrams per deciliter. This is a level that is not attainable for a large number of patients without PCSK9 inhibitor therapy.

Another molecule that we are excited about is olpasiran. At AHA, we presented Phase 2 data where Olpasiran dosed 75 milligrams or higher every 12 weeks reduced Lp(a) concentrations by 95% to 100% in patients with established atherosclerotic cardiovascular disease with baseline Lp(a) levels of approximately 260 nanomoles per liter. Olpasiran appeared both safe and well tolerated in this study. We are encouraged by these data, particularly our dosing frequency, safety and tolerability profile degree of Lp(a) reduction. We have initiated a Phase 3 outcome study and 6,000 subjects with atherosclerotic cardiovascular disease and significantly elevated Lp(a) levels of at least 200 nanomolars per liter.

Now, turning to obesity. In December, we presented data from a Phase 1 study where AMG 133 appeared safe, well-tolerated and demonstrated a 14.5% reduction in body weight at day 85 following 3 monthly subcutaneous injections. Body weight reductions were observed up to 150 days after the final AMG 133 administration. Given these favorable attributes, we are now enrolling a 570-subject Phase 2 study to explore AMG 133 in patients with obesity with or without diabetes and related comorbidities. The study will also investigate different dosing levels and regimens.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

We understand that our vendor lost the primary line and the backup line, so we've gone to an alternative, which is this Webex. Again, apologies for the disruption. Let's ask Dave Reese to pick up where he left off before the call was interrupted, which was the summary of AGM 133. Dave, over to you.



**David Reese**  
**Executive Vice President, Research and Development**

Thanks, Bob. Beyond AMG 133, we have other obesity molecules in our portfolio including AMG 786, a Phase 1 small molecule, plus multiple preclinical compounds, all with different mechanisms of action other than GLP-1 or GIPR based therapies. Turning to Inflammation, we're excited about the recent CHMP approval of TEZSPIRE for self-administration in a pre-filled, single-use pen. Beyond severe asthma, we are investigating additional indications, including two Phase 3 studies in chronic rhinosinusitis with nasal polyps and in eosinophilic esophagitis; the latter was initiated in 2022. We also have two Phase 2 studies underway, including chronic spontaneous urticaria, where we expect data in the first half of 2023, and in chronic obstructive pulmonary disease, which is now fully enrolled.

For rocatinimab, a first in class anti-OX40 monoclonal antibody being investigated in patients with moderate to severe atopic dermatitis, we are enrolling the ROCKET clinical development program, a suite of 6 studies that will establish safety and efficacy in a broad population of patients with atopic dermatitis, including biologic naïve, biologic or JAK experienced, diverse ethnic groups and adolescents.

We also remain excited about our Oncology pipeline. In December, data were presented from the BLINCYTO registration enabling E1910 study conducted by the National Cancer Institute and the ECOG-ACRIN Cancer Research Group demonstrating superior overall survival with BLINCYTO plus consolidation chemotherapy versus standard of care in adults with first-line minimal residual disease negative Philadelphia chromosome-negative B-cell acute lymphoblastic leukemia. We anticipate that these data will change practice and look forward to submitting the data to regulatory authorities.

We also presented data from a Phase 1b dose-escalation study of subcutaneously administered BLINCYTO that demonstrated an acceptable safety profile and anti-leukemia activity in patients with relapsed/refractory B-cell ALL. The strong efficacy we've seen in first-line Philadelphia negative ALL along with the subcutaneous data provide confidence in the long-term potential of BLINCYTO.

Filing activities continue on the LUMAKRAS CodeBreak 200 and Dose Comparison studies, and we anticipate completing submission to the FDA and other regulatory authorities in first quarter of 2023.

Beyond these studies, we continue to explore novel combinations which will be key to moving into earlier lines of treatment. One study I'd highlight is a Phase 3 trial of LUMAKRAS in combination with Vectibix in third-line colorectal cancer, with data readout now anticipated in the second half of 2023.

In the bezarituzumab program, we have two Phase 3 trials underway in patients with first-line gastric cancer. We are also pursuing multiple Phase 1 studies intended to fully explore the potential of bezarituzumab in gastric cancer and other tumor types.

Tarlatamab, a BiTE molecule targeting DLL3 continues to advance quickly in clinical development. In November, a recommended Phase 2 dose was agreed to with the FDA for DeLLphi-301, a potentially registrational Phase 2 study of tarlatamab in heavily pretreated patients with small-cell lung cancer. This study continues to enroll patients, with data readout anticipated in second-half 2023. We also have multiple ongoing Phase 1 studies and plan to initiate a Phase 3 study evaluating tarlatamab in second-line small cell lung cancer as we seek to move the molecule into earlier lines of therapy.

In our Biosimilars portfolio, Phase 3 studies to support an interchangeability designation in the U.S. for AMJEVITA and for ABP 654 an investigational biosimilar to Stelara are ongoing, with data readout anticipated in the first half of 2023.

Finally, from a discovery research perspective, we are pleased with the progress of our Generative Biology efforts, including our collaborations with Generate Biomedicines and Arrakis Therapeutics. We are equally excited about three new collaborations; the first two are early research collaborations with LegoChem Biosciences and Synaffix focused on antibody drug conjugates. We view ADCs as another tool that will enable us to utilize the best modality to interdict a particular therapeutic target, with applications both within and outside of oncology. The third partnership is a collaboration with Illumina and Nashville Biosciences in support of our Human Data efforts, where we will perform whole genome sequencing on 35,000 Black individuals, a group that has historically been underrepresented in genetic research.

In conclusion, I'd like to thank my Amgen colleagues for their dedication and commitment to delivering consistent, high-quality results as we continue to progress our innovative pipeline and develop new technologies. With that, I'll now turn it over to Peter.

**Peter Griffith**  
**Executive Vice President and Chief Financial Officer**

Thank you, Dave. We are pleased with our fourth quarter and full year execution including our execution on our multiple capital allocation priorities. Recall, at Amgen capital allocation is a forethought, not an afterthought. First, we continued our focus on internal and external innovation, investing over \$4.3 billion in our organic pipeline while also making investments in external innovation demonstrated by our acquisition of ChemoCentryx with the first in class and best in class product Tavneos. Additionally, we announced the acquisition of Horizon Therapeutics that we anticipate will close in the first half of 2023. These two acquisitions further strengthen our portfolio of first-in-class and



best-in-class therapeutics. Second, we continue to invest in our business, including advancing construction on our new environmentally friendly facilities in Ohio and North Carolina. These facilities help ensure we supply “every patient, every time” given the current and projected volume growth of our priority brands. And third, we returned capital to shareholders through growing dividends, including \$1.94 per share in the quarter, representing a 10% increase from Q4 2021. During 2022, we also executed share repurchases approximating 26.1 million of our shares for \$6.3 billion.

So now, let us walk through our fourth quarter and full year financial results before discussing our 2023 guidance. The financial results are shown on slides 42 to 46 of the slide deck. Q4 revenues of \$6.8 billion were unchanged year-over-year. Product sales grew 4% driven by 10% volume growth. Full year revenues grew 1% year-over-year with product sales increasing 2% driven by 9% volume growth.

Q4 Non-GAAP EPS of \$4.09 declined 7% versus our recast Q4 2021 results. Excluding the impact of foreign currency, EPS declined 4%. Recall our Q4 2021 results included approximately \$200 million of favorable impact to other income and expense, resulting from a gain on our BeiGene investment. Full year non-GAAP EPS of \$17.69 grew 27% versus our recast 2021 results.

Non-GAAP Q4 operating expenses were unchanged year-over-year while full year non-GAAP operating expenses declined 12%. The full year includes the impacts in 2021 of the \$1.5B Five Prime IPR&D charge and the \$400M licensing payment to KKC for rocatinlimab.

We advanced our pipeline and invested in product launch activities in 2022 while delivering a 51% non-GAAP operating margin as a % of product sales.

On a non-GAAP basis, Q4 cost of sales as a percent of product sales decreased 1.2 percentage points on a year-over year basis down to 16.3%.

For the full year, cost of sales as a percentage of product sales decreased by 0.5 percentage points, down to 15.9%. Both the quarter and full year improvements were primarily due to fewer COVID-19 antibody shipments and lower manufacturing costs, partially offset by changes in our product mix.

Non-GAAP R&D spend in the fourth quarter decreased 2% year-over-year, primarily due to higher business development activity in 2021, including our upfront payments in connection with our Genera Biomedicines and Arrakis Therapeutics collaborations, along with lower marketed product support. This was partially offset by higher support for key assets in early- and late-stage programs. However, adjusted for 2021 BD activity, Q4 2022 R&D investment increased 7% year-over-year. And for the full year, non-GAAP R&D spend declined 8% based on the same drivers as the fourth quarter. However, adjusted for BD activity, full year 2022 R&D investment increased by 5%.

Q4 non-GAAP SG&A expenses increased 2% year-over-year, driven by higher marketed product support, including investments in our priority products, TEZSPIRE, EVENITY and Repatha. For the full year, SG&A expenses were unchanged year-over-year as increased investments for all priority brands were offset by productivity gains, continuous improvement and reallocation for mature brands. Non-GAAP other income and expenses were about \$470 million in expense in the fourth quarter, a \$250 million increase year-over-year, primarily driven by the previously mentioned gains in 2021 that we recognized from our investment in BeiGene. For the full year, non-GAAP other income and expenses were approximately \$1.7 billion.

So now turning to the outlook for the business 2023. Our outlook is Amgen-only on a stand-alone basis without any adjustments for the announced Horizon acquisition. It's important to remember that that currently -- current publicly available consensus estimates are derived from a combination of estimates of Amgen as stand-alone company, along with estimates from some analysts who have already added Horizon into their estimates. So our 2023 revenue guidance is \$26.0 billion to \$27.2 billion, and our non-GAAP earnings per share guidance is \$17.40 to \$18.60 per share.

So now let me review several key points related to our guidance. For total revenue, we expect the year-over-year comparison will not include about \$700 million related to several items from 2022 that we do not expect benefit from in 2023. We assume we will not generate COVID-19 antibody revenues in 2023. We also assume a lower amount of Nplate sales in 2023 compared to 2022. Recall, 2022 included a significant purchase of Nplate by the United States government in the second half of year.

Also, several favorable changes to estimated sales deductions that occurred in 2022 and the sale of our generics business in Turkey, which closed late in 2022.

For product sales, we project volume growth at a portfolio level, driven by strong growth in our priority products, TEZSPIRE, EVENITY, Repatha, Prolia and TAVNEOS. Consistent with industry trends and our recent history, we expect mid-single-digit price declines in our portfolio in 2023.

Turning to Neulasta and our oncology biosimilars. We expect the recent trends to continue through 2023. This will likely result in full year Neulasta sales less than \$700 million. Further, we expect less than \$750 million in combined product sales for our oncology biosimilars, KANJINTI and MVASI. And finally, we expect product sales of less than \$300 million for EPOGEN as we transition through the expiry of our contract with DaVita.

For the full year, we're guiding other revenues to a range of \$1.2 billion to \$1.5 billion. Note that we recognized about \$300 million of revenue from our COVID antibody collaboration with Lilly in 2022 that we don't anticipate repeating in 2023. So we will continue to manage our operating expenses consistent with our historical cost discipline. So even with increasing 2023 sales volumes, declining net

selling prices and inflationary pressures on costs, we still project full year non-GAAP operating expenses to be flat versus 2022 as we continue our focus on driving productivity and cost efficiencies across the enterprise.

We project non-GAAP cost of sales to be in the range of 16% to 17% as a percentage of product sales. Recall that we mentioned during our Q3 earnings discussion that tax law changes enacted by Puerto Rico in June 2022 replaced the Puerto Rico Excise Tax, the PRET, in favor of an income tax. This change will increase our income tax expense beginning in 2023 while reducing our cost of sales by roughly an equivalent amount. Note, however, there will be a negative impact in 2023 of approximately \$125 million related to the amount of the PRET that is currently capitalized in inventory that will be charged to cost of goods sold in the first half of 2023, with most of the charge recognized in the first quarter without a corresponding tax benefit.

We expect non-GAAP R&D expenses in 2023 to increase 3% to 4% year-over-year compared to our 2022 expenses as we advanced a number of the programs Dr. Reese referenced earlier. This is consistent with our first capital allocation priority to invest in the best innovation, and our operating expense discipline provides us the capital to do just that. And for non-GAAP SG&A spend, we expect 2023 amounts as a percentage of product sales to slightly decrease year-over-year, driven by productivity improvements.

These all lead to a projected non-GAAP operating margin as a percent of product sales of roughly 50% on a full year basis. We expect non-GAAP other income and expense of approximately \$1.4 billion. The expected year-over-year improvement is driven by a change in our accounting for BeiGene investment we are making in 2023. Beginning in January 2023, we'll no longer record our share of BeiGene results in other income and expense under the equity method of accounting on our non-GAAP income statement. We'll now mark to market our investment with the impact recorded only on our GAAP income statement.

We expect a non-GAAP tax rate of 18% to 19%. This rate reflects the new Puerto Rico income tax, which as I explained earlier, replaced the PRET beginning in 2023. We expect share repurchases not to exceed \$500 million in 2023, and we expect that we will continue to meaningfully increase our dividend. We expect capital expenditures of approximately \$925 million in 2023, consistent with our capital allocation priority to invest in our business, including in our new environmentally-friendly facilities in Ohio, North Carolina. And after we complete those facilities, we expect our capital expenditures to return their historical levels.

I'd also like to make some specific comments around the first quarter of 2023. I'm encouraged that our business is performing as expected through the first month of the year. However, consistent with our historical revenue patterns, we expect revenue in the first quarter of the year to be the lowest revenue the year and slightly below revenue in Q1 2022. At a portfolio level, we expect product sales to be unchanged from Q1 2022 and other revenues to be lower on a year-over-year basis due to the reasons set out above, including about \$225 million related to COVID antibody sales in the first quarter of 2022.

We anticipate about \$80 million of foreign exchange headwinds in Q1 2023 compared to 2022. The total of all these items creates greater than \$400 million of headwinds versus the first quarter 2022. So, these revenue patterns, along with the timing of expenses, are expected to translate into our Q1 non-GAAP operating margin being below 50% as a percentage of product sales, although we continue to expect operating margin as a percentage of product sales to be roughly 50% for all of 2023. Recall, this is all Amgen stand-alone. We will continue to focus on our legacy of execution excellence.

In summary, despite macroeconomic headwinds, we delivered another strong year of financial results in 2022, keeping us on track with our long-term commitments to deliver through 2030 and beyond. Our confidence in the long-term growth of Amgen is strong, and we look forward to completing the announced acquisition of Horizon during the first half of 2023, which will only strengthen our growth prospects. We would expect to provide updated guidance as appropriate at some point after the transaction closes. This concludes the financial update. My thanks to our 25,000-plus colleagues at Amgen around the world for their commitment to serving patients and their tireless efforts in 2022. I'll now turn it back over to Bob for our Q&A.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Okay. Well, thank you, Peter and Dave, for soldiering on despite the technical difficulties. And again, apologies to all of you who've dialed in to join us on the call and who found some disruption in the proceedings here.

A number of you have e-mailed your questions to Arvind. What I'd like to suggest is that any of you who have questions, directly e-mail them now to Arvind, and Arvind will read them, and we'll try to answer here in the room. And let me just assure all of you that we will rearrange our schedule and be available to answer questions if we don't get to it on this conference call, be available to Arvind and his team to answer questions you may have after we wrap up. So, with that, let me turn to Arvind, and we'll tackle the questions that you've already submitted.

## Q&A

### **Arvind Sood** **Vice President, Investor Relations**

Yes. Thanks, Bob. And apologies to everybody for the technical difficulties that we have had. And as Bob said, just please e-mail your questions to me directly. So, the first question that we have is from Yaron Werber of Cowen, and he submitted 2 questions. His first question is that Amgen will move to fair value from equity method of accounting for BeiGene. As you also now own less than 19.9% equity in BeiGene, will Amgen stop consolidating BeiGene's losses and profits from now on? And then the second question is, can you discuss when you plan to file the high concentration of AMJEVITA once you get the Phase 3 interchangeable data in the first half of 2023?

### **Robert Bradway** **Chairman and Chief Executive Officer**

Okay. We do that in two pieces. Peter, why don't you hit the accounting question?

### **Peter Griffith** **Executive Vice President, Chief Financial Officer**

Yes, quick question -- quick answer. Thank you, Yaron, for the question. On BeiGene equity method of accounting, as I said in my remarks, we will record, in our GAAP income statement, the mark-to-market but that won't be recorded in our non-GAAP income statement. So the answer is we will not include any earnings from -- or losses as our share of BeiGene going forward in our non-GAAP income statement.

### **Robert Bradway** **Chairman and Chief Executive Officer**

Okay. And then on AMJEVITA, why don't we do a 2-parter there? Dave Reese and then Murdo, you may want to add some thoughts.

### **David Reese** **Executive Vice President, Research and Development**

Yes. In terms of the filing time lines, once we have the data in hand, we'll be then giving guidance as to when we expect filing and potential approval of that after the appropriate regulatory interactions. It's important, I think, as Bob put this in context, let me ask Murdo to comment here.

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes. Thanks, Dave. We have had some inbound questions on this, as you can imagine, during the day, given that we are launching. So far, launch is progressing well. We have product making its way into the channel, and we're already receiving inbound interest in AMJEVITA from payers, prescribers and patients.

One thing that's important to remember is the current product that we have in the market is a lower concentration, original concentration AMJEVITA or adalimumab, but it is citrate-free, meaning that the patient experience here is still one where we minimize the injection site pain by having a citrate-free formulation. And patient experience here has been positive in our clinical trials, and we anticipate that not having a high concentration will not be a barrier in the market. These are very low volumes that are injected through an auto-injectable pen. And we've seen very, very good reliability of patients being able to administer.

In addition, of course, we provide nurse support for patients. And then while it wasn't asked, I think it's also important to note that we are providing financial assistance, support and reimbursement support for both prescribers and patients as we launch the product. So really a full suite of services and support that you would expect for a branded launch being applied to the launch of the first biosimilar, adalimumab, to launch in the U.S., that is AMJEVITA.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Okay. Thank you, Murdo and Dave. Let's go to the next question, Arvind.

**Arvind Sood**  
**Vice President, Investor Relations**

So, the next question is from Geoff Meacham BofA Merrill Lynch. And his question is, he said, I know you have AMJEVITA but are you expecting an indirect impact in the second half of '23 or the first half of '24 from all the HUMIRA biosimilars and STELARA, on Otezla and ENBREL mainly? And he is interested in the volume and price impact.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Okay. Murdo, you want to share your thoughts on that?



**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

It's hard for me, obviously, to comment on what competitors may do as other biosimilars of adalimumab enter the market beyond July. But what we have seen coming into 2023 is a good cycle of reimbursement negotiations, and we've been able to secure a very broad coverage for both ENBREL and Otezla. We expect that insurance coverage to continue throughout the course of 2023. And as is usual, we had small concessions on net price to secure that broad reimbursement, but nothing unusual compared to prior years.

**Arvind Sood**  
**Vice President, Investor Relations**

The next question is from Chris Raymond from Piper Sandler. And he has two questions. The first one is on Otezla. And Chris says, I know there are a lot of puts and takes on this market, and I know you guys have highlighted a tailwind of mild-to-moderate psoriasis patients coming into therapy. But Otezla is kind of unique in that there is a sizable discontinuation rate. Just with that, if you're probably not going away, talk about why we shouldn't be more concerned about Sotyktu and maybe just as importantly, the next-generation TYK2 molecules that are coming behind it. Especially noticing that a decline Q-over-Q both in the U.S. and rest of the world, even with a 9% inventory build, any color on how you grow through this coming competition would be very helpful. And then he has a question on AMJEVITA.

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Okay. So first on Otezla, I would start with the fact that we are the only systemic product indicated for a broad range of psoriasis patients without regard to the severity, and really makes us the ideal first-line first systemic post-topical choice of therapy. And that is the positioning of the brand. The size of that market is very large. There's 4 million patients with a mild to moderate form of psoriasis. About 1.5 million of those patients would be regarded as not doing as well they could on topical treatment by potential switching to a systemic like OTEZLA.

As I mentioned just a few moments ago, Otezla also enjoys very broad frontline access, that is it doesn't require that you step through another systemic therapy. And it also means that prescribers can make it the first choice. And these are busy dermatologists. They want something that's easy. They don't want a lot of prior paperwork. And they want to be able to provide an ability for patients to start quickly on their therapy. Only Otezla offers that in the psoriasis market.

I think what we're seeing right now is an effect of a number free goods programs that were launched at the end of last year and continue into this quarter. When physicians have free goods programs or sometimes referred to as bridging programs, usually used at the beginning of a product launch when there hasn't been an opportunity to secure access with pharmacy benefit managers, physicians will sometimes use those to try novel therapies coming into the market.

However, as those novel therapies go through the negotiation process with PBMs and payers, oftentimes, it becomes more difficult to try those novel therapies because of the nature of the access that they result with. And I think that's really where the sustained advantage of Otezla in that first-line systemic post-topical prebiologic patient population really allows us a long-term growth opportunity. And we continue to feel confident in the long-term growth of this brand.

And we have a very strong commercial presence in a number of markets around the world, and we continue to feel good from what we're hearing from our prescribing base of dermatologists. I will say that the short-term impact of these free good programs, we're watching it very closely, and we're making sure that we continue to be competitive in the marketplace.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. Chris, the second question is the same as the question that we have from Salveen Richter of Goldman Sachs. And she says on AMJEVITA, could you offer more details on how the dual pricing option will work and drive uptick? And how should we think about net pricing? What are your expectations for the market in midyear once more biosimilars enter?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Well, maybe I can answer the second part first. We don't comment on product-specific pricing, and so I really can't answer the net price. I think it's fair to say that as additional entrants come into the market, net prices usually go down. We've seen that in our other biosimilars business, but we would expect that to happen here.

With respect to the two list price approach that we've employed here at this launch, this is really to address the complexity of the U.S. market. Pharmacy benefit managers have a business model that requires that they negotiate rebates with manufacturers, and so they would prefer a high list price and negotiate rebates to net the price down and then pass those rebates through to their upstream employer clients.

There are other stakeholders and customers in the health care system that prefer a net price-based model and don't care about the difference between list and net or gross price and net price. And so for those, we have the lower net price product available. So just a reminder, we have a high list price at 5% below HUMIRA, and then we have a low list price at 55% below HUMIRA.

We also intend to ensure that AMJEVITA is an affordable medicine for patients by providing co-pay assistance as well as helping patients secure reimbursement through the insurer. We are also pleased to report that we enjoy broad access out of the gate on day 1 launch with the three national pharmacy benefit managers, so broad parity coverage alongside HUMIRA.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Let me just -- I note that we're up to the half past the hour, but we will continue to take questions for long necessary here to answer those questions and until there is a recording of this that will be available in the form of a transcript for those of you have conflicts and can't stay beyond the set time. So Arvind, why don't you go to the next question?

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Yes. The next question is from Colin Bristow for UBS. And here's a question on the obesity pipeline. What update should we expect to get this year? Will we see data from the remaining three cohorts from the Phase 1 study? And then on AMG 786, when should we expect updates, more disclosure on this asset and program?

**David Reese**  
**Executive Vice President, Research and Development**

Yes. In terms of the obesity pipeline, AMG 133, the two additional cohorts you're referring to, I don't know that we'll see data over the course of this year on that. If that changes, of course, I'll provide guidance. AMG 786 is a small molecule with a different mechanism of action, as indicated to GLP-1 or Gipper receptor agonist or antagonist. So that's going through dose escalation over the course of the year. I'll provide guidance in terms of when we may see data from that program. And of course, at the time of data availability, we'll talk about the target as well.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Okay. Thanks, David. Arvind, let's go to the next question.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

So the next question is from Evan Seigerman from BMO Capital Markets. And Evan wanted to know, he said with slowing LUMAKRAS sales, can you expand on how you may have revised your commercial strategy to better align with the commercial potential of the assets?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes. I'm not sure we have a slowing overall volume growth. I think what we saw and I mentioned this, it might not have come through clearly on the audio, but in the quarter, we did see a price effect based on reaching reimbursement decision finalization in France. And so we had a \$12 million charge in the quarter against LUMAKRAS. It grew 7% volume in the quarter. But I think we anticipated the opportunity for LUMAKRAS in second-line being limited to the incident population. And we are commercially and medically sized appropriately for that opportunity. I think as we expand into earlier lines of therapy or other tumor types, we will continue to invest behind the product.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Okay. The next question is from Michael Yee of Jeffries. And Michael wants to know, he said, on 2023 guidance, can you clarify what the input is for revenue growth versus EPS growth range? Specifically, is there a positive impact from BeiGene accounting? And does the tax rate of 18% to 19% negatively impact EPS? Or is COGS offset, as explained last year, is 2023 OpEx growing more than revenue?

**Peter Griffith**  
**Executive Vice President, Chief Financial Officer**

Arvind, let me start by working our way from the tax question. So on the tax side of it, the 18% to 19% is increases by the PRET amount. Although, as I have highlighted both last year and this year, we have a small carryover effect of about \$125 million that's currently capitalized in cost of goods sold that will be released that -- excuse me, currently capitalized in inventory that will be released in the cost of goods sold, primarily during the first quarter without a corresponding tax benefit.

So, the answer is, going forward, after that \$125 million works its way through cost of goods sold, it will be roughly equivalent to move from the Puerto Rico Excise Tax or the PRET, which was recorded in cost of goods sold down to the actual income tax rate.

The question on guidance. And I think the question was, what's included from BeiGene and what's not. As I said earlier to Yaron's question, what won't be included now is our share of either losses or gains in BeiGene's income. So we will include, on a mark-to-market basis in our GAAP income statement, the results of BeiGene and then the movements in the security but not in our non-GAAP income statement. We will no longer record our share of losses or their income.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Let me just say, Michael, and to the prior question from Evan, if you need more detail on that to make sure fully understand what we're saying in our response, just let us know, we'll get back to you. I think particularly, Evan, for your question, if you're not familiar with that mechanism that's common to us in France, happy just to provide more color for you. Again, Michael, I know a lot going on here, and apologies for the disruption and don't know if you were able to follow all the slides earlier. So if you need more color, let us know, we'll call you back after the conference call. Okay. Go ahead, Arvind, to the next question.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Okay. Then we have a second question from Salveen asking, could you put the upcoming TEPEZZA Phase 4 data and chronic TED in context for us? What do you need to see? How would positive data expand the opportunity for drug?

**Robert Bradway**  
**Chairman and Chief Executive Officer**

We are subject to the restrictions that we have on our ability to say anything beyond what's in the public documents. You want to address that?

**David Reese**  
**Executive Vice President, Research and Development**

Yes. I mean, I think we're restricted, of course, by Irish takeover rules here. What we can say is that it's

worth reminding everyone that the current label is broad and encompasses patients with thyroid eye disease, the -- due to autoimmune thyroiditis. This is primarily a study that will generate data in a population that we believe will help with reimbursement and with payers. And let me ask Murdo to comment on that.

I would point out that mechanistically, there is no difference between chronic thyroid eye disease and the acute form of the disease. In fact, it's a semantic definition as to when the disease progresses to the chronic form but the underlying pathogenic mechanism of being driven in large part by IGF1R is intact. And therefore, based on prior data and mechanistically, we're optimistic about that study. Murdo?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes. Look, I think the Horizon team is doing a very good job commercializing this product and continue to help many patients within the broad current indication, as Dave mentioned. And I think additional data here could be additive to the already very promising growth of the product.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Okay. Thanks, Salveen, for your question. Let's go to the next one, Arvind.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

The next one is from Christopher Schott of JPMorgan. And Christopher is saying, can you elaborate on Otezla in 2023? Bristol's suggesting that they are seeing some strong initial uptake in their bridge program and would be interested how much of this market expansion for orals versus something you're seeing in Otezla. And you mentioned an impact from competitor free drug impact over the next few quarters. Do you anticipate that will lessen as the year continues or an impact for much of the year?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes. It's a similar question to one asked earlier, but perhaps I can elaborate a little bit for Chris. It's fairly clear that dermatologists want to use the easiest product and safest and well-understood product when moving to a first systemic treatment post topically. Many of these topical patients are hesitant to try a systemic agent. And so I think this is where Otezla's profile studied extensively with over 700,000 patients globally having experienced this product, the safety and efficacy of Otezla is extremely well



understood.

As I mentioned earlier, the frontline access coverage that we've secured in the U.S. without a lot of prior authorization requirement, the convenience of that for dermatology practices is very clear, and it makes it a really good first-line treatment, systemic treatment, especially for a patient with milder or more moderate disease. For moderate or severe disease, it is likely that you're going to need to use something like a biologic or a second-line agent.

And we think that given that SOTYKTU has yet to go through the market access process and secure payer reimbursement, we're not really seeing how it's actually going to be used longer term in the marketplace. And I think sometimes, these free good programs can distort what the actual uptake curve will be for a product.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Then Murdo, there is a second question from Chris. He's asking, how are you thinking about ENBREL pricing dynamics over time, given the expected significant price declines in the Humira market? I know you've talked about price continuing to erode but not accelerate. Can you remind us why we shouldn't expect a bigger step-down in price in 2023 or 2024 as the HUMIRA market price resets down significantly?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Well, as I mentioned before, we're primarily through our 2023 cycle and we've secured very good access. We've had to concede a bit of price, as I mentioned, but not anything that looks precipitous compared to prior years. So, we're pleased with that. ENBREL is an important product for many indications. We see that the safety and efficacy profile of ENBREL is well understood. I think physicians also want choice. And I think that's where PBMs are also open to having more than one TNF product on their formulary. And I think that's really what we've been able to secure and what we continue to think we'll be able to achieve in the future.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

Let's go to the next question.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

The next question is from Mohit Bansal from Wells Fargo. And his question is, could you talk a little bit more about your HUMIRA biosimilar negotiations thus far? Seems like AbbVie has parity access with the majority of them and the pricing is different for the first half versus the second half and there's more competition. Are your contracts similar? And how should we think about the cadence of launch as the year progresses?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Well, I can't comment on a competitor's contracts with PBMs or payers. What I can say is we've secured broad access for AMJEVITA at the three national PBMs. We continue to work with other customers to provide access for providers and patients alike. And we'll continue to compete effectively as we have done everywhere else in the world with this product. And outside of the U.S., we were able to establish a leadership position with AMGEVITA. And we think, given the services that we've provided and the commercial footprint we have, we're in a very good competitive position vis-à-vis other biosimilars.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

I know a number of you have submitted questions, so we're continuing to work through the list. Anybody who hasn't yet shot Arvind an e-mail, we're going to go through those and we've got couple of handfuls still to go. So let's, Arvind, go to the next question.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Yes. The next one is a question by Greg Renza of RBC Capital Markets, and Dave, this is for you. We were interested in hearing some color on the antibody drug conjugate strategy in light of the recent deals. How is the team approaching the space?

**David Reese**  
**Executive Vice President, Research and Development**

Yes. Thanks, Greg. What I view this is as another modality in our toolkit. We've been watching the

antibody drug conjugate technology quite closely for the past several years. It's advanced, so what we feel is that we'll use ADCs on appropriate targets. I view it as an addition and an extension of our modalities. These collaborations bring together our experience on target identification and validation as well as, of course, antibody generation with some of the newer conjugation technology. So as that progresses, more to come, but you should view this as additive to our armamentarium.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Okay. The next question is by Tim Anderson of Wolfe Research. And his question is on AMJEVITA in the U.S. And he's asking, any commentary and your comfort with sell-side consensus for U.S. sales, which seems to be around \$600 million in 2023? And anything you can say about contract specifics such as whether there's price protection, if any of them go beyond 2023?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes, we don't give product-specific guidance. And this is a new event in the U.S. biosimilar market, given this is the first big pharmacy benefit product to go up. So we will continue to update all of you as the launch progresses. We have said we think this will be a gradual slope on this launch, and I'm going to be happy to keep you apprised as we go forward.

**Arvind Sood**  
**Vice President, Head of Investor Relations**

Okay. The next one is by Dave Risinger of SVB Securities, and he has two questions. The first one is for you, Dave. Please discuss key novel drug candidate readouts to watch in 2023. And the second one for you, Murdo. How do you expect formulary positioning for AMJEVITA to potentially change in January of 2024 after AMJEVITA is assigned an interchangeability designation?

**David Reese**  
**Executive Vice President, Research and Development**

Yes. Thanks, David. This is a year where certainly my focus, my team's focus will be on execution, a huge amount to carry forward in the pipeline. So things that I would keep an eye on, how well are we enrolling the Phase 3 olpasiran trial? How well are we enrolling the AMG 133 Phase 2 trial? In the general medicine portfolio, in inflammation, how are the suite of rocatinlumab trials enrolling? How are

we delivering on TEZSPIRE additional indications? And then finally, in oncology, things to keep an eye on are the tarlatumab program, not only the Phase 2 potentially registrational trial readout in the second half of the year but also initiation of a Phase 3 trial in second-line disease. These are some of the top line things that I'll be paying attention to. And then there are, of course, a host of others earlier in the pipeline and in discovery research.

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

And just on the AMJEVITA question, I would say that we have a commitment to continuing to make sure that the product attributes of our biosimilars provide payers, providers and patients with all of the benefits that they're looking for. And we're also trying to ensure that there is no reason to switch away from AMJEVITA. So we hope that interchangeability, the high concentration and the fact that we already have a citrate-free product on the market, along with the services we provide, along with the fact that this is an Amgen team of people who understand the inflammation indications of this product very well, and they have relationships with the customers that prescribe HUMIRA, we feel really good about the durability of AMJEVITA long term beyond 2024.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is from Umer Raffat from Evercore and he has 2 questions. The first one is for you, Dave, on OX40 and the monthly dosing in Phase 3. He said and I don't see an arm investigating extended intervals quarterly or biannually. I'm just trying to tie the Phase 3 dosing interval versus the durable efficacy seen through 6 months post last dose. And the second question is for you, Peter, that the tax rate stepped up from 14% to 18% to 19%. Just wanted to get some additional color.

**David Reese**  
**Executive Vice President, Research and Development**

Yes. Regarding the dosing of rocatinlumab. As we've indicated before, we will explore different dosing paradigms here. And as that suite of Phase 3 trials fully launches, I think it will become clear what we're looking for there based on both the mechanism of action of the molecule as well as patient convenience. Peter?

**Peter Griffith**  
**Executive Vice President, Chief Financial Officer**

Umer, good question on tax. Again, it's just a change in what I would say the real estate on the P&L, which is the PRET moves from the cost of sales line down to income tax expense in connection with the change in Puerto Rico for us from a PRET to the actual income tax in Puerto Rico, which began here in 2023. So that's the nature of that change and that's where the 18% to 19% comes in from where we've been here historically.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is from Jay Olson of Oppenheimer. And Jay is asking, can you talk about your plans for geographic diversification? It seems like ex U.S. revenues have become a small percentage of Amgen's total revenues over the past few quarters. And we were wondering what underlying dynamics drove that shift in geographical mix and if there are any future launches or other dynamics that might push the geographical mix back in favor of ex U.S. growth.

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes, we are actually very pleased with the expansion internationally of the Amgen footprint being in over 100 markets. We continue to launch products and secure reimbursement around the world. I talked about LUMAKRAS. And most recently in China, we've been able to secure national reimbursement drug listing for both Prolia and Repatha. Our Japanese affiliate is growing well.

In the recent history, I think what you're seeing is a function of just timing launches coming a bit earlier in the U.S. and also some of our partnering products. I think longer term, what we've got is a very interesting portfolio of products that will continue to make their way around the world. The announced Horizon acquisition has a very large opportunity internationally. And we see our JPAC region is actually our fastest-growing potential opportunity longer term. So I wouldn't look at short-term movement from quarter-to-quarter. The long-term prevailing trend is that we will grow quickly outside the United States.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is for you, Murdo, from Michael Schmidt of Guggenheim Partners. And he's

asking, how confident are you in achieving low double-digit Otezla growth in 2023 and beyond, given the current pattern of essentially flat sales since 2020 of \$2.2 billion?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Yes, I think we remain quite confident in our long-term growth of Otezla. We are in a period where there's a lot of new product entrants in the the market competing for new patient starts. I think the unique positioning of the product, as I mentioned, allows us to source a very large pool of patients. And our coverage around the world and particularly in the U.S. from an insurance reimbursement perspective allows us to penetrate that market. So we feel very good about the continued prospects to grow Otezla.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is from Robyn Karnauskas from Truist Securities. So she's asking, big picture, your guidance implies potentially flat growth. Given biosimilar pressures and pricing pressures, do you think 2023 is a trough year? And regarding the guidance range, can you give pushes and pulls on the biosimilar range?

**Robert Bradway**  
**Chairman and Chief Executive Officer**

So Robyn, maybe I'll start on the last piece, and then Peter, you can reiterate what we said about '23. But as I said in my remarks, Robyn, we have 6 further biosimilar launches planned between now and the end of the decade in the United States and other countries around the world. And it is the launch of those molecules through time which will enable us to continue to grow that franchise.

So I would reiterate what I said earlier in my prepared comments. I think you've heard Murdo address as well the attractive opportunities that we think we'll have here, in particular, with AMJEVITA though we're in the first day of launch. And with respect to '23, Peter, I don't know whether you want to say anything in addition to what you already have about the outlook for the year.



**Peter Griffith**  
**Executive Vice President, Chief Financial Officer**

Thanks. I think we covered it earlier. I'd just note a couple of items that happened in 2022 that we didn't expect benefit from in '23, just to reiterate those. We don't expect any and assume any COVID-19 antibody revenues in '23. We're assuming a lower amount of Nplate sales in '23, Robyn, compared to '22. Recall, '22 had the significant purchase by the U.S. government in the second half of the year. We had several favorable changes to estimated sales deductions that occurred in '22, and we sold the generics business in Turkey, which closed late in '22. So a couple of puts and takes around those.

And so we look forward to a year in 2023 with strong growth in our priority products, TEZSPIRE, EVENITY, Repatha, Prolia, TAVNEOS. And also -- and that's in light of -- consistent with the industry trends we talked about in our recent history with mid-single-digit price declines in our portfolio, but good volume growth. I think maybe to go back to the question Jay asked, too, we expect strong volume growth outside the United States in 2023. So we're looking forward to taking on '23 with a lot of aggressiveness.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is from Matt Phipps of William Blair. And Matt's saying the oncology biosimilar 2023 guidance suggests a year-over-year decline of 38% versus a 30% year-over-year decline from '21 to '22. Is the rate of erosion in the oncology biosimilars expected to continue to get larger beyond 2023 or will this eventually hit something of a floor?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

I wouldn't say we expect it to get larger but we will continue to see a decline in that business, which is a function of the average selling price decline that we've seen thus far.

**Arvind Sood**  
**Vice President, Investor Relations**

Yaron Werber of Cowen. He said I'm confused by the tax rate going up to 18% to 19% while COGS are 16% to 17%. Hence, I don't see any offsets in the COGS line. What am I missing?

**Peter Griffith**  
**Executive Vice President, Chief Financial Officer**

I think the answer to that is that our volume growth, the volume growth is quite large and that's really the offset, Yaron. That's a good question. And so we see that happening. We also -- in terms of the move of the PRET down there, recall, too, in cost of sales this year, we've got \$125 million coming in off of the release out of inventory into cost of sales without any corresponding tax provision. And so the percent of sales versus a percent of pretax too, you've got to be thinking about that in terms of the income tax provision itself. So that's the puts and the takes on that. But when you strip it all back, it's really that move of the PRET down into the income tax expense that increases that effective rate to 18% to 19%.

**Arvind Sood**  
**Vice President, Investor Relations**

Okay. The next question is from Trung Huynh from Credit Suisse. Thanks for the comments on Otezla and ENBREL. So can you add a bit more color into the dynamics in immunology? Are there any changes in the channel and mix of patients? Has there been any formulary disruptions?

**Murdo Gordon**  
**Executive Vice President, Global Commercial Operations**

Overall, our immunology business looks very good. I think we're very pleased with the TEZSPIRE launch. We continue to see broad phenotypes of patients regardless of biomarker status being treated. We are seeing de novo patients who haven't seen a biologic before in their treatment of uncontrolled asthma. And we're also seeing patients being switched from other products within the class. And so we expect that area of autoimmune disease growing in terms of the biologic penetration of severe uncontrolled asthma. And we're well positioned to compete for that expanded treatment pattern.

ENBREL continues to serve many patients. And the trends there are fairly predictable and fairly consistent. Otezla, as we've mentioned, is seeing some pressure from new free drug programs, both for our topicals as well as new entrant oral SOTYKTU. And then we also have just picked up TAVNEOS, which we're really excited about, a product that treats a severe autoimmune disease, ANCA-associated vasculitis, very young product, very early in its life cycle and I think a lot of growth there to be had.

And then, of course, last but certainly not least, on the branded side, the announced acquisition of

Horizon. So I think the inflammation area, along with our own innovative pipeline and the pipeline of Horizon is a very good growth opportunity for us long term. And last but not least, here we are on the first day of launch of a novel biosimilar to the largest product in the U.S., and that's HUMIRA. So I think we've got a lot of opportunities for growth ahead.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

I think we're down to our last question, Arvind, if you want to read that.

**Arvind Sood**  
**Vice President, Investor Relations**

Yes. Let me read the last question, Bob, and after that, you might have some concluding comments. So the last question is from Brian Skorney of Baird, and Brian wants to know, do you expect this to be more of a longer-term tax rate, assuming no major changes to corporate tax rates in the U.S.?

**Peter Griffith**  
**Executive Vice President, Chief Financial Officer**

Yes, Brian, I think, as you know, we don't give long-term guidance on tax rates. And so we won't go beyond this year, so 18% to 19%. And go back to Yaron just to make sure we understand that the change in the PRET. The PRET is a percentage of, its cost of sales as opposed to the income tax rate, which is pretax income. So that's a little bit of the difference too that Yaron asked about. So 18% to 19% this year is where we're at, and that's where we'll -- that's what we'll give you for now.

**Robert Bradway**  
**Chairman and Chief Executive Officer**

All right. Well, thank you very much, again, for your patience. Apologies that we had a little bit of difficulty with our vendor's connection earlier on the call. So if you have any further questions, shoot them into Arvind. We'll be around here this afternoon, Peter, Murdo, Dave and myself, to answer any further questions you might have. And we appreciate your joining the call and look forward to talking to you during the course of 2023. Thank you.

## **Forward-Looking Statements**

This communication contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Tenebio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the proposed acquisition of Horizon Therapeutics plc, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this communication and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors,

or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.