Q4 2018 Earnings Call

Company Participants

- Arvind K. Sood, Vice President, Investor Relations
- David M. Reese, Executive Vice President-Research & Development
- David W. Meline, Executive Vice President & Chief Financial Officer
- Murdo Gordon, Executive Vice President-Global Commercial Operations
- Robert A. Bradway, Chairman & Chief Executive Officer

Other Participants

- Alethia Young, Analyst
- Christopher J. Raymond, Analyst
- Cory W. Kasimov, Analyst
- Geoffrey C. Porges, Analyst
- Geoffrey Meacham, Analyst
- Kennen MacKay, Analyst
- Matthew K. Harrison, Analyst
- Michael J. Yee, Analyst
- Phil Nadeau, Analyst
- Robyn Karnauskas, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Ying Huang, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

My name is Ian, and I'll be your conference facilitator today for Amgen's Fourth Quarter 2018 Earnings Call. All lines have been placed on mute to prevent any background noise. There will be a question-and-answer session at the conclusion of the last speakers' prepared remarks. In order to ensure that everyone has a chance to participate, we would like to request that you limit yourself to asking one question during the Q&A session.

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

Arvind K. Sood {BIO 4246286 <GO>}

Okay. Thank you, Ian. Good afternoon, everybody. Thanks for joining us today. Let's go ahead and jump right in as we have a lot of ground to cover. I think 2018 is a good illustration of how the capabilities we have developed over the past five years, will help drive long-term growth for our shareholders. To describe this in much greater detail, I'm joined today by our Chairman and CEO, Bob Bradway. After Bob's strategic overview, our CFO, David Meline, will review our financial results for the fourth quarter and full year 2018 and provide guidance for 2019.

Our Head of Global Commercial Operations, Murdo Gordon, will then review our product performance, following which Dave Reese, our Head of R&D, will provide a pipeline update. We will use slides to guide our discussion today and you should have received a link separately.

Just a reminder that we'll use non-GAAP financial measures in today's presentation and some of the statements will be forward-looking statements. Our 10-K and subsequent filings identify factors that could cause our actual results to differ materially.

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

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Arvind, and let me welcome all of you to our fourth quarter call. While the bulk of this call will be dedicated to discussing our performance in 2018 and our outlook for 2019, I'd like to begin the call today by discussing the transformation journey we've been on at Amgen for the past five years. One aspect of that transformation was significantly improved financial performance.

Five years ago, we made a number of financial commitments, earnings per share, margin expansion and so forth and I'm pleased to announce that we met or exceeded each one of these ambitious financial targets. David will provide more specifics on this in a few moments.

Larger goal of our transformation, however, was to dramatically enhance our ability to compete. And here too, we have made great progress. Over the past five years, we launched nine new products, including in two new therapeutic areas, expanded our global presence to about 100 countries, generated our largest-ever number of innovative and first-in-class molecules in our pipeline, reduced our development cycle time by an average of about 36 months, expanded our industry-leading human genetics capabilities, stood up a biosimilars business and deployed a first-of-its-kind, highly efficient, next generation biologics manufacturing capability. While our transformation is not complete, we're in a much better position than ever before to serve patients and to deliver long-term growth.

Our performance in 2018 is a good example of our capabilities. We generated double-digit volume-driven growth, which was a key focus of our strategy, from innovative

medicines that address serious unmet needs, including Repatha in cardiovascular disease, Prolia in osteoporosis, KYPROLIS in cancer and Aimovig in migraine.

Our ability to develop and commercialize innovative therapies is particularly illustrated in the early success of Aimovig, our first-in-class differentiated biologic for the prevention of migraine, where we quickly established and have since maintained a leadership position.

We also believe that biosimilars represent an important, evolving growth opportunity. We achieved several important milestones with our biosimilars portfolio last year, including our first two launches and we expect many more milestones in the years to come.

Lifecycle management has also been an important source of our performance over the last several years. We believe, we will continue to generate strong cash flows from mature brands, including Enbrel, Neulasta and our ESA and calcimimetic franchises. Murdo will provide more details in a moment about our commercial success.

Our R&D strategy is aimed at advancing differentiated, best-in-class or first-in-class molecules that deliver large effect sizes against serious illnesses. We've made tremendous progress, both in terms of the quantity and quality of potential new medicines in our innovative pipeline. We continue to leverage our industry-leading human genetics work at deCODE to identify, prioritize and accelerate R&D programs with genetic validation and we have made great strides with respect to the speed with which we are advancing our pipeline, cutting years out of the cycle time for certain molecules, several of which will have important data readouts this year. Dave Reese will cover our position in R&D in greater detail momentarily.

As you're well aware, innovation is flourishing in our industry. And with the flow of new medicines, there are acute concerns about the price of innovative therapies and ensuring patients have access to them. We remain committed to working with the administration and congressional leaders in the House and Senate as well as stakeholders throughout the healthcare system to address concerns over the cost of prescription drugs without sacrificing innovation.

You will recall our decision to forego price increases scheduled for July of last year as well as our recent decision to lower the list price of Repatha by 60%. In fact, our net selling prices declined in 2018, and will decline further in 2019. For many Amgen medicines, there are no planned price increases.

As has been the case for the past few years, our strategy for growth will be driven by volume, not price. Our fourth quarter product sales growth of 8% is evidence of our ability to succeed in this new environment. With a solid balance sheet, strong and consistent free cash flow generation, robust investments across the portfolio and a thoughtful capital deployment strategy, we are confident in our ability to drive long-term volume-driven growth and provide attractive returns for our shareholders.

I'm excited about the future of Amgen and the potential for long-term growth driven by medicines like Repatha, Prolia, KYPROLIS and Aimovig, our emerging portfolio of

biosimilars and the many potential new innovations advancing rapidly through our pipeline.

While we have profoundly transformed the company over the last several years, our mission to serve patients has not changed. And on that note, I'd like to thank my Amgen colleagues around the globe for their continued devotion to supporting Amgen's mission to serve patients.

With that, let me turn the call over to David Meline, our Chief Financial Officer.

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. Before reviewing our results and guidance, I would also like to take a moment to reflect on our performance over the last several years. In 2013, we anticipated the coming realities of an increasingly competitive and dynamic industry landscapes. Accordingly, we embarked on an organizational initiative to prepare for long-term success by transforming the business to achieve maximum speed, agility and efficiency. We also set aggressive operational goals for the period through 2018 that would enable us to better serve patients and deliver solid, sustainable returns to shareholders while investing to ensure the long-term health of the business.

As we have now completed the first five years of our transformation, I wanted to summarize the results of our efforts. First, I'm pleased to confirm that we achieved double-digit non-GAAP EPS growth, with 14% annual growth for the period, with EPS rising from $7.60 to $14.40 or 89% in the period.

Second, we exceeded our $1.5 billion gross cost savings target by delivering $1.9 billion of annual savings versus the 2013 base. Transformation efforts reduced 2018 operating expense on a like-for-like basis as a percent of sales by 9 percentage points. It is important to recognize that we delivered these financial results while launching multiple products and building new capabilities.

Third, we had an operational goal to achieve significant improvement in our operating efficiency, agility and speed, with a resulting outcome of a non-GAAP operating margin between 52% and 54% by 2018, a goal that at the midpoint represented a 15-point margin improvement. As you know, we achieved this objective starting in 2016, two years ahead of our commitment.

Fourth, through our next-generation biomanufacturing capability as well as other efforts to optimize our fixed capital infrastructure, we reduced our facility footprint by about 24%, exceeding our target of 23% footprint reduction.

Finally, based on today's 2018 earnings report, we've provided returns to shareholders of 89% or $42 billion in total, well above our goal of returning at least 60% of non-GAAP net income on average during the 2014 to 2018 period. In summary, we delivered on all of our commitments, which positions Amgen very well for the next phase of its development.

Looking ahead, we are excited to build on our recent transformation successes, including maintaining and improving on our leading process development and manufacturing capabilities, driving a research and development innovation and continuing to build our market and global presence. Additionally, we're embedding a permanent productivity capability into our business. We expect our productivity capability will continue to support disciplined cost management, contribute to funding strategic growth investments, such as the 2019 investment in our early oncology programs and continued optimization of our operating model.

Now let's turn to the fourth quarter financial results on page 7 of the slide deck. Revenues at $6.2 billion increased 7% year-over-year. This quarter we saw worldwide product sales growth to $6 billion as unit demand from our growth and launch products more than offset mature product declines. We are particularly encouraged by our 10% year-over-year volume growth in total worldwide business.

Foreign exchange had a negative 1% impact to fourth quarter worldwide sales on a year-over-year basis. Other revenues at $229 million were down 2% versus 2017. Our Q4 non-GAAP operating income at $2.7 billion increased 6% from prior year. Non-GAAP operating margin was 45.3% for the quarter.

As previously indicated, our operating expenses reflected the typical underlying fourth quarter pattern. We also increased investment in Aimovig in support of its rapid growth as well as other in-market products in support of greater volume-driven growth. Additionally, this quarter we invested an incremental $90 million year-over-year in external innovation opportunities, including expansion of our genetics capability. These increases were partially offset by continued favorable expense impacts from our transformation initiatives across all operating expense categories.

Other income and expenses were a net $197 million expense in Q4. This is unfavorable by $166 million on a year-over-year basis. This year-over-year unfavorability was due primarily to lower interest income on lower cash balances as well as market value fluctuations of publicly traded securities held in our ventures portfolio.

The non-GAAP tax rate was 13.3% for the quarter, a 3.3-point improvement versus Q4 of 2017, reflecting favorable impacts of U.S. corporate tax reform. Non-GAAP net income increased 4% and non-GAAP earnings per share increased 18% year-over-year for the fourth quarter, supported by a 12% reduction in share count versus Q4 of 2017.

Please find a summary of our 2018 full year results on page 8 of the presentation. Our 2018 full year revenues increased 4% to $23.7 billion, while our non-GAAP earnings per share grew 14% to $14.40 per share. For the full year, we saw a 3% increase in worldwide product sales growth at $22.5 billion. Other revenues increased $160 million to $1.1 billion, due largely to the year-over-year favorable impact of milestone payments.

For the full year, non-GAAP operating income at $11.9 billion grew 2% from the prior year and our non-GAAP operating margin was 52.6% for the year. In total, non-GAAP operating expenses increased 6% year-over-year to $11.9 billion as increased investment in

both R&D and our launched products exceeded the benefits from our ongoing transformation initiatives.

To put this in perspective, through the end of 2018, overall net operating expenses increased less than 1% on a five-year CAGR as we reinvested our transformation savings to broaden our capabilities, launch multiple products in new therapeutic areas and generate innovative first-in-class molecules, including our emerging oncology programs.

Other income and expenses were unfavorable by $410 million on a year-over-year basis due to lower interest income on our lower cash balances and portfolio rebalancing. The non-GAAP tax rate was 13.5% for the total year, down 4.5 points versus 2017, due to the impacts of U.S. corporate tax reform.

Turning next to cash flow and the balance sheet on page 9. For the full year 2018, Amgen continued to demonstrate strong and stable cash flow generation, reflecting a portfolio dominated by differentiated biologic products, coupled with an industry competitive cost structure.

2018 free cash flow was $10.6 billion versus $10.5 billion in 2017. Debt outstanding at year-end totaled $33.9 billion and carries a weighted average interest rate of 4% and an average maturity of 11.5 years.

In 2018, we returned a total of over $21 billion to shareholders, including deployment of $17.9 billion to repurchase 94.5 million shares at an average of $189 per share. Additionally, for 2018, we increased our dividend per share by 15% to $1.32 per quarter, with dividend payments totaling $3.5 billion.

Based on our confidence in the future outlook for the enterprise and our continued commitment to a balanced capital allocation strategy, we also announced a 10% increase to the dividend to $1.45 per share for the first quarter of 2019.

Turning to the outlook for the business for 2019 on page 10. 2019 will be another important year for Amgen as we continue investing in the pipeline, building out our global business and supporting our new product growth. In anticipation of this opportunity, we transformed the business over the past several years and more recently embedded a permanent productivity capability to enable us to fully invest from a position of strength. This business model enables us to deliver industry-leading financial performance while continuing to invest for long-term growth and success.

Our 2019 revenue guidance is $21.8 billion to $22.9 billion, and our non-GAAP earnings per share guidance is $13.10 to $14.30 per share. Our non-GAAP tax rate guidance is 14% to 15% and we expect capital expenditures of approximately $700 million this year.

There are several key assumptions embedded in our outlook that I will take a moment to share. First, our revenue guidance range reflects, both continued solid positive growth

momentum from our newer products, as well as evolving competitive dynamics related to our mature products.

We have important incremental growth opportunities driven by recently launched products including Aimovig, Repatha, and biosimilars and international expansion, as well as our emerging oncology programs. We also recognize the potential challenges including further generic competition to Sensipar, continued competitive dynamics for Enbrel and competition against Aranesp and Neulasta.

With regard to net selling prices, as referenced, overall net selling price decreased by 1% in 2018. We expect net selling prices to decline by mid-single digits in 2019.

Finally, we benefit from the added flexibility enabled by our transformation and productivity capabilities to use our strong cash flow and balance sheet to invest in the continued growth of the company. With regard to Sensipar, we are confident in the strength of our intellectual property. However, uncertainty as to the timing and intensity of competition will remain until the outcome of litigation becomes clear. Our guidance reflects this uncertainty.

Note that Sensipar sales will be lower than 2018 in all scenarios as the result of recent short-live generic entry, continued adoption of Parsabiv and a non-recurrence of the substantially higher purchases in Q1 of 2018, due to the reimbursement change from Part D to Part B.

As you model revenue in 2019, note that historically the first quarter represents the lowest product sales quarter of the year. As a percent of the full year, product sales for the first quarter should look similar to the percentage we saw in Q1 of 2018. Murdo will provide further details related to first quarter sales in his remarks. With respect to other revenue, we expect about $1.1 billion for the full year 2019, reflecting the non-recurring nature of milestone payments received in 2018.

From an operating expense perspective, our transformation enabled us to establish a highly efficient cost profile. From this lean baseline, we expect to continue to generate incremental savings through our productivity improvement capability and manage costs in a very disciplined manner, while making the investments required to rapidly advance our pipeline and maximize the value of our marketed products.

Overall, we expect 2019 operating expense to be flat to down from 2018 on an absolute basis. We anticipate R&D expenses to rise as our pipeline advances, cost of sales to be flat to slightly up depending on volume and SG&A to decline as launch expenses normalize and we continue with our resource allocation discipline. Finally, we expect all categories to benefit from our productivity program. With regard to our 2019 guidance, our non-GAAP tax rate is forecasted between 14% and 15%. This incorporates a 21% tax rate on U.S. earnings and a 10.5% tax rate on ex-U.S. earnings.

With regard to capital deployment, our actions will continue to reflect the following principles.

First, we will invest in our business to expand our pipeline and seek to drive long-term revenue through volume growth, globally in both large and specialty care markets. Second, we will remain committed to achieving an optimal capital structure in order to minimize our weighted average cost of capital by fully deploying cash flows over time as well as deploying excess accumulated capital, reflecting our confidence in the future and remaining excess cash position will continue to support a growing dividend, including the 10% increase in the first quarter of 2019, as well as continued share repurchase in 2019 and beyond. At year-end 2018, we have a remaining unused board authorization to purchase up to $5.1 billion of our common stock.

Finally, today's revenue and non-GAAP EPS guidance ranges are again wider than we have historically provided at the start of each year. This wide range is primarily a reflection of uncertainties related to our Sensipar sales, coupled with other ongoing uncertainties that I outlined earlier. Consistent with our usual practice, our guidance today does not include the impact of potential business development activities.

In summary, we delivered another year of strong financial results in 2018, and we remain confident in the outlook for Amgen's success in 2019 and beyond. This concludes the financial update.

I now turn the call over to Murdo.

Murdo Gordon {BIO 18450783 <GO>}

Thanks, David. I'll take a few minutes to reflect on our 2018 performance and then review our Q4 product-specific performance.

In 2018, we accomplished a great deal, growing sales 3%, driven by 5% volume growth. In the U.S., we launched two products: First, Aimovig, an innovative first-in-class therapy for the prevention of migraine. Aimovig reached over 150,000 patients during 2018 and represents a strong launch trajectory.

We also launched Parsabiv, which provides nephrologists with better control for their SHPT patients given its mode of administration. Parsabiv generated over $300 million of sales in the U.S. the first year of launch, again, representative of the benefit that it brings, as well as Amgen's strength in nephrology.

We made great strides in driving volume growth across much of our portfolio. Take Prolia as an example. In the eight-plus years since launched, we've delivered double-digit volume growth in every quarter. This illustrates the consistency and durability of growth opportunities in diseases with large underserved patient populations.

With Repatha we've demonstrated our competitiveness with leading market shares, while improving patient access and affordability. The fundamental characteristics of Repatha are similar to Prolia, both address an asymptomatic disease with high numbers of undertreated patients. The physical, emotional and financial costs of events to patients and society, whether they be fractures in the case of Prolia or stroke or heart attacks in the

case of Repatha, are exceedingly large. The patients at highest risk are identifiable in therapies such as Prolia and Repatha can prevent such outcomes.

Sales of our hematology and oncology portfolio of XGEVA, KYPROLIS, Vectibix, Nplate, BLINCYTO and IMLYGIC exceeded $4.4 billion, growing 14% over last year. This is a therapeutic area where we have strong global capabilities that we will leverage as our pipeline matures.

While our mature brands of Enbrel, Neulasta, NEUPOGEN, EPOGEN and Aranesp face intensifying competition, our teams continue to promote and demonstrate the value that these brands provide. With decades of clinical experience and Amgen's assurance of high-quality supply, we expect these brands to continue to generate value for many years into the future.

Outside of the U.S., we launched our first two biosimilar products: KANJINTI, a biosimilar to Herceptin; and AMGEVITA, a biosimilar to Humira. We expect to launch additional biosimilars in 2019 across multiple geographies and continue to advance additional biosimilar assets through development. We remain confident in the biosimilar business opportunity that we embarked on nearly a decade ago and expect these assets to contribute significantly to Amgen's growth.

Also, outside the U.S. where we faced biosimilar competition for many years, we had strong volume growth of 14% in 2018, demonstrating the growth potential of our newer portfolio. These markets serve as a model for Amgen's future growth profile. In addition, our ex-U.S. business represents a growing portion of our overall revenue base due to our international expansion efforts.

Finally, we continue to invest in our portfolio, particularly those brands with longer periods of patent protection, including Enbrel, Prolia and Aimovig. Those investments have taken the form of evidence generation, patient-friendly devices and formulations, as well as consumer and healthcare provider awareness efforts. We are encouraged by the promotional responsiveness of these brands and continue to seek additional investment opportunities that can both drive volume growth and generate shareholder returns.

Now moving to fourth quarter results, you find reference information on our product sales on slides 12 and 13. Fourth quarter reported sales grew at 8% year-over-year, driven by 10% volume growth.

Let me start with Repatha on slide 14. Q4 sales of Repatha grew by 62% year-over-year, as we continue to compete effectively, with a leading share in the PCSK9 class of approximately 60% globally. For the full year, Repatha grew by 72%, with volume nearly doubling versus 2017.

In 2018, we were able to secure improved payer utilization management criteria and help HCPs treat more patients. Additionally, we launched our new lower list price Repatha where we reduced the list price by 60%. We've seen strong uptake of this product,

representing over 25% of all units in the U.S. as we exited the fourth quarter. To date, plans formally covering lower list price Repatha represent only 43% of Medicare lives.

We're encouraging plans to move more rapidly to not only cover lower list price Repatha but also to provide coverage with low fixed co-pay, given the significant potential benefit this can provide Medicare patients and to reduce their out-of-pocket costs. We look forward to working with the plans and the U.S. administration to see how we can get this important treatment to patients more rapidly.

At a macro level, I'll remind you that the blended net price for Repatha in the U.S. will decline in 2019, as new contracts went into effect in January. While this lower net price may impact reported Repatha sales near-term, we expect to see a positive impact on volume growth and reported net sales over the longer timeframe.

Regarding our ex-U.S. business, we continue to work with country authorities to optimize access. Overall, our priority remains to help the large population of high-risk cardiovascular patients that can benefit from Repatha.

On to Prolia on slide 15. Prolia delivered another strong quarter, with sales increasing 14% year-over-year, driven by 12% volume growth. As we typically see, we also had sequential growth in the fourth quarter. For the full year, Prolia grew 16%. Let me remind you that overall penetration is still in the mid-20% range across many markets, indicating significant potential for improved treatment. We expect Prolia will remain a very strong growth driver.

Moving to our hem/onc business, the portfolio of KYPROLIS, XGEVA, Nplate, Vectibix, BLINCYTO and IMLYGIC collectively totaled $1.1 billion in the quarter, growing 13% year-over-year. While there may be periodic quarterly fluctuations due to purchasing patterns, we expect this portfolio to continue as a growth engine and provide the foundation for both innovative and biosimilar additions to our oncology portfolio.

Looking at additional details for some of the larger brands, if we start with XGEVA on slide 17. In Q4, XGEVA grew 17% year-over-year, primarily from volume, as we hold close to 60% share in the U.S. Our share in multiple myeloma patients continues to grow steadily with our label expansion in 2018. On a full year basis, XGEVA grew 13%.

On to KYPROLIS, which in Q4 grew 11% year-on-year, driven primarily by growth in markets outside of the U.S. Since its launch, KYPROLIS has delivered a suite of clinical evidence, demonstrating its ability to meaningfully extend overall survival in patients with relapsed or refractory multiple myeloma. Our team continues to emphasize KYPROLIS overall survival benefit and we have seen new patient share gradually increase.

Also, there are promising signs for our newly introduced once-weekly administration with incremental growth in 2nd-line usage of Kd. On a full year basis, KYPROLIS grew 16%.

Let me also cover our filgrastim brands starting on slide 19. In Q4, Neulasta sales increased 5% year-over-year, which included a $55 million purchase from BARDA. For the full year 2018, Neulasta sales declined by 1%. As we anticipated, we now have two biosimilar competitors in the U.S. facing one competitor during Q4, we retained 96% share of the long-acting market, with Onpro, a majority share at over 60%.

A second U.S. competitor was approved late 2018 and launched early this month. Our guidance anticipates the possibility for other competitors to enter the U.S. during 2019.

In Europe, we now face three long-acting biosimilar competitors, which have launched over the last four months and expect additional entrants during 2019. Consistent with our long-held expectations related to Europe with numerous competitors launching in a short time window, we expect European sales to decline over 25% year-over-year.

More broadly, with the uncertainty over the eventual number of competitors on a global basis and their launch timing, there is a range of possible outcomes for Neulasta in 2019. We remain confident that our experience, established record of quality, dependable supply and innovative solutions, such as Onpro, will serve us well.

Turning to slide 20, NEUPOGEN exited the fourth quarter with roughly a third share of the short-acting segment in the U.S.

Moving to Enbrel for both Q4 and the full year, sales declined 8%, primarily driven by volume and net selling price declines. In general, we expect recent trends to continue. Recall that the first quarter represents the lowest sales of the year due to insurance reverifications and resetting of deductibles and channel inventory fluctuations. As a percent of the full year, the first quarter should look similar to 2018.

Switching to nephrology, starting on slide 22, Q4 EPOGEN sales declined 2% due to lower net selling price in a category that's becoming increasingly competitive. For the full year 2018, sales declined by 8%. With the launch of a biosimilar competitor late last year and our contractual pricing commitments with DaVita, the net price decline for EPOGEN will increase significantly in 2019 and is already in effect.

Aranesp declined 3% year-over-year in Q4, primarily driven by increased competition from a long-acting product in the independent and mid-sized dialysis organizations. For the full year, Aranesp declined 9%. Recall that the short-acting biosimilars approved to compete in all market segments in the U.S.

As reference, slide 24 shows the breakout by segment of our ESA business. We expect sales to decline at a faster rate in 2019 than 2018, with both long-acting and short-acting competition in the U.S.

With regards to calcimimetics, we continue to see strong utilization of Parsabiv at independent and mid-sized dialysis providers who have incorporated it into their protocols. However, the rate of adoption with those customers slowed in Q4 as Parsabiv

already represented a majority of calcimimetic utilization for their patients. We continue to see gradual adoptions of Parsabiv with FMC and DaVita and expect most of the future growth to come from these customers.

Turning to Sensipar, the outlook remains uncertain given ongoing litigation leading to a range of possible outcomes. And you heard David characterize our guidance related to Sensipar. Let me reiterate the points that he made. Recall that Q1 of 2018 had substantially higher purchases than normal run rates due to the reimbursement change from Part D to Part B. Also, looking forward, there will be volume erosion due to continued Parsabiv uptake. And finally, the short-lived generic entry will impact 2019 sales.

Regarding 2018 performance, Q4 sales increased 8%, primarily driven by changes in accounting estimates, offset by lower volume due to the continued adoption of Parsabiv. Sales grew 3% on a full year basis.

Shifting gears from our innovative products to our biosimilars portfolio, our European launches for KANJINTI and AMGEVITA are underway. While it's still early in the launch cycle, the market is playing out as we anticipated and we're pleased with our performance to date.

Outside of the U.S., we see important differences between products and markets in terms of biosimilar uptake and price erosion. Recent launches in markets, such as Norway and the Netherlands, are experiencing strong uptake at more discounted pricing levels. While in other larger markets, including Germany and France, there's a more balanced dynamic and sustainable opportunity. Our strategy is to focus primarily on these more sustainable markets, which we expect will drive our biosimilar revenues in the next several years. We also expect incremental contribution from competing selectively in certain tender-driven markets.

Across Europe, there is significant demand for high-quality, reliable biosimilars. While some have speculated as to the strength of the biosimilar market in the U.S., we see biosimilars representing an important market for the future. Using NEUPOGEN as an example, where biosimilars continue to gain share, demonstrating that they can successfully compete in the U.S. market. We're planning for additional launches in 2019 and expect this business to be a growth driver for years to come.

I'd like to close the product review section of my comments with Aimovig. We continue to be excited by the strong response from physician and patient community following the launch of this innovative therapy. Overall, the CGRP market grew at over 150% quarter-over-quarter in Q4, with Aimovig exiting 2018 with the majority share, demonstrating our first mover advantage, strong product profile and ability to compete. We recently launched our DTC campaign and see early promising results.

I know there's been a great deal of interest in the number of prescriptions that are being paid for. So let me share that. During Q4, the percentage paid was 50%, which was up from prior quarter at 35%. We also expect to double contractor coverage in Q1 versus Q4.

Before closing out Aimovig comments, I should call out that the fourth quarter sales of $95 million benefited from $20 million of changes in prior period accounting estimates as we realized higher average net selling prices from quarters two and three versus our prior estimates. And like Enbrel, the first quarter for Aimovig will also experience insurance reverifications and resetting of deductibles, leading it to be a lower quarter than subsequent ones. We expect Aimovig to continue to be a growth driver for Amgen.

In summary, we continue to market a portfolio exemplified by important medicines that treat serious diseases. I'm pleased with the execution and consistency of performance in 2018, demonstrating that we have established a strong foundation for the future. Our portfolio will continue to evolve during 2019 and we're prepared to maximize on the opportunities to bring Amgen's products to a greater number of patients.

Now I'd like to turn the call over to Dave Reese.

David M. Reese {BIO 19782623 <GO>}

Thanks, Murdo. As we enter 2019, I've never felt better about our effort, progress and productivity in R&D. Our investment in human genetics continues, powered by deCODE and their work on the Icelandic population; more than 1 million participants from outside Iceland, and in the future, up to an additional 0.5 million patients following our agreement with a leading U.S. integrated delivery network.

Today, over 75% of our pipeline has some degree of human genetic validation compared to just 15% five years ago. This increases the conviction we have in certain programs and gives us the confidence to make more aggressive strategic investments from discovery through clinical development that can improve cycle time significantly.

In fact, through our use of genetics and our transformation efforts, we estimate that we have reduced the development timelines in some of our programs by an average of three years. To complement our human genetics work, we're partnering with SomaLogic to analyze 5,000 proteins in up to 40,000 individuals for whom sequencing data are available. To our knowledge, this is the largest proteomics experiment ever conducted and may enhance our insights into disease biology.

R&D is firing on all cylinders as we have advanced a record number of programs. One of our key productivity metrics is the number of molecules we commit to take forward into human testing, the formation of so-called product teams. I'm pleased to report that over the last two years, we formed more product teams than any prior two years in Amgen's history.

In the same period, we also filed 20 INDs, approximately 70% of these being first-in-class molecules, and we also began 15 first-in-human clinical studies. Several of these will begin reading out this year.

I'll begin with an update on oncology. In December, we had the opportunity at ASH to present the initial clinical data from our BCMA BiTE, AMG 420 in multiple myeloma and

our CD33 BiTE, AMG 330 in AML. The data were very well received by the medical community, most notably the AMG 420 data, which demonstrated a 70% response rate and a 40% MRD negative complete response rate at our target dose in heavily pretreated patients. We look forward to additional data from those programs this year, along with initial data from our half-life extended BiTE programs, AMG 701, directed against BCMA and potentially AMG 673, directed against CD33.

We also expect initial data from our small molecule KRAS G12C inhibitor, AMG 510 in the first half of the year. This particular mutation is easily identifiable and present in about 15% to 25% of lung adenocarcinomas and 2% to 4% of a wide range of other solid tumors, including pancreatic cancer and colorectal cancer. This is an example of a program that we accelerated significantly. We were the first into the clinic and are now moving through dose escalation, where we are seeing interesting early hints of clinical activity.

We also expect data from our Mcl-1 inhibitor program in multiple myeloma in AML from both our IV and oral formulations, AMG 176 and AMG 397, respectively. Our preclinical data suggest that these molecules could be additive or synergistic with a BCL-2 inhibitor, and we will be advancing combination studies as we move forward.

We also expect data this year from AMG 596, a first-generation EGFRvIII BiTE under investigation in patients with glioblastoma, a setting where a short half-life molecule is preferable due to potential on-target toxicity within the CNS. This mutation is present in about 25% of glioblastomas and represents a true tumor-specific antigen.

We're also pleased to report that a single-arm Phase 3 trial of KYPROLIS and dexamethasone, Kd, met its response rate primary endpoint in China in patients with relapsed and refractory multiple myeloma.

Finally, in the oncology pipeline, later this year, we expect to conduct the primary analysis of our Phase 3 study of KYPROLIS in combination with dexamethasone and DARZALEX, Kd-DARA versus Kd alone in relapsed and refractory myeloma.

In cardiovascular, the Repatha indication was recently expanded in China, making it the first PCSK9 inhibitor approved there to reduce the risk of myocardial infarction, stroke and coronary revascularization in adults with established atherosclerotic cardiovascular disease. In our other atherosclerosis clinical program, we are impressed with the initial clinical data we are seeing with AMG 890, an siRNA that targets Lp(a), high levels of which are genetically determined and associated with an increased risk of cardiovascular disease. We look forward to sharing those data with you later this year or in early 2020.

In bone, EVENITY was recently approved in Japan for the treatment of osteoporosis patients at high risk for fracture, and we were pleased that the FDA Advisory Committee voted in favor of approval for the treatment of postmenopausal women with osteoporosis at high risk for fracture in the United States. We will continue working with FDA towards registration and along with our partner, UCB, look forward to bringing this effective medicine to osteoporosis patients at high risk for fracture in the U.S. and around the world.

Finally, we continue to advance our biosimilar programs with regulatory submissions completed in the U.S. and EU for ABP 710, our biosimilar REMICADE. On December 28, we refiled our BLA with FDA for KANJINTI, our biosimilar Herceptin, and expect a six-month review.

ABP 798, our biosimilar Rituxan, met all of its primarily and secondary endpoints in a Phase 3 trial in patients with rheumatoid arthritis, and we anticipate the completion of the second Phase 3 trial in non-Hodgkin's lymphoma later this year. We've also begun screening patients in the Phase 3 study of ABP 959, our biosimilar Soliris.

Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you. We've covered a lot of ground now. Ian, why don't we open up the line to questions? And if you wouldn't mind, please remind the callers what the process is for asking questions.

Q&A

Operator

Certainly. And our first question is from line of Ying Huang from Bank of America Merrill Lynch.

Q - Ying Huang {BIO 16664520 <GO>}

Hi. Good afternoon. Thanks for taking my questions. First question I have is regarding your assumption for Neulasta in the guidance, are you assuming there will be a third entry for Neulasta biosimilar? And then, are you also assuming the net price in terms of decline similar to the 2018 or not?

And then next question is, if you don't consummate a big M&A transaction, would you consider another ASR this year in 2019? Thank you.

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

Okay. Couple of questions there. First on Neulasta, I think both Murdo and David addressed it. Murdo, do you want to reiterate what you said on the call?

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Sure. On Neulasta, we're assuming that we will have, as expected, the two competitors in the market as well as potential additional competitors before the end of 2019 in the U.S. We're also assuming some additional competition outside the U.S.

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

David, do you want to just give (00:47:26) guidance more broadly?

A - David W. Meline {BIO 6397419 <GO>}

Yeah, sure. Yeah. Yeah. In terms of the capital and cash deployment, of course, our priorities are the same, which is our first priority is to invest in the business, both internally at Amgen as well as looking very actively at potential additions to the portfolio through business development. And, obviously, we have plenty of financial flexibility to be able to accomplish that.

We're also committed to return excess cash to shareholders through time. And I would observe that we had quite significant returns to shareholders last year, over $21 billion. And I would say from a repurchase perspective, I would look at the pace at which we've been operating as a reasonable guide for us into 2019. And then more specifically as to the ASR question, we haven't made a determination as to whether we pursue something of that sort. But, obviously, if we decided to, we'd be communicating that.

Operator

And our next question is from line of Matthew Harrison from Morgan Stanley.

Q - Matthew K. Harrison {BIO 17603148 <GO>}

Great. Good afternoon. So two questions from me, just related to guidance as well. Can you just help us? It's still not clear to us how much inventory Teva launched into the channel for Sensipar. Can you just tell us how much of a headwind that's expected to be for Sensipar this year?

And then on EPOGEN, and I guess Aranesp as well, you talked about significant year-over-year price declines. Can you help us with order of magnitude? Are these single- or double-digit year-over-year kind of price declines for those products? Thanks.

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

Yeah. So maybe I'd start on the Sensipar question. And I guess what I'd say, first of all, in all scenarios that we've got for Sensipar in 2019, as I said, we do expect a year-over-year decline in sales, driven by the Part D to B switch last year, Parsabiv taking more share of the market and the fact that there was the temporary entrant of a generic competitor.

What's true is our agreement does not allow us to comment on the amount of product put into the market. But what I would say is we did indicate that if you look at our overall sales in the first quarter, we think as a percent of the total year, they'll be comparable to 2018. And I think it's fair to assume that the impact on the market from the Sensipar generic was likely to be certainly impacting Q1.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. And, Matthew, we're expecting trends to be fairly stable in our Aranesp and our EPOGEN business going forward.

Operator

Our next question is from the line of Chris Raymond from Piper Jaffray.

Q - Christopher J. Raymond {BIO 4690861 <GO>}

Thanks. Maybe just a Repatha question. Murdo, I just want to make sure I understand what you're talking about with respect to net price. I think when you guys announced the new pricing structure and the new SKU, you took pains to say that not to expect a change in the blended net price going forward, but when I look at slide 14, it looks like you're guiding to a lower net price. So is that sort of a long-term data point or is there something else going on there?

And then maybe just a part two to that question. Just kind of curious. You've mentioned 12 to 18 months to get folks to migrate to that lower priced SKU. Just kind of curious how that conversation goes with payers who continue to opt for the higher priced SKU. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, thanks for the question. Overall, the experience with Repatha has been very good through the fourth quarter and we're optimistic that we'll continue to make good inroads this year.

If you recall, we were contracting through the middle of last year to improve utilization management criteria for Repatha and we've been competitively doing that. In addition, with the introduction of the new low list price, we were able to directly address the out-of-pocket expenses for some Medicare Part D patients.

What we're signaling is that we will have some step-down in net ASP with new contracts going into effect in 2019. However, we do expect that that will be offset with volume growth throughout the course of the year.

The other thing that I would point out, just to your question on how those conversations go, is we did launch the low list price Repatha late in the bid cycle for Medicare Part D plans for payers at the end of last year. So we weren't expecting to be broadly used and listed on their formularies in the first part of this year. So we're working for off-cycle additions and we've been able to do that and we've been able to drive about 25% of our out-movement as the low list price of Repatha and that continues to climb and we've been able to see some out-of-pocket costs being reduced at the counter for Medicare Part D patients, who need access to this medicine. I would say it's going according to plan, but we are doing everything we can to work with payers to accelerate that.

Operator

And our next question is from the line of Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. We're just wondering with respect to Aimovig, if you can give us any update there on the formulary dynamics in terms of where you'd stand? How many decisions are outstanding, any key differences versus Repatha as we think about the longer-term pricing outlook there? And then would love an update on the monthly formulation in terms of when we might expect that to launch. Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, I'll handle the first part and then maybe turn over to Dave Reese for the change in formulation. Overall, we're really pleased with Aimovig. We priced this product for access. It's been well received by payers for the most part. What's happened to date has been that we've received pretty good coverage with most payers even on a non-contracted basis, allowing the product to be reimbursed on the basis of physician at that station alone.

What we are seeing now into the first quarter is an increase in the number of paid prescription. So that jumped from 35% to about half of our total prescriptions in the fourth quarter. What we will see though is, from Q4 to Q1, is we will see an increase in our contracted business and that will have a short-term step-down in net selling price, but then as the year progresses, we should stabilize because we'll have a smaller and smaller percentage of our business that is through free goods program versus contracted paid for.

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

On the question, Terence, of when we expect to hear from FDA – yeah, I mean, we've – this is Dave Reese. We've submitted that. It's under FDA review. We'll provide guidance as those discussions are moved further along with the agency.

Operator

And our next question is from line of Geoffrey Meacham from Barclays.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Hey, everyone. Thanks for taking the question. Question for Dave on the oncology pipeline. There's a lot to digest on slide 30 and you've got a lot of programs and I don't think this includes your recent IO collaboration. So the question is how do you prioritize? And more importantly, when you look at trying to fill the revenue gap from biosimilars, are there oncology programs that you'd call out that are closer to starting a Phase 3? Thanks.

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

Sure. So I think you raise an important question about how we prioritize. That's really based on emerging data. As we develop a broad-based plan to advance these agents, we went through a detailed prioritization exercise and we would expect that over the course of the year there will be puts and takes based on emerging data, and we fully intend to invest resources behind those programs that are showing evidence of efficacy, the kind of transformative efficacy that we're aiming for.

In terms of those programs that may be closer to Phase 3, that's a little harder to speculate on. I think the KRAS program, the Mcl-1 programs and some of the BCMA BiTEs in the early portfolio can transition to potential registration quality trials. I wouldn't necessarily use the Phase 3 nomenclature here. Again, all of that will be driven by emerging data.

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

I think, Geoff, if you look at the oncology portfolio, just that segment alone, I think we're expecting reported results on seven of these assets during the course of 2019. So this will be an active year for us to share data with all of you.

Operator

And our next question is from the line of Ronny Gal from Bernstein.

Q - Ronny Gal {BIO 15022045 <GO>}

Good evening. Congratulations on nice results and thanks for squeezing me in. I guess just like my peers, I'm trying to work through the ups and downs of the guidance. So really two questions there. First, when we think about additional Sensipar competition, when is the earliest in your low case, you assume it could come? Is it midyear or is it even earlier than that, just based on the timing of the trial?

And second, if we look at Aimovig, you kind of mentioned that you'll have higher paid prescriptions. I was wondering if you can give us a feel for where the pricing might end on the contract. I think Teva mentioned something between $4,000 and $4,500 as kind of like the prevailing price when the market settles down. Is that roughly around what you guys think it will end up? Or is that range going to be you higher than that?

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

Okay. Why don't we do it in two parts? David, why don't you address Sensipar, and...

A - David W. Meline {BIO 6397419 <GO>}

Yeah. So in terms of – if you look at the guidance that we provided, which, as I said, is a wider range than traditionally we would have, the primary driver of that increase in range of course is the uncertainty on Sensipar. And as to your question specifically, what we're anticipating now is that the litigation that's presently underway would conclude by around midyear and that's how we're reflecting one of the scenarios in guidance to reflect that scenario.

A - Murdo Gordon {BIO 18450783 <GO>}

And on Aimovig, I think I answered most of this before. And rather than give price specific guidance on the product, I would say that we're pleased with how we've contracted for access so far. It is a competitive category. And then the other variable that we have to think about is the percentage of our prescriptions that get filled as paid prescriptions versus free goods.

Operator

And our next question is from line of Michael Yee from Jefferies.

Q - Michael J. Yee {BIO 15077976 <GO>}

Thanks. Good afternoon. Question for Bob. In the past, you've talked about various degrees of appetite for M&A. You talked about overcapacity in the industry. Maybe you could just revisit your thoughts around the degree of appetite and more importantly I'm sure you're aware of the various industry chatter about mega-mergers and where Amgen's view is on mega-mergers. So maybe just comment about that and to what degree you can clear that up for people? Thanks.

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

Sure, Michael. I think our view on this has been consistent now for a while, which is we're looking at opportunities to invest in the business. Our focus is on innovation. We're likely to look most closely in those areas where we feel we can add value and create value for our shareholders. So that would imply the therapeutic areas that we're focused on.

We do think there will be opportunities. We think we have the flexibility to look at those, the balance sheet and the management resources to look at those transactions. And with stocks down considerably from where they were a year ago, I would expect that we will continue to look and look across the waterfront of smaller and larger deals. Obviously, there are more smaller ones than large ones. So we tend to spend more of our time looking at those. But we're consistent with what we said now for a while. We're looking across the waterfront to find ways to invest in the industry in ways that we think we can add value for our shareholders, not just the target shareholders.

Operator

And our next question is from the line of Geoffrey Porges from SVB Leerink.

Q - Geoffrey C. Porges {BIO 3112036 <GO>}

Thank you very much. David, you spent quite a bit of time talking about the last five years and I just would like you to give us some sense of your outlook for the next five years. I'm sure you have a very detailed operating plan in place already, but many of the trends that have been highlighted on this call and in your guidance have been coming for some time, Neulasta, Sensipar, et cetera. So could you give us a sense of how long it might be before you see the current R&D portfolio providing enough opportunity to offset what's likely to be several years of erosion of these very successful legacy products?

A - David W. Meline {BIO 6397419 <GO>}

Sure. So, yeah, I'm trying to think of how to frame the answer to the question, Geoff. So, certainly what we see now and if I look as an example, the performance in the fourth quarter, even the full year in 2018, where we have had and we continue to see increasing competition against our legacy products, we're quite pleased to see that our global volume growth last quarter was 10%. And for the company in 2018 was 5% volume

growth, so that gives us some positive confidence as we look at the existing portfolio of products that are in the market right now that they are going to provide very strong and stable growth, which will help us to offset the impact of our legacy declines.

What's also true this year is we have an increasing portfolio of our own biosimilars in the market, which are also going to support growth for the company. And then, finally, as you're asking about what about the emerging portfolio, both of our late-stage trials of products that are more in Phase 3 already and the emerging oncology portfolio, quite frankly it's a little bit early notwithstanding you're giving me credit for a lot of detail. It's a little imprecise right now, especially on these earlier stage products, but we are encouraged by the speed at which they're coming forward. And certainly in the oncology area, these products have a chance to impact quite quickly as compared to in some of the other therapeutic areas, so that's the best I can offer you.

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

And I think I'd reiterate, Geoff, what we've said in a variety of different ways, which is we think we're well positioned now to deliver on our long-term growth aspirations. So, look forward to doing just that.

Operator

And our next question is from the line of Umer Raffat from Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thanks so much for taking my questions. I actually had a question for David and David. So the first one was on – and they can pick whichever one.

A - David W. Meline {BIO 6397419 <GO>}

Okay.

Q - Umer Raffat {BIO 16743519 <GO>}

First one was on operating margin. And my question really was not so much looking for guidance, but hoping to understand is there – as we enter – as revenues grow in future, would you expect the dollar OpEx to grow slower than that? That was first.

And the second one is, KRAS is something, and I think some of your comments at a few conferences in the last few weeks have generated a lot of investor interest. So my question is, from these early scans in this relatively new trial, what are you seeing on the G12C, and would you think of this drug as a potentially best-in-class? Thank you very much.

A - David W. Meline {BIO 6397419 <GO>}

Yeah, so in terms of, Umer, operating expenses and trends there, what I would say is a couple things. One is, as we know, we put the company in a really nice position in terms

of our financial performance based on the work that we've done over these last several years and we enter the period in 2019 with quite a lean cost structure.

What's also true as I mentioned in my comments, the good news is there's always more opportunities. The business changes, we see that there's more productivity to be had and we think that will be an important source of financial flexibility to allow us to continue to invest going forward and I talked about the trends that we expect in the different categories this year.

I think your longer-term question, which is do we expect that in the context of a growing revenue base that we're going to get leverage off of that revenue vis-a-vis our expenses, I would say that certainly we'd be committed to that type of performance for the company through time. And I would say, as we move into the future, we'll be able to give you some more specifics as to how we're thinking about that.

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

Yeah. And in regards to the KRAS question. As you know, this has been a Holy Grail target for 35 or 40 years now. We're very happy to be first in the clinic. We're moving briskly through the Phase 1 dose escalation. We expect to be able to share, hopefully by midyear, initial results from that first-in-human trial. In terms of best-in-class, we're really only right now in terms of where we are in dose escalation. Ultimately, everything will depend on clinical data. I don't think it's really helpful to speculate much beyond that.

Operator

And our next question is from the line of Robyn Karnauskas from Citi.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi, guys. Thanks for taking the question. So I just wanted to clarify a couple things on just the Neulasta guidance. So first of all, is Onpro protecting you at all? I know Mylan said that they have 18% to 20% share in the injectable market. And going with that, how much insight, how much of comfort do you think you really have into the two generics that are on the market right now and their impact on 2019? Meaning, is that – is the range a little bit less than what you're saying that you described for Sensipar for your guidance? Thanks.

A - David W. Meline {BIO 6397419 <GO>}

Yeah. Robyn, let me try to go over some of the things that we are seeing with Neulasta. As we expected at the end of last year, we saw an additional long-acting biosimilar approved. And we have so far seen their actions in the market as consistent with what we had expected. We are seeing very good uptake of Onpro. We're over 60% penetrated now with Onpro across our business. And, we would anticipate that that differentiated offering of having both, Onpro and our other formulation, that we will be able to drive some differentiation with institutions, clinics and providers.

And so that is indeed the differentiated strategy that we'll pursue going forward. However, given that we're going to have now two long-acting biosimilars and we're assuming that there's a potential for additional before the end of the year, we would expect to see some share erosion in 2019.

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

Maybe I'd add. If you look, it comes back a bit, I think your question to the guidance and how broad it is. And as I said earlier, Robyn, the primary driver of that additional guidance range is, of course, Sensipar. But I think it's fair to say that there are other factors embedded there. So if not for Sensipar, perhaps our guidance would have been a little bit broader than traditionally would be the case, including the uncertainties around the path for Neulasta, which is obviously an important product for us.

Operator

And our next question is from the line of Cory Kasimov from JPMorgan.

Q - Cory W. Kasimov {BIO 3009346 <GO>}

Hey. Good afternoon, guys. Thanks for taking the question. I guess wanted to ask about when you might expect an initial verdict from the litigation around Enbrel's IP. And can you walk us through the potential scenario that you see there?

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

Well, Cory, as you point out in your question, we were in the District Court defending the intellectual property around Enbrel. We feel good about the intellectual property surrounding Enbrel. But the District Court needs to render a judgment, and we think that'll happen at some point later this quarter. And then, obviously – well, could even be later than that, Cory. But then, obviously, whatever the decision is – and I would remind you that Sandoz has agreed they infringed. And so the question is whether the IP is valid. And whatever the decision, I'm sure you can expect that there will be appeals. So this process will run on now for a little while, I would suspect.

Operator

And our next question is from the line of Alethia Young from Cantor Fitzgerald.

Q - Alethia Young {BIO 17451976 <GO>}

Hey, guys. Thanks for taking my question. Just one on EVENITY. If it happens to be approved, I guess have your perspectives or views changed on what's the potential market opportunity?

And then just one quick one on Enbrel. I see that the quarter-over-quarter trends have been fairly stable. I'm just wondering if we should think about kind of the trends over the next couple quarters in 2019; should they be stable as well? Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Maybe I'll start with Enbrel. I would say that we have seen stability in Enbrel, both in share performance as well as price evolution and I think that both of those will continue to be stable going into the New Year, at least over the foreseeable few quarters.

And then on EVENITY, we continue to see EVENITY as a really good complement to our overall focus on bone health. And with the approval in Japan for high-risk patients and the FDA decision with the Ad Comm. Most of that is consistent with what we had planned for the product and how it would be positioned in the market. However, there's still a lot of work and discussions still to have with the FDA.

Operator

And our next question is from the line of Kennen MacKay from RBC Capital Markets.

Q - Kennen MacKay {BIO 18821382 <GO>}

Hi. Thanks for taking the question. For David on the biosimilar franchise, you mentioned you began the Phase 3 study of biosimilar Soliris. Can you confirm that you've enrolled patients into that study? And if so, was the team waiting on any gating factors prior to moving ahead with the trial?

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

Yeah. I can confirm that we're screening patients. We expect enrollment to begin anytime now. The launch of the trial was really predicated on regulatory discussions that we had around the world to agree on the appropriate design, our endpoints and approvability.

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

I think the other thing, maybe I'll add, Kennen, on that is we think we're in pretty good shape here. We think we're excited to run the trial and establish biosimilarity, safety and efficacy. And with the recent patent decision in Europe in our favor, we're looking forward to having those data, seeking registration and beginning to serve patients.

Operator

And our next question is from the line of Salim Syed from Mizuho.

Q - Salim Syed {BIO 16887281 <GO>}

Yeah. Hi, guys. Thanks for taking the question. One on just Repatha, the lower price SKU. So when you're looking at your percentage of revenues coming from that lower price SKU, could you give us the payer split, Medicare, Medicaid and from commercial? Is its anywhere close to the natural distribution that you put out when you had the call in October? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah. Thanks, Salim. It's actually, right now, of total units that were sent that we're selling, it's over 25%. And it's roughly 43% of Medicare lives that have coverage and it does skew a little more to Medicare than it does commercial at this point in time. But it's evolving fairly rapidly and I wouldn't say that's steady state by any stretch.

A - Arvind K. Sood {BIO 4246286 <GO>}

Hey, Ian, as it's 6:15 on the East Coast, why don't we take two more questions, please.

Operator

Certainly. And our next question is from the line of Phil Nadeau from Cowen & Co.

Q - Phil Nadeau {BIO 4838409 <GO>}

Good evening. Thanks for taking my question. Just one on the overall pricing dynamics. David, in the prepared remarks, you mentioned that pricing was going to decline mid-single digits in 2019. That's versus 1% in 2018. Can you discuss what you expect longer term on pricing? Is 2019 the new normal or are there some elements in 2019 due to the competitive product launches and price cuts that will make that a worse year for net pricing than we should expect in the future? Thanks.

A - David W. Meline {BIO 6397419 <GO>}

Yeah. So, we wanted to communicate the outlook for net price for 2019. And I guess what I would say is that from a macro perspective in the U.S. market, I think we've been quite consistent in expecting that we would see more pressure on price combination of increasing intensity of competition, the concerns about affordability that are expressed in the regulatory and political environment. And then I would say, in addition to that for us specifically, in 2019, as Murdo commented, there are some specific cases where we have products that are either facing new competition in their post-exclusivity period or other factors that are impacting pricing.

So I wouldn't draw a conclusion that that's a new permanent level of price performance for Amgen, but I would say that it is fair to assume and we've been assuming a tougher pricing environment, which is why we've gone about putting ourselves in a very competitive position from a efficiency and cost perspective and why we continue to be very careful in terms of making sure we're going after new pipeline products that really change the standard-of-care, because those are the products where we'll be able to get a return going forward.

A - Arvind K. Sood {BIO 4246286 <GO>}

Ian, let's take one last question, after which Bob will make some concluding comments.

Operator

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A - Arvind K. Sood {BIO 4246286 <GO>}

Okay. If there are no further questions, Bob, do you want to make some closing comments?

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

Sure. Thank you all again for dialing into our fourth quarter call. We're excited about the outlook for the future. I hope by now, we've established with you and our shareholders as I know we have with our staff, a good track record of delivering against our financial commitments. And we look forward to doing that again this year.

With the actions that we've taken to transform the company, we think we're well positioned to deliver our long-term growth aspirations. And we're encouraged as you've heard us say in this Q&A about the momentum that we see for our newer products and the pipeline of differentiated first-in-class molecules that we're rapidly advancing.

So, with our strong balance sheet and cash flows, we expect to continue to invest in this business and to deliver return for our shareholders.

So thanks for joining and we'll look forward to talking to you again in April. And, of course, in the meantime Arvind and his team are here to take any questions if you didn't get a chance to ask them on the call.

A - Arvind K. Sood {BIO 4246286 <GO>}

Thank you, everybody.

Operator

Ladies and gentlemen, this does conclude today's Amgen's Fourth Quarter 2018 Financial Results Conference Call. We thank you for your participation. You may now disconnect.