Q1 2018 Earnings Call

Company Participants

- Anthony C. Hooper, Executive Vice President, Global Commercial Operations
- Arvind K. Sood, Vice President, Investor Relations
- David W. Meline, Executive Vice President and Chief Financial Officer
- Robert A. Bradway, Chairman & Chief Executive Officer
- Sean E. Harper, Executive Vice President-Research & Development

Other Participants

- Aharon Gal, Analyst
- Alethia Young, Analyst
- Carter Gould, Analyst
- Christopher J. Raymond, Analyst
- Cory W. Kasimov, Analyst
- Eric Schmidt, Analyst
- Geoffrey C. Porges, Analyst
- Geoffrey Meacham, Analyst
- Kennen MacKay, Analyst
- Maryana Breitman, Analyst
- Matthew K. Harrison, Analyst
- Michael J. Yee, Analyst
- Nick Abbott, Analyst
- Salim Syed, Analyst
- Srikripa Devarakonda, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Ying Huang, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

My name is Ian, and I will be your conference facilitator today for Amgen's first quarter 2018 financial results conference call. All lines have been placed on mute to prevent any background noise. There will be a question-and-answer session at the conclusion of the last speaker's prepared remarks.

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. I would like to welcome you to our conference call for the first quarter of 2018.

I think we are off to a solid start, with new and recently launched products continuing to deliver volume-driven growth, including our most recent launch, PARSABIV. We also have notable catalysts to look forward to, like our upcoming FDA action date for Aimovig for migraine prevention.

Our Chairman and CEO, Bob Bradway, will lead the discussion today with a strategic overview, followed by our CFO, David Meline, who will review our results for the first quarter and provide updated guidance for 2018. Tony Hooper, our head of Global Commercial Operations, will dig into our product performance during the quarter, followed by our head of R&D, Sean Harper, who will provide a pipeline update. We will use slides corresponding to our prepared comments today, and a link to those slides was sent earlier.

We plan on using non-GAAP financial measures in today's presentation to provide information which may be used for understanding our ongoing business performance. However, these non-GAAP financial measures should be considered together with GAAP results, and reconciliations of these measures are available in the schedules accompanying today's press release, our Form 8-K, and also on the Investor Relations section of our website.

So just a reminder that some of the statements made during the course of our presentation are forward-looking statements, and our (sic) 2017 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. Mr. Bradway?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Arvind. Thank you all for joining us.

As you can see, we're off to a solid start in 2018, with 3% growth in product sales, leading us to 10% growth in non-GAAP earnings per share. We had double-digit unit growth in all of our new and recently launched products, including Repatha, KYPROLIS, Prolia, and XGEVA. We also generated strong volume growth outside of the U.S., where our legacy brands have faced competition for some time. Repatha, KYPROLIS, Prolia, XGEVA, and soon Aimovig are clear examples of innovative medicines that address real unmet needs. These will be important drivers of our long-term growth.

In addition, we continue to invest in R&D to develop new game-changing medicines like omecamtiv, trastuzumab, and in the earlier stage, molecules like our IL-2 mutein, all of which have clear potential value propositions for patients and society.

In addition, the broad promise of our BiTE platform is coming into focus across a number of molecules in our cancer pipeline. The recent approval for BLINCYTO in ALL patients with minimal residual disease gives us confidence in this approach to immuno-oncology for both liquid and solid tumors.

We're looking forward to launching Aimovig, our first neuroscience therapeutic, which is in turn a first-in-class CGRP antibody for migraine prevention. Together with Novartis, we're ready to launch Aimovig this quarter in the U.S. We hope to redefine migraine prevention for relevant patients, physicians, and payers, given the urgent unmet need and the pent-up demand for a better therapy in this disease. Current therapies do not adequately address this debilitating disease, and migraine has gone underappreciated and undertreated for too long.

Later this year we'll see our biosimilar effort begin to come to fruition as we launch AMGEVITA, our biosimilar of Humira, internationally. We have a compelling opportunity to leverage our decades of biotechnology experience to create and reliably supply high-quality biosimilars to patients worldwide.

While gaining regulatory approval of biosimilars has proven challenging for many in the field, we have successfully executed on our plans, receiving first-cycle approvals for AMGEVITA and MVASI, our biosimilar to Avastin. We have our next opportunity for approval with KANJINTI, our biosimilar version of Herceptin, on May 28 in the U.S.

We believe biosimilars can be an important growth opportunity for us as we begin to launch our products globally.

Our balance sheet and after-tax cash flows are strong, enabling us to invest in long-term innovative growth opportunities and to return capital to our shareholders. Our priorities for the use of cash continue to be investment in innovation and supporting the launches of our growth products while continuing to build out our global presence.

Following tax reform, we announced plans to build a new state-of-the-art next-generation biomanufacturing facility in Rhode Island, which will result in the creation of many new highly skilled jobs. This new plant, which is the first of its kind in the United States, will employ Amgen's proven next-generation biomanufacturing capabilities and manufacture products for the U.S. and global markets.

As for business development, we continue to look for innovative opportunities that are consistent with our areas of strategic focus while remaining disciplined about the path to earning return for our shareholders. We have a strong track record of returning capital to our shareholders, which we plan to maintain. Since initiating our dividend seven years ago, we have raised it on average 25% a year, while also returning excess capital through significant programmatic share buybacks, like those which we've undertaken this year.

Briefly addressing the political environment, let me say that over the coming weeks and months, we will continue to work with Congress and the administration to advocate for policies that improve the affordability and access to important new medicines while seeking ways to constructively modernize the Medicare program.

In closing, let me just thank all of our Amgen staff around the world. As I look at our business today and into the future, our outlook remains strong, as we continue to deliver for patients and shareholders.

Let me turn the call now to David.

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob.

We're pleased with our solid revenue and earnings growth in the first quarter, as our transformation efforts continue to enable investments in support of volume-driven growth during a time of portfolio transition.

Turning to the financial results on page 6 of the slide deck, worldwide revenues at $5.6 billion in the first quarter grew 2% year over year. Worldwide product sales at $5.3 billion in the first quarter grew 3% year over year, as strong unit demand for our new products outweighed declines in our mature brands. We were particularly encouraged by our 11% year-over-year volume growth in Europe, reflecting the value of our innovative products in a market where we have experienced biosimilar competition and portfolio transition for a number of years.

Other revenues at $211 million decreased $54 million year over year due to an unfavorable compare related to milestone payments received in Q1 of 2017, partially offset by higher royalty income in Q1 of this year.

Non-GAAP operating income at $3 billion grew 1% from prior year. Non-GAAP operating margin was 56.9% for the first quarter. As in prior years, our operating margin is expected to be lower in the remaining quarters of the year, driven by the timing of expenses. As mentioned last quarter, we continue to evaluate incremental investments in our products and pipeline as well as external opportunities to drive growth and maximize shareholder value.

On a non-GAAP basis, cost of sales as a percent of product sales improved by 0.4 points to 12.7%, driven by lower royalty expense, partially offset by increasing manufacturing costs.

Research and development expenses at $739 million were relatively unchanged in the first quarter of 2018 versus last year. Research and development as a percent of product sales at 13.8% is lower in Q1, consistent with previous years. Going forward, research and

development expense as a percent of product sales is expected to normalize to around 2017 levels.

SG&A expenses increased 6% on a year-over-year basis, primarily driven by launch preparations for Aimovig and our biosimilar products, in addition to making greater investments in Prolia to capitalize on its full potential. Similar to our R&D expense profile, the SG&A percentage of sales is traditionally lowest in Q1, and we expect the full year to normalize at or above 2017 levels, as we continue to invest in our launch and growth products.

In aggregate, non-GAAP operating expenses increased 2% year over year. We remain on track to exceed our 2018 commitment of $1.5 billion in transformation savings while investing those savings to launch and support new products, build out new therapeutic areas, advance our biosimilar business, increase our global presence, and continue to provide meaningful returns to shareholders.

Other income and expenses were a net $182 million expense in Q1. This is unfavorable by $51 million on a year-over-year basis. The non-GAAP tax rate was 13.7% for the quarter, a 4.8-point decrease versus the first quarter of 2017, reflecting the lower U.S. federal statutory rate due to tax reform. Non-GAAP net income increased 6% and non-GAAP earnings per share increased 10% year over year for the first quarter to $3.47 per share.

Turning next to cash flow and the balance sheet on page 7, free cash flow was $2.6 billion for the quarter, driven by higher net income. As expenses normalize for the remainder of the year, we would expect free cash flow in subsequent quarters to be somewhat reduced from Q1 levels. In addition, earlier this month we paid $600 million, which represented the first of eight annual installments of the cash repatriation tax. This payment will impact our Q2 free cash flow.

We continue to provide significant cash returns to shareholders consistent with our commitments, as we deployed $10.8 billion in Q1 to repurchase 56.4 million shares. We plan to repurchase an incremental $2 billion to $4 billion of our shares in Q2. Additionally, our first quarter dividend increased to $1.32 per share, an increase of 15% over last year.

Cash and investments totaled $32.2 billion, a decrease of approximately $6.2 billion from the first quarter of last year. This decrease reflects the successful execution of our Dutch auction tender offer in Q1 in addition to our significant buyback and dividend deployments over the past 12 months, offset by our free cash flow generation during that same period. Our debt balance stands at $35.5 billion as of March 31, carrying a weighted average interest rate of 3.8% and an average maturity of 12 years.

Turning to the outlook for the business for 2018 on page 8, we remain on track with our plans to continue to invest in our pipeline, build out our global presence, and increase spend in support of long-term volume growth across large patient populations. Today, we are revising our 2018 guidance, which reflects our solid Q1 growth as well as the revised tax outlook.

Overall, our revised revenue guidance is $21.9 billion to $22.8 billion versus previous guidance of $21.8 billion to $22.8 billion. This continues to reflect a range of potential Sensipar generic competition outcomes as well as new potential competition for Neulasta and Aranesp, at the same time contemplating the year-to-date sales performance for our calcimimetics portfolio.

With regard to our non-GAAP earnings per share guidance, we are revising the outlook to $12.80 to $13.70 a share versus prior guidance of $12.60 to $13.70. Further, we are revising our non-GAAP tax rate guidance to 13.5% to 14.5% versus prior guidance of 14% to 15%, as we have realized some favorable one-time items in 2018 associated with the implementation of tax reform. We continue to expect capital expenditures of approximately $750 million this year.

This concludes the financial update. I now turn the call over to Tony.

Anthony C. Hooper {BIO 6284080 <GO>}

Thank you, David, and good afternoon, everyone. You'll find our product sales starting on slide number 10.

Our business continues to shift to more volume-driven growth, as we continue to launch innovative products targeting large patient populations with unmet medical needs. We're off to a solid start to the year, with all of our newer products delivering double-digit growth. The total portfolio grew at about 3%, as the legacy brands offset some of this volume growth. As has been the trend for the last number of quarters, our ex-U.S. business continues to grow more rapidly, generating 7% growth excluding the impact of foreign exchange, fueled by 9% volume growth.

In many of our ex-U.S. markets, we've already experienced a majority of the decline of our mature brands, demonstrating the growth potential of our newer portfolio. These markets serve as a model for the overall company's future growth profile.

We are also in deep preparation for the upcoming launches of Aimovig for migraine sufferers and the first of our biosimilar portfolio. A majority of the sales team is trained and in place, and subsequent investment levels will continue ramping up throughout the year.

Let me now turn to our brand performance. Prolia, the leading brand osteoporosis therapy, grew 16% year over year, primarily from volume. We continue to drive growth of new patients as well as improved repeat injection rates. This resulted in an increasing share of the postmenopausal osteoporosis segment, as patients and physicians realized the benefits and value of Prolia.

As a reminder, given its six-month dosing interval, Prolia exhibits a seasonal sales pattern, with quarter one and quarter three representing lower sales than quarters two and four. Overall market penetration, however, is still low in the 20%, indicating significant potential

for improved diagnosis and treatment. With its unique profile and through an increased investment, we expect Prolia will remain a very strong growth driver.

Let's now move to the oncology, starting with KYPROLIS. KYPROLIS grew 17% year on year, driven primarily by our ex-U.S. business. The majority of second-line usage in Europe is in the triplet regimen, and KYPROLIS has continued to take market share from Velcade. In the U.S. the overall multiple myeloma market, defined as all lines of treatment, grew in the first quarter. KYPROLIS has stable share, with room to grow in the second-line segment. Our focus message to physicians remains clear. Patients who have relapsed will actually live longer when treated with regimens that include KYPROLIS.

XGEVA grew 11% year over year, primarily from volume, although we believe more than half of this growth is from a buy-in that should burn off over coming quarters. Since our label expansion into multiple myeloma in January 2018, our teams have been emphasizing XGEVA's clinical benefits of preventing skeletal-related events in patients with multiple myeloma. It's still early days, but anecdotally, we're receiving positive feedback from physicians and institutions, as many multiple myeloma patients cannot receive optimal therapy with bisphosphonates.

Whilst we're not providing a slide, let me comment on the other products in our oncology portfolio. The combined sales of Nplate, Vectibix, IMLYGIC, and BLINCYTO exceeded $400 million in the quarter. Sales growth of these brands at 16%, 15%, 20%, and 44% respectively was driven primarily by volume growth, with some benefit from a buy-in during the quarter. I'm particularly pleased by the performance of BLINCYTO, which is our first product on the BiTE platform. You'll hear more about this from Sean as well as his views on other products emerging from the platform.

Turning now to Neulasta, Neulasta sales decreased 5% year over year, as we continue to see a slight decline in the use of myelosuppressive chemotherapeutic agents. We also saw a small buy-in that will burn off in the second quarter.

We continue to drive adoption of Onpro in the U.S. and exited quarter one at a 62% share. Onpro's utilization in the U.S. markets further underscores the value of this patent-protected technology in providing convenience for patients and lower rates of hospitalization due to fever or neutropenia. We expect to see more global utilization of Onpro in 2018. As a reminder, we recently received positive CHMP opinion for Onpro in Europe and are in the late stages of launch preparation in several markets.

For NEUPOGEN, we continue to compete effectively, holding just under 40% market share in the short-acting market in the U.S. as we exit quarter one. This was after four-plus years of facing competition.

Moving now to Enbrel, sales declined 6% year over year, with market growth and volume trends consistent with recent quarters. This stands in contrast to the trend break in market growth experienced in quarter one 2017. Recall that during quarter one, patients experienced insurance reverification and resetting of deductibles, some of which resulted

in higher patient assistance costs relative to later quarters. Consistent with our prior disclosure, we continue to expect 2018 net selling price to decline slightly versus 2017.

While early days, the launch of Enbrel Mini with AutoTouch has been met with very positive feedback from both patients and customers. And we're excited about this opportunity this innovative, patient-centric delivery system provides.

As a final note, purchasing patterns in the supply chain for Enbrel can cause quarterly fluctuations. As we noted previously, quarter one represents the lowest quarter of the year, slightly over 20%, with the balance distributed fairly evenly through the rest of the year. Unit declines and net selling price trends for the balance of the year are expected to continue, consistent with those seen in quarter one.

Switching now to our ESA portfolio, slide number 18 shows the quarter one 2018 composition of our ESA business and provides a year-on-year growth percentage for the different segments. EPOGEN declined 10% year over year. Underlying volume remains relatively stable, while we recognize a lower net selling price as a result of our extended supply agreement with DaVita.

Aranesp declined 11% year over year, with lower unit demand of 8%, primarily based on increased competition. Recall that last quarter we provided disclosure that our long-acting competitor had extended their product more broadly into the small to mid-sized dialysis centers and that we expected to lose some of this business as early as quarter one 2018. We have volume and share-based contracts with some of these customers, and we'll continue to compete on an account-by-account basis. We're also prepared to compete with a potential short-acting biosimilar in all customer segments, including hospitals and oncology clinics, if and when such a biosimilar is approved by the FDA. Our long track record of safety, efficacy, and reliable supply is a competitive advantage.

Turning now to calcimimetics, we've launched PARSABIV in several markets, including the U.S., and it's off to a strong start. As the head-to-head clinical data showed, PARSABIV demonstrated a greater level of efficacy when compared to Sensipar. Since it's administered in the patients' existing IV line during dialysis, it puts control in the hands of the healthcare provider, which could also drive an improved level of adherence. Nephrologists continue to be positive and are excited about having this product available.

In the U.S. so far, we have a solid uptake in the mid-sized dialysis providers. The larger free-standing dialysis clinics continue to run pilots to determine the eventual treatment protocols. We expect to see adoption increase gradually over time.

Turning now to Sensipar, where year-over-year growth was 18%, as a reminder, the reimbursement mechanism for Sensipar in the U.S. changed from Part D to Part B in the beginning of 2018. This also altered the supply chain for patients, most of whom now receive Sensipar directly from the dialysis provider versus more traditional pharmacies.

We believe the providers ordered additional supply during quarter one in order to minimize potential patient treatment interruption. We also believe that the new supply chain is now normalized, and quarterly volume should return to more historical run rates, assuming continued exclusivity and taking into account some transition to PARSABIV.

As David mentioned, the 2018 outlook for Sensipar is still somewhat uncertain given the ongoing litigation. It is, of course, conceivable that competitors may be able to bring generic products to market at some point in 2018, although we believe we have a strong litigation position.

With Repatha, we continue to compete effectively, maintaining a majority share on a global basis. With outcomes data in our Repatha label, our team has been speaking directly to the benefits of treating patients with Repatha and its ability to reduce the risk of heart attack by 27% and stroke by 21%. Repatha grew 151% year over year, primarily from volume. Overall fulfillment rates in the U.S. continue to improve as utilization management criteria evolve.

Over the past few months, we've seen access to Repatha continue to improve, and we remain committed to ensuring access and affordability for high-risk cardiovascular patients. We've been negotiating with several payers for months to expand patient access to Repatha and offering significant discounts, with multiple offers pending.

As the market leader, a majority of new PCSK9 inhibitor prescriptions offer Repatha, the only PCSK9 inhibitor approved by the FDA to prevent heart attacks and strokes in patients with established ASCVD disease.

In addition, we have unequivocally demonstrated that treating patients to the lowest LDL level possible is the best treatment approach, including for patients with baseline LDL levels as low as 70 milligrams per deciliter. Our priority remains reaching the large population of high-risk cardiovascular patients. The cost to society of not treating these patients is unacceptable, and we're looking at all options to improve access for appropriate high-risk patients. We also look forward to having the Repatha label updated and expanded with the outcomes data outside the U.S. soon.

Let me finish where I started. We continue to transition to a portfolio exemplified by volume-driven growth, with performance in many countries outside the U.S. as proof points. A majority of our brands grew double digits. Our performance in our mature brands as well as some of the new ones demonstrate our ability to compete. This gives us confidence as we prepare for our upcoming launches.

So let me close by thanking all the Amgen staff that work so hard to get these important products to patients and for the strong start to 2018.

Now, I'll pass you to Sean.

Sean E. Harper {BIO 16272195 <GO>}

Thanks, Tony, and good afternoon. I'll begin my comments today with a brief overview of some key milestones from Q1, and then highlight a few early-stage innovative programs we find particularly promising.

We recently received several important regulatory decisions in Europe, including the approval of an expanded indication for XGEVA to prevent skeletal-related events in patients with multiple myeloma. We also received several positive opinions from the CHMP, including recommendations for the addition of our cardiovascular outcomes data to the Repatha label, a Neulasta label variation to include the Onpro kit, and a marketing authorization for KANJINTI, our biosimilar Herceptin. I would note that KANJINTI has a BsUFA [Biosimilar User Fee Act] action date next month in the United States.

Also in the U.S., BLINCYTO received accelerated approval and Orphan designation for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia with minimal residual disease, or MRD. There are now technologies that allow for exquisite sensitivity in detecting at a molecular level whether residuals disease is present. MRD is the strongest prognostic factor for relapse in ALL patients. And in our Phase 2 study of ALL patients in complete remission that were positive for MRD, 81% achieved MRD negativity after a single cycle of BLINCYTO.

This was the first-ever approval for the treatment of MRD by FDA, and we're gratified that our first BiTE therapy has meaningfully advanced the oncology field. This approval represents a paradigm shift, not only in the treatment of ALL, but also potentially in other diseases where extremely potent therapies are being employed. As such, we're incorporating MRD into all of our clinical studies as appropriate, and we continue to develop therapies that drive deep and durable responses. For the first time, there's talk of actually achieving cures in what have been fatal diseases, and we're excited to help lead the way.

We had the opportunity to highlight pre-clinical data from several of our Phase 1 assets at the American Association for Cancer Research meeting early this month. The antiapoptotic family members MCL-1 and BCL-2 are understood to play key roles in the pathogenesis of acute myeloid leukemia, or AML, a grievous disease that affects four times as many people as ALL, with approximately 20,000 new cases and 10,000 deaths per year in the United States alone.

At AACR, we presented promising data showing marked improvements in activity and potency with the combination of our MCL-1 inhibitor, AMG 176, and the BCL-2 inhibitor, venetoclax, compared to either agent alone in pre-clinical settings. A Phase 1 study of AMG 176's monotherapy is currently enrolling in relapsed refractory multiple myeloma and AML patients.

We also discussed our unique ability to target the antigen DLL3, a very exciting target with both BiTE and CAR-T technologies. Small-cell lung cancer is an aggressive disease with very poor outcomes and accounts for about 10% to 15% of all lung cancers. Despite this, there have been no significant advances in the treatment of this devastating disease in decades.

DLL3 expression is highly restricted to small-cell lung cancer, and we've developed two very potent modalities for clinical testing: AMG 757, our half-life extended BiTE, that's currently enrolling patients in Phase 1; and AMG 119, our DLL3 CAR-T developed with Kite, that we expect to begin enrolling very soon. We're really anxious to see the effects of targeting DLL3 with immuno-oncology approaches, which we believe will be more effective compared to a traditional antibody or antibody-drug conjugate approach.

We also presented pre-clinical data characterizing our half-life extended BCMA BiTE for multiple myeloma, AMG 701, and our FLT3 CAR-T program for AML. At the Society of Interventional Radiology Meeting in March, we presented Phase 1 safety data from our hepatic injection study of IMLYGIC, and we're now moving into Phase 2 in combination with KEYTRUDA in hepatocellular carcinoma and a number of tumor types with liver metastases.

All of these programs underscore our differentiated multi-modality approach to our immuno-oncology platform, where in addition to IMLYGIC, we're currently advancing more than a dozen early-stage BiTE molecules, with seven already in the clinic and three CAR-Ts through our collaboration with Kite. We're particularly interested in the potential for BiTEs in solid tumors, and we've been seeing some very encouraging early activity. We look forward to initial clinical data from AMG 420, our BCMA BiTE for multiple myeloma, and AMG 330, our CD33 BiTE for AML, by the end of this year.

Briefly on Aimovig, our CGRP receptor antagonist antibody, we continue to work with FDA toward our May 17 PDUFA action date, and data are being presented today at the American Academy of Neurology from a study in patients with migraine who have previously failed two to four preventive treatments. These unique results add to the consistent body of evidence for Aimovig across the spectrum of migraine patients, from treatment-naive through those who have failed multiple therapies.

Finally, I'd like to spend a few minutes on one of our early inflammation programs, AMG 592, an IL-2 mutein. Current therapies for autoimmune diseases suppress the immune system. While this approach is effective and therapies such as Enbrel have changed the practice of medicine, significant unmet need remains for many of these diseases.

In a normally functioning immune system, regulatory T cells, or Tregs, maintain balance between self and non-self-recognition by negatively regulating effector cells. In the autoimmune disease state, this balance is off, favoring the effector cells with impaired Treg responses having been identified in multiple human diseases, including through human genetics. IL-2 is the dominant growth factor for Tregs. But in its native form, it has significant toxicity associated with administration.

With AMG 592, we've designed an IL-2 mutein with an extended half-life that preferentially binds to the IL-2 receptor so as to selectively promote Treg growth and function. At last year's American Society of Hematology meeting, we presented Phase 1a data in healthy volunteers that showed a single dose of AMG 592 was well-tolerated and resulted in dose-dependent increases in Tregs with minimal increases in effector cells, as shown on slide 30.

Based on these exciting results, we've already initiated proof-of-concept studies in chronic graft versus host disease, rheumatoid arthritis, and systemic lupus erythematosus. We're very excited about the potential for AMG 592 and believe that this approach could be quite powerful in a number of inflammatory diseases.

In closing, I want to thank our staff for their dedication to developing breakthrough medicines for the benefit of patients. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Sean. Ian, why don't we turn over to our question time now? And perhaps you could remind our callers of the procedure for asking questions.

Q&A

Operator

Certainly. Our first question is from the line of Geoffrey Meacham from Barclays.

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Good afternoon, guys. Thanks a lot for the question. Tony, for Aimovig, I know we're close to the launch, and I realize it's competitive. But maybe, if you could, help us with how you see the size and scale of the commercial organization. And from a reimbursement perspective, maybe what are the lessons to be learned from the PCSK9 experience when you look to the migraine launch? Thank you.

A - Anthony C. Hooper {BIO 6284080 <GO>}

So, Geoff, let me try and answer it in two ways. As you know, we are going to market together with Novartis. Novartis have a rich history of presence in the neuroscience market, both in terms of the sales force and an outstanding medical organization. We are complementing it, with both teams calling on specialists as well as some of the primary care physicians who have a propensity to look after patients with severe headaches or migraines.

From a timing perspective, we clearly are in the lead. We look forward to launching first. Unlike the PCSK9 situation where we had to follow, we will actually be setting the price ourselves. And this is clearly a market where patients have huge symptoms and actually know when they're not being properly treated, so we look forward to a large bolus of patients who want to come on this drug as quickly as possible.

Operator

And our next question is from the line of Andrew Peters from Deutsche Bank.

Q - Maryana Breitman {BIO 20116057 <GO>}

Yes. Hi, guys. Thank you for taking my questions. It's Maryana Breitman for Andrew Peters. I wanted to ask about possible strategic moves. Do you see (36:24) like new platform or technical capability, or (36:33) individual products? And what stage products would those be?

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

Boy, I'm afraid your phone line was breaking up, so we couldn't hear the question. Do you want to try to repeat that? And then, Ian, if we can't hear it this time, maybe you can recycle her towards the bottom end of the call. Sorry, why don't you try again? Let's see if we can hear you.

Q - Maryana Breitman {BIO 20116057 <GO>}

Can you hear me now?

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

Not great. Why don't we get you on a different line and ask our operator, Ian, to help you get back in the queue.

Q - Maryana Breitman {BIO 20116057 <GO>}

Okay, thank you.

Operator

All right. While we cycle her back through, 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. Bob, I think previously on some of the prior calls you referred to excess capacity in the system. I was just wondering if you can update us on your latest thoughts there, particularly in light of some of the consolidation we're seeing on the services side of the industry. Thanks a lot.

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

Nothing new, Terence. As I said in my remarks, we're continuing to look at ways to use our balance sheet to strengthen the business, continuing to look at ways to invest in innovation. So we've made, I think, our points on that topic well known, and I wouldn't say there's been any change over the course of the last quarter.

Operator

And our next question is from the line of Christopher Raymond from Piper Jaffray.

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

Hey, thanks, guys, just one question on Enbrel. I'm struck, Tony, by your prepared comments. I know you talked about this last quarter that Q1 would represent – I think you said 20% of the annual number for full-year 2018. Just doing the math, I think that would infer Enbrel revenue of about $5.5 billion for the full year. And I know you guys don't want to give guidance that's any more granular than you've already given, but that number is a lot bigger than consensus and would actually imply an up year-on-year number, which would seem to be a reversal from what we saw 2016 to 2017. So I just wonder if you could verify, first of all, if that math is right. And maybe talk about the driver there in terms of that trend reversal. Thanks.

A - Anthony C. Hooper {BIO 6284080 <GO>}

So let me confirm again that Quarter 1 is normally a fairly low quarter because of the need for reverification, for the need for the reset of deductibles, so patients pick up in the second quarter. We said last quarter that we expected this quarter to be about 20% of the total annual revenue, and it probably landed up being at about 21% – almost 22% of what I expect the full year to be. So my numbers don't get as high as yours.

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

Got it, thank you.

Operator

And our next question is from the line of Ying Huang from Bank of America Merrill Lynch.

Q - Ying Huang {BIO 16664520 <GO>}

Hi, thanks for taking my question. I was wondering. Maybe, Tony, can you comment on the recent ICER [Institute for Clinical and Economic Review] draft analysis on the cost/benefit of Aimovig? And they actually proposed a range of the pricing. Would you actually take that into your consideration when you price Aimovig? Thanks.

A - Anthony C. Hooper {BIO 6284080 <GO>}

Ying, so a couple things. One, it is a draft publication by ICER. They are requesting public comments, up to and including I think the 8th of May. So a number of organizations are busy commenting on that.

It is the second publication. Obviously, if you remember that there has already been one publication, which took place on the 23rd of March, in the Journal of Medical Economics, authored by a number of headache specialists and economists, which laid out a very clear value range for this particular category. The ICER report doesn't seem to take into account things such as absenteeism and presenteeism, which we would argue is really an important thing to look at from both an employee perspective and an employer perspective. But all of these ranges fall within a reasonable level that we'll be discussing with the payers.

Operator

And our next question is from the line of Alethia Young from Credit Suisse.

Q - Alethia Young {BIO 17451976 <GO>}

Okay, guys, thanks for taking my question. Just a question on AMG 592. I'm just curious if there's any particular pre-clinical work that suggests an opportunity favors maybe lupus, RA, or GvHD, or is it still an open question? And is there also the possibility for less frequent dosing there?

A - Sean E. Harper {BIO 16272195 <GO>}

So this is a half-life extended construct that we've designed. And I think that we have some – of course, we have pre-clinical models of these diseases. But I would say that when you're working with such a different mechanism than has ever been applied to autoimmune disease before, our faith in the predictive nature of these animal models of diseases like lupus and RA and so on is modest. So we use all kinds of scientific reasoning in the animal models to guide us into the initial set of experiments that we chose. But it's fair to say that, like was the case when, for example, TNF inhibitors came available or IL-17s and so on, it's ultimately important to screen through humans with these diseases to determine whether the mechanism can be fruitful.

Operator

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

Q - Srikripa Devarakonda {BIO 21185204 <GO>}

Hi, this is Kripa on for Robyn. So like you mentioned earlier, you're developing therapies using multiple modes such as BiTEs and CAR-Ts to target the same indications, I know you have a lot in the pipeline. I was just wondering if you can take us through your thought process on how you decide to target the same indication with two different modalities or how you decide to go in one direction versus the other.

A - Sean E. Harper {BIO 16272195 <GO>}

Right, so it's a good question. The first thing I would point out is that at the moment, moving into the clinic, we really just have a few CAR-Ts. And we deliberately matched a couple of them with BiTEs so that we could actually scientifically determine pros and cons of these technologies because the data that exist today are very much apples and oranges in terms of the patient populations and the way that they've been pre-conditioned, for example, before being treated with, let's say, a CAR-T cell versus BLINCYTO, even when you get into diseases that are on the surface the same, ALL for example, or the various forms of CD19 positive lymphoma.

So I don't want you to get the impression that for lots and lots of our targets we have double programs. We have a couple that are designed specifically to hopefully in humans give us some understanding of whether the benefit/risk looks better for one of these type of technologies versus another. And so that's an approach, and we'd like to understand that in both hematologic and in solid tumor settings.

Ultimately, what will determine what we move forward with primarily in oncology is going to be efficacy with an acceptable amount of safety. And what we really don't know yet is whether you can get some generally similar kind of a clinical benefit from, for example, a BiTE intervention versus a CAR-T. It would be hard to imagine that you would select a CAR-T under those circumstances given lots of considered practical considerations, cost of goods and things of that sort. So it's early days. I don't think anyone has ever really made these comparisons. There's a lot of speculation, and we're hoping to shed some actual light on these clinical questions.

Operator

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

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

Thanks very much for taking the question. Sean, you list on your development milestones still romosozumab in both U.S. ready for submission and European review. Could you give us an update on your expectations for the labeled indication and the size of the addressable patient population for romosozumab now?

A - Sean E. Harper {BIO 16272195 <GO>}

Sure, I think that with romo, we're at this point where we're well into a process of scouring the entire clinical database experience with the molecule to make sure that we have every cardiovascular event that may have occurred in any of the trials, and then run them through a new blinded adjudication process. And while that may sound easy, it's actually quite time consuming and requires coordination between us and another clinical center, in this case, TIMI. So that's underway, and I think the results of that are going to be very important in determining where we end up with the product.

Obviously, the unmet need for this kind of anabolic product is very strong, the compelling need for it. The efficacy was very favorable, and it's a short period of treatment, one year. So I think what we really need to understand is do we believe that there's actually a cardiovascular risk because, as you know, Geoff, we have two studies. They can't both be true. One of them says there's a risk; the other one says no. So if we get some additional information from this reanalysis, it could tip the scales in one direction or the other. We're just seeking the truth, and then whatever the truth is will make its way into the label.

So it's a little bit hard to know where that benefit/risk will land and whether we'll be talking about a patient population that has a particularly significant level of unmet need and, therefore, it makes sense to use it in a context in which we actually believe there's a cardiovascular risk versus that the cardiovascular risk seems to be much less of a true phenomenon. So that's the best I can do to characterize it at this moment.

Operator

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

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

Hi, thanks for the question. I had a question for Bob. I guess there was a large M&A deal in the space last week, but I guess more important, big picture, your view of the environment given that there has not been that many deals. Do you feel for Amgen it is more of a case of not finding things that are good fits, or it's a price issue? I guess maybe you could talk about the overall dynamic when you are looking at all of these different biotech companies. Thanks so much.

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

Again, I think we have a track record of being pretty disciplined. And the way we evaluate targets, our focus is on being confident that we have a pathway for our shareholders to earn a return. But we're looking for ways to invest in our industry. We're interested in innovation that aligns well with our six therapeutic areas that we focus in and opportunities that are consistent with our desire to advance innovation globally. But I think, Mike, historically valuations have been challenged in this sector. We see a little bit of adjustment taking place now, and we'll continue to be thoughtful in reviewing all the different opportunities that we think help us earn a return for our shareholders and help make a difference for patients.

Operator

And our next question is from the line of Eric Schmidt from Cowen and Company.

Q - Eric Schmidt {BIO 1505721 <GO>}

Hey, congrats on a great start to 2018. Maybe a question for Tony on Repatha, since the presentation of the ODYSSEY data, have you seen any changes in market share or any change in your pricing discussions with payers? Thank you.

A - Operator

Eric, we saw an increase in the NBRx's after the outcomes data came into Repatha's label. Since the ACC, we've seen relatively little change in the marketplace to date.

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 question. Bob, my question is there's been a lot of investor feedback on a possible merger of equals, like a transformative deal between Amgen and a big pharma name, a European pharma name in particular. How do you feel about a transformative M&A situation? Is that something you're open to philosophically, or is the focus really more on SMID biotech?

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

Our focus, Umer, is on finding opportunities to invest in innovation where, again, we think we can make a difference, innovation that's focused in the areas that are important to us,

and opportunities that enable us to continue to expand our global footprint. So I think speculation rises and falls through time in our industry, but our focus on those things has been consistent, as has our determination to have a pathway to earn a return for our shareholders through our business development activities.

Operator

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

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

Hey, good afternoon. Thanks for taking the question. I wanted to ask about CGRP and recognizing the competitive nature of this class. But with the article out this morning commenting on Express Scripts' intention to push for lower list prices on the CGRP class to limit out-of-pocket costs borne by patients and implement a pay-for-performance type of model, would you say this is consistent with the interactions you've had with payers and maybe how you're thinking about different pricing models for this class following on the heels of some of the more unconventional pricing schemas you've implemented for PCSK9s? Thanks.

A - Anthony C. Hooper {BIO 6284080 <GO>}

So, Cory, let me start that one, and I'll ask Sean to talk about the differentiation between our product and the others that are trying to come to market. Clearly, we are in the lead, as I said, and coming to market first is important. It allows us to set the baseline price.

We have looked very carefully at the value-based pricing that's come forward. We've listened to the affordability question in the marketplace. We're delighted to hear that ESI are looking at value-based prices and look forward to them opening up access in those situations to allow access to appropriate patients. And we will continue to come forward with prices that are responsible that take into account the co-pay requirements as best we can. We have a number of risk-based contracts on the table with Repatha, and we're quite prepared to talk to payers about risk-based contracts with Aimovig. So let me ask Sean to talk a little bit about why we think this drug is actually very different to the others coming to market.

A - Sean E. Harper {BIO 16272195 <GO>}

Tony, I think that there's a number of things to just point to in terms of the advantage besides being first to market. First of all, we are a receptor antagonist, and that is still the case. We're the only receptor antagonist in the clinic. And we chose that path for a number of reasons, but one of them was potency. And so we seem to be the only product that doesn't require loading doses or intravenous administration, which can be quite an awkward thing for patients and providers in general. We recently developed the data, and this is being presented today in this population of highly refractory patients who have failed as many as four prior prophylactic therapies. And the data look really strong in that group, and so that's a differentiated data set.

And I think also, remember that when physicians are dealing with patients and it is idiosyncratic either adverse reactions or lack of or presence of efficacy, they have to choose between different agents within a class. And generally speaking, a physician is – if they started with, for example, one of the ligand-sequestering antibodies, going to another ligand-sequestering antibody doesn't make a whole lot of sense compared to trying a receptor antagonist. So we hope that us being the only receptor antagonist would result in more therapeutic options for physicians who are trying to manage this very challenging condition.

Operator

And our next question is from the line of Carter Gould from UBS Equities.

Q - Carter Gould {BIO 20035589 <GO>}

Good afternoon, guys, thanks for taking the question. I guess a commercial question for Tony on XGEVA. I'm hoping to get a little bit more detail on the uptick in the quarter, if you could maybe probably give some rough detail on the size of the buy-in versus how much was driven by myeloma. You provided some anecdotes from physicians and institutions, but maybe some commentary on how access is going in this indication. Thank you.

A - Anthony C. Hooper {BIO 6284080 <GO>}

Okay, Carter. So it's a great indication to have to expand the label. We estimate there's about 100,000 multiple myeloma patients in the U.S. that potentially could benefit from the product. Because it's a Part B product, I don't see the prescriptions as tightly as I do with the Part D product, so we tend to look back about six to eight weeks in arrears. It is clear that there's a large number of patients who could benefit from this. The feedback has been good. The buy-in probably accounts for about 30 million in the quarter, which we expect to burn off quite quickly. But everything we've heard to date has been positive.

Operator

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

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

Great, good afternoon. Thanks for taking the question. I just wanted to ask a question on PARSABIV, if I could. I understand the financial and growth prospects for the next year or two while the product is outside of the bundle. Maybe you could just talk to us about what happens with this product and how you think about it as a potentially longer-term growth driver once it gets added into the bundle and what the scenarios are for that. Thanks.

A - Anthony C. Hooper {BIO 6284080 <GO>}

Matthew, tough to calculate that. As you know, TDAPA will run for a minimum of two years. CMS will do a full evaluation of the benefit of the drug. We've looked at our head-to-head trial. We feel that it's fairly beneficial from an efficacy perspective. We also believe because of the IV line administration during dialysis that adherence will improve, and by

definition the real-world situation will deliver a higher level of value to both the patients and the dialysis units. And therefore, it's not an and/all. It's really evaluating the benefit the drug brings and then how that is calculated into the future bundles going forward post TDAPA.

Operator

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

Q - Kennen MacKay {BIO 18821382 <GO>}

Hey, thanks for taking the question, maybe another one for Tony. I was just wondering if you could elaborate, just what was going on with Aranesp surrounding the competition at some of the smaller providers? And then on the long-term estimates and guidance, I'm wondering if you're accounting for HIF prolyl hydroxylase inhibitors in the coming years here. Thank you.

A - Anthony C. Hooper {BIO 6284080 <GO>}

Okay. So Aranesp, as you know, is bifurcated into a whole lot of pieces. More than half our business is outside the United States, where the business continues to be fairly stable other than foreign exchange. Inside the U.S., it is divided between the dialysis nephrology business, the hospital nephrology business, and the oncology areas. Oncology has been declining for some time, so we see no change there. In the nephrology dialysis, there has been a movement from a competitor, a long-acting competitor from FMC that has now moved into some of the IDOs and the MDOs. And some of the decline you're seeing, we do have volume and shared contracts with a few of these people, and we'll continue to fight account by account. And then on the nephrology hospital, there's a strange compare versus first quarter 2017, which included a large clinical trial purchase from a competitor.

Operator

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

Q - Aharon Gal

Hi, everybody, and thanks for squeezing me in. Tony, I'm afraid this one is for you as well around the PCSK9. As we think about the contracts you're trying to sign out with the payers, are we looking for open access or are you looking to close out this account with a single award, or is a competitor interested in doing that and you're following him?

And second, you mentioned the issue around how low does one need to go with LDL-C, and I was wondering if you or Sean can comment on the JAMA article showing fading of the benefit when you start a patient below 100 LDL-C.

A - Anthony C. Hooper {BIO 6284080 <GO>}

So I think we've always said that we would always want to have a situation where the physician has a choice on behalf of the patient, so I would always advocate for having an open formulary. We do talk consistently about looking for ways and means to have access for this high-risk patient population. There are about 3.4 million patients in the high-risk population. We think a very, very small percentage, a single digit penetration has been made into that population to date. And then I'll let Sean talk about the scientific discussion around lowering LDL.

A - Sean E. Harper {BIO 16272195 <GO>}

So I'm familiar with the JAMA article that you're referring to that was just published. It's a meta-analysis. I'd point you to the accompanying editorial, which I thought was pretty good at outlining some of the likely confounding that occurred in that meta-analysis. The problem with these meta-analyses is when they go back in time 20-plus years and look at mortality, they're very confounded by the case fatality rates that occur when people are hospitalized in the studies or experience heart attack and stroke, for example.

So if you go back to, for example, the for 4S study or Western Scotland studies, the case fatality rate for a heart attack back in those days was like 30%, now it's 4%. So you really end up with a very confounded analysis, which says well gee, when you start with a high LDL and you lower it to a mid-range, you get this big benefit on mortality. That's just what they were doing back then because there were no statins, and so people came in at very high LDL levels and they got reduced. And nowadays they come in at much lower LDL levels, and it's virtually impossible to demonstrate a statistically significant reduction in mortality, which has not happened in a long time in lipid-lowering trials.

So I think that it's very confounded. I think the editorial speaks to most of that, and also just talks about just shouldn't we pay attention to the biology and our understanding holistically about how these products work and the data that emerged from all the studies that have happened in this field, whether they be with statins or products like ezetimibe or now the PCSK9 inhibitors.

The overall clear picture is that no matter where your LDL starts, if you lower it substantially in a patient who is at high risk, you're going to get a very large risk reduction. It is true that if a patient starts at a high LDL, they have a higher risk because LDL is a risk factor. So in absolute terms, you get a little bit more benefit for treating patients who have higher LDLs. But the relative risk reduction appears to be consistent across trend, and the highest quality data show a very clear picture of lower is better without any safety concern. So that's my comments on it.

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

Ian, as it's going past 6:00 PM on the East Coast, why don't we take two last questions, after which Bob will make some closing comments?

Operator

Certainly. Our next question is from the line of Salim Syed from Mizuho Securities.

Q - Salim Syed {BIO 16887281 <GO>}

Hi, great, guys. Thanks for the question. I just had one on Repatha. So the ACC treatment guidelines some people expect it to come out this year at the AHA Conference in 2018. That's in November, I believe. Do you have that same view? And then how do you expect – what do you expect to come out of that as a practical incremental revenue opportunity for Repatha, if they lower the target LDL levels? Thank you.

A - Sean E. Harper {BIO 16272195 <GO>}

I'd just comment that I think you're right, that this sort of general expectation is that they're due around the AHA timeframe. And at this point, one assumes that they're not going to be waiting around for another data set that I can think of in lipid lowering land. So I think it's pretty likely that they'll come out. And I think that if you look at the pathway update that was done some months ago, it likely is indicative directionally of where they're likely to go as the data has accumulated.

A - Anthony C. Hooper {BIO 6284080 <GO>}

And then from a revenue perspective, I would imagine it will be very difficult for payers to have utilization management criteria that differ to the guidelines that are published by the AHA and the ACC.

Operator

And our next question is from James Birchenough from Wells Fargo Securities.

Q - Nick Abbott {BIO 20802722 <GO>}

Good afternoon. Thanks for squeezing us in at the end. It's Nick in for Jim. Just going back to CAR-T, I'm wondering if you can comment on Amgen's investment in this space with respect to developing commercially ready as opposed to academic components such as vectors, closed manufacturing systems.

And then for solid tumors, many assume that to get success with CAR-T, you'll need to take a combination approach. Do you share that view? Thank you.

A - Sean E. Harper {BIO 16272195 <GO>}

Let me answer the second question first. I think that – I believe that in most disease settings, whether you're dealing with a CAR-T or the bispecific T cell engaging-type technology, particularly in solid tumor settings but even in some settings such as lymphoma, people will hypothesize that there could be additive or synergistic effects between checkpoint inhibition and the use of these targeted antigen-focused approaches. So I think time will tell, but you can expect to see many of these agents developed where an arm in the clinical trial will be to combine the product with a checkpoint inhibitor in addition to looking at its activity alone. I hope that's answered that part of the question.

And, Tony, I think there was a component of the question having to do with the more of the commercial landscape. I mean, these are Phase 1. We're just getting ready to start enrolling the first patient in our first CAR-T program in Phase 1, so we're certainly working with Tony's organization, but it's very early stage at this point.

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

And, Nick, I'm not sure as well if you're referring to the manufacturing. But anyway, you can follow up with Arvind and his team, who are here for a while this evening if we didn't get to the full breadth of your question.

Anyway, let me just wrap up by thanking you all for joining the call. As you can see, we're off to a good start here at the first quarter 2018. We think we're in a strong position heading into the balance of the year, and we're feeling confident about the long-term outlook for growth of the company. So we look forward to joining with you again here after the second quarter. Thank you.

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

Great. Thanks, everybody. Thanks, Ian.

Operator

Ladies and gentlemen, this does conclude Amgen's first quarter 2018 financial results conference call. We thank you greatly for your participation. You may now disconnect.