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Q2 2018 Earnings Call

Company Participants

- Anthony C. Hooper, Executive Vice President, Global Commercial Operations
- Arvind K. Sood, Vice President, Investor Relations
- David M. Reese, Senior Vice President, Translational Sciences
- 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
- Brian P. Skorney, Analyst
- Carter Gould, Analyst
- Christopher J. Raymond, Analyst
- Cory W. Kasimov, Analyst
- Geoff Meacham, Analyst
- Geoffrey C. Porges, Analyst
- Jim Birchenough, Analyst
- Kennen MacKay, Analyst
- Matthew K. Harrison, Analyst
- Michael J. Yee, Analyst
- Phil Nadeau, Analyst
- Salim Syed, 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 Second 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. 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>}

Thanks, Ian. Good afternoon, everybody. Thanks for taking the time to participate in our second quarter results conference call today. We realize it's a very busy day with a number of companies reporting but, unfortunately, we are going to add to your already long day as we have a lot to discuss today.

Our Chairman and CEO, Bob Bradway, will open up the discussion today with an overview of our business, the environment we operate in and management succession. Our CFO, David Meline, will then review our financial results for the second quarter in some detail and provide updated guidance for 2018. Tony Hooper, who leads our Global Commercial Operations, will give you an update on how our products are performing, particularly those that have been launched recently. And then our Head of R&D, Sean Harper, will provide a pipeline update.

We will use slides to guide our discussion today and a link to these slides was sent separately. My customary reminder that we will 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. But before I do, I would like to sign a fun fact for the day. The crossword puzzle in The New York Times today, 30 down, the answer is Amgen.

So, with that, Bob, over to you.

Robert A. Bradway {BIO 1850760 <GO>}

Okay, Arvind. Thank you, and good afternoon, everyone, and welcome to the call. On today's call, I'll provide an overview of our second quarter performance, share some thoughts on the rapidly-changing U.S. healthcare environment and, of course, comment on the succession plans that we announced earlier today for two senior leaders you know very well, Sean Harper and Tony Hooper.

First, our performance. Our second quarter results demonstrate that we continue to execute effectively on our long-term growth strategy, as we delivered 4% top-line growth and 17% growth in non-GAAP earnings per share. An important part of our strategy is to increasingly focus on volume-driven growth, and our results reflect the progress that we're making on that objective.

Unit volumes increased, in many cases by double-digits, for all our newer products, including Repatha, KYPROLIS, Prolia and XGEVA. We also continue to generate strong volume-driven growth outside the U.S., where our legacy brands have faced competition

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now for many years. This includes 9% growth in the second quarter. We remain confident that our newer product launches, as well as the medicines advancing through our pipeline, will enable us to drive attractive, volume-driven growth globally over the long-term.

Let me give you a few examples of some of the newer medicines that we're seeing driving our growth. In the second quarter, we launched Aimovig in the U.S., where it is the first and only CGRP inhibitor approved for migraine prevention. Aimovig also marks Amgen's first entry into a new therapeutic area for us, which is neuroscience. We've been very encouraged by the enthusiastic reception for Aimovig from physicians and especially from migraine patients who have waited a long time for a new treatment option like this.

We're also encouraged by the progress we're making with Repatha which we believe can play an important role in the fight against cardiovascular disease, the world's number one killer. As you know, Repatha significantly lowers LDL cholesterol, which is a leading, modifiable risk factor for cardiovascular disease. We have and will continue to work to expand access to Repatha globally.

Building on our decades of leadership in nephrology, we're seeing strong early adoption of Parsabiv, which is the first new treatment in more than a decade for secondary hyperparathyroidism in patients on hemodialysis. And, lastly, I'm pleased to report that we recently launched our first biosimilar, KANJINTI, which is a biosimilar to Herceptin in Europe.

We've put a strategic stake in the ground a few years ago to build a world-class biosimilars business, and we continue to believe that biosimilars represent a meaningful growth opportunity for us. We look forward to launching AMGEVITA, which is our biosimilar to Humira internationally later this year, and to launching a steady stream of biosimilars in the years to come.

My comments on biosimilars provide a good transition to a discussion of the healthcare environment in the U.S. As you know, just this past week, the FDA published its Biosimilar Action Plan. We're encouraged by the FDA's actions as well as by others in the Trump administration, and we welcome the opportunity for open dialog. Although we believe biosimilars can help address the issue of rising healthcare costs in general and concerns over drug pricing in particular, we also recognize that biosimilars alone aren't enough.

Fundamentally, we believe that innovation is the key to alleviating the massive financial burden placed on society by chronic diseases like cancer, neurologic disorders and cardiovascular disease. And without innovation and improved access to it, the burden of chronic disease, which already runs into the hundreds of billions of dollars annually for any single one of these diseases, will only grow larger as the population ages.

And we'll continue to work with our colleagues in the industry to engage with the administration, Congress and the entire healthcare community to find ways to promote innovation, while also ensuring that our medicines are accessible and affordable for the patients who need them. We appreciate the administration's engagement on this

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important issue. And as to prices, we made decision a few months ago not to increase the prices of any of our medicines at midyear, and we have no plans to change that for the balance of the year.

My final order of business before I turn the call over to David Meline is to discuss the executive succession announcements that we issued today. One of the hallmarks of a well-run company is the carefully considered succession planning process, and I believe that Amgen has done this well through our nearly 40-year history. And I'm confident we'll do so again as Sean Harper and Tony Hooper step-down from their roles in anticipation of their forthcoming retirements.

I can't express strongly enough my deep appreciation for the contributions these two leaders have made to Amgen. They've played a critical role in transforming Amgen into the company we are today and their legacies will continue in the teams they've built and the patients that we'll serve. And above all, Sean and Tony have maintained a relentless focus on Amgen's mission to serve patients and we're a better company for it.

As you all know, I have great respect and admiration for Sean and Tony and they've been great partners and colleagues. And while they leave big shoes to fill, I'm excited about the two leaders who are succeeding them and I know Sean and Tony are committed to working with me and my team to ensure that our new leaders successfully transition into their roles.

Now, let me start with Dave Reese, who is known to many of you and is someone that I've worked closely with over the past decade. Dave has been with Amgen since 2005 and he's been closely involved with virtually all of the medicines that have emerged from our pipeline since then. An oncologist by training, Dave has led discovery research and parts of clinical development and he's also played a critical role in building our early-stage oncology pipeline, particularly our portfolio of BiTE molecules which we find especially promising.

His background includes past faculty appointments at UCLA and UCSF, and we're excited to have him assuming the new responsibilities here at Amgen today. Dave has joined us on the call and he'll have an opportunity to say a few words a little later this afternoon.

Meanwhile, Tony's successor, Murdo Gordon, will be joining us in September from Bristol-Myers Squibb, where he most recently served as Chief Commercial Officer. His experience and capabilities are a perfect fit for where we are going strategically. Murdo has global experience at a time when we're looking to continue to expand our geographic presence.

He's operated in a number of our core therapeutic areas of focus, including cardiovascular disease, neuroscience, inflammation and oncology. And in addition, during his time at Bristol, Murdo led Commercial Operations in the U.S., which, as you know, is our largest market, and also had responsibility for value and access, which as I discussed earlier is an increasingly important component of today's dynamic healthcare environment.

Tony will be at his role through much of the third quarter and he'll join us in welcoming Murdo on this earnings call in October. I'm looking forward to having Murdo and Dave become part of our leadership team and both are exceptional, highly accomplished leaders well-suited for the opportunities ahead.

With that, let me turn to David Meline for financial highlights.

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David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. Overall, we're pleased with our strong performance in the second quarter as investments in support of our newer products delivered growth and our business continued to generate strong cash flow.

Turning to the financial results on page 6 of the slide deck, worldwide revenues at $6.1 billion in the second quarter grew 4% year-over-year. Worldwide product sales at $5.7 billion in the second quarter grew 2% year-over-year as strong unit demand from our newer products outpaced declines in our mature brands. We're also encouraged by the sustained double-digit volume growth from our ex-U.S. markets.

Other revenues at $380 million increased $144 million year-over-year due to a milestone payment received related to our Aimovig partnership with Novartis. Non-GAAP operating income at $3.1 billion grew 2% from prior-year. Non-GAAP operating margin at 55.1% for the quarter.

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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 continued 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 increased by 0.4 points to 13.1%, driven by higher manufacturing cost and unfavorable product mix, partially offset by lower royalty revenue – expense. Research and development expenses at $850 million or 15% of product sales were relatively unchanged in the second quarter of 2018 versus last year. For the full year, we expect research and development expense as a percent of product sales to be comparable to 2017 levels.

SG&A expenses increased 14% on a year-over-year basis, primarily driven by investments in product launches and marketed product support. We expect Q3 and Q4 spend levels to be consistent with Q2 as we continue to invest in our launch and growth products. In aggregate, non-GAAP operating expenses increased 7% year-over-year. Other income and expenses were a net $185 million expense in Q2. This is unfavorable by $29 million on a year-over-year basis.

The non-GAAP tax rate was 14.2% for the quarter, a 3.2 point decrease versus the second quarter of 2017, due to the impacts of U.S. corporate tax reform, offset partially by a prior-year benefit associated with the effective settlement of certain state and federal tax

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matters. Non-GAAP net income increased 5%, and non-GAAP earnings per share increased 17% year-over-year for the second quarter to $3.83 a share.

Turning next to cash flow and the balance sheet on page 7. The company generated $1.9 billion of free cash flow in the second quarter of 2018 versus $2.1 billion in the second quarter of 2017, driven by higher cash taxes resulting from the first installment of the repatriation tax paid in Q2 of 2018, partially offset by lower ongoing income tax liability as well as higher net income. We continue to provide significant cash returns to shareholders, consistent with our commitment to deploy excess cash over time.

In Q2, we deployed $3.2 billion to repurchase 18.2 million shares at an average of $175 per share. Further, we plan to deploy an incremental $3 billion to $5 billion for share repurchase in the second half of 2018. Lastly, our second quarter dividend increased to $1.32 per share, an increase of 15% over last year.

Cash and investments totaled $29.4 billion, a decrease of $10 billion from the second quarter of last year. This decrease over the last 12 months was primarily driven by $19 billion of cash returned to shareholders in the form of dividends and share buybacks, partially offset by over $10 billion of free cash flow generated in the same period. Our debt balance stands at $34.5 billion as of June 30, carrying a weighted-average interest rate of 3.9% and an average maturity of 11.7 years.

Turning to the outlook for the business for 2018 on page 8. We remain on track with our plans to continue investing in our pipeline, building out our global presence and increasing spend in support of long-term volume growth across large patient populations, while delivering solid business performance.

Today, we are revising our 2018 guidance, which reflects our strong Q2 performance and outlook for the second half of the year. Our latest revenue guidance is $22.5 billion to $23.2 billion versus prior guidance of $21.9 billion to $22.8 billion. This guidance reflects our solid performance to-date as well as our confidence of continued good performance while recognizing uncertainties related to potential new competition for Neulasta and Aranesp and a range of potential Sensipar generic competition outcomes.

With regard to our non-GAAP earnings per share guidance, we are revising the outlook to $13.30 to $14 per share versus previous guidance of $12.80 to $13.70 per share. We are reaffirming our prior non-GAAP tax rate guidance of 13.5% to 14.5%. We continue to expect capital expenditures of approximately $750 million this year. In this regard, we are breaking ground on our new manufacturing facility in Rhode Island in the next week.

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

Anthony C. Hooper {BIO 6284080 <GO>}

Thank you very much, David, and good afternoon, folks. You'll find our product sales starting on slide number 10. I'm also pleased to report we delivered a solid second quarter, with 2% year-over-year product sales growth.

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Let me first add to Bob and David's comments regarding our focus on volume-driven growth. We recognized early on that the evolving U.S. landscape should lead us to focus investments in brands that serve large patient populations in addition to our traditional focus on more targeted specialized therapies. We also made the strategic decision to advance and bring to market a broad biosimilar portfolio. We're making good progress on all these fronts.

As evidence, you can see our strong growth in Prolia and Repatha and our early success with Aimovig, three medicines that treat diseases affecting tens of millions around the world. We're also now in the market with our first biosimilar with several more to follow. In addition, our continued volume growth outside the U.S. serves as a model for what growth in the U.S. can look like in the future.

With regard to U.S. pricing, in evaluating factors contributing to our reported sales growth, changes in net selling price had minimal to no impact over the last 18 months, and we expect that trend to continue going forward. We've not increased the list prices of any of our medicines since the administration's drug pricing blueprint was issued. And in May, we decided not to execute list price increases that have been planned for July. This reflects our commitment to identifying opportunities to improve affordability and access for patients. While there is no simple fixes, we want to be part of the solution.

To summarize our sales performance for the quarter, we continued to generate double-digit growth, primarily driven by volume for several of our newer products and those with label expansions such as KYPROLIS, XGEVA, BLINCYTO and Parsabiv. And, once again, sales growth outside the U.S. was very strong, increasing by 9% excluding the impact of foreign exchange, driven by 14% volume growth.

Let me now turn to our brands. Prolia delivered another outstanding quarter, with sales increasing 21%, with 16% volume growth year-over-year and share gains in both the U.S. and international markets. Moving now to oncology, let me start with KYPROLIS. KYPROLIS grew 25% year-on-year, driven primarily by our ex-U.S. business. Our European business benefited this quarter from a $27 million clinical trial purchase. Just recently, we received approval to include overall survival data from the ASPIRE study to both the U.S. and EU labels. I'm also pleased to announce that we recently received reimbursement for KYPROLIS in France and we look forward to a rapid uptake in that country.

XGEVA grew 14% year-over-year, primarily from volume, as we expanded into multiple myeloma with our label update this January. Turning now to Neulasta where sales increased 1% year-over-year, but consistent with recent trends we saw slight reduction in the overall market segment in the second quarter, resulting in a small decline in volume.

We continue to drive the adoption of Onpro in the U.S. and exited quarter two at 63% share of Neulasta unit sales. Onpro's increased utilization underscores the value it provides to patients and providers, which we believe will be a clear differentiator versus potential competition. We expect to see more global utilization of Onpro in 2018, with recent launches in Germany, the UK, the Netherlands, Poland, Ireland and Austria.

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Regarding potential new entrants, we are prepared to compete if and when they enter the market and have years of experience competing in the short-acting G-CSF market across the globe as well as experience competing in select markets outside the U.S. in the long-acting GCF market. We're confident in our capabilities, and we know that reliability of quality supply is a key factor for our customers.

For NEUPOGEN, we exited the second quarter holding 37% of the short-acting segment in the U.S. Some of our competitors and public officials have made statements that the U.S. biosimilar market is not working. We have a different point of view. NEUPOGEN was the first major biologic to face biosimilar competition in the U.S. The fact that our biosimilar now holds the majority share of this segment less than three years post-launch proves that biosimilars can find a meaningful place in the U.S. market just as they have in Europe. This also gives us confidence in the future of the Amgen biosimilar portfolio.

With respect to remainder of our oncology portfolio, the combined sales of Nplate, Vectibix, IMLYGIC and BLINCYTO were $426 million in the quarter, representing 10% year-on-year growth with 11% coming from volume increases. Enbrel sales declined 11% year-over-year with market growth, segment share and net selling price constant with recent trends. You'll recall that second quarter 2017 benefited from a significant inventory build creating an unfavorable year-over-year comparison.

On a quarter-over-quarter basis, sales increased 18%. We continue to be pleased with the launch of Enbrel Mini with AutoTouch which has been met with positive feedback from both patients and physicians. Overall, we expect fundamental drivers of Enbrel to follow the recent trends.

Switching now to our ESA portfolio, EPOGEN declined 14% year-over-year due to competition and a lower net selling price driven by extended supply agreements with DaVita. Aranesp declined 12% year-over-year, primarily driven by increased competition.

We've been competing against a long-acting product in the independent and midsize dialysis organizations since the beginning of the year. We have volume and share-based contracts in place with some of these customers and we'll continue to compete on an account-by-account basis. We're also prepared to compete with the recently approved short-acting biosimilar in all customer segments, including hospitals and clinics. Nonetheless, we expect to lose some share in these segments once the product is available.

Let's now turn to our calcimimetics. Parsabiv has launched in several markets, including the U.S., where we have a solid uptake at the independent and mid-sized dialysis providers. Both FMC and DaVita continue to run pilots to determine the eventual treatment protocols. So looking ahead, we expect to see adoption continue to increase gradually over time.

Turning to Sensipar, sales declined 2% year-over-year with the launch of Parsabiv. As David mentioned, the 2018 outlook for Sensipar is still uncertain given the ongoing

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litigation. It remains possible that a generic competition may enter the market later this year.

Repatha sales grew 78% year-over-year, primarily from volume, as we continue to compete effectively, maintaining a majority share on a global basis. With outcomes data added to our label in the U.S. in December and more recently in Europe and Japan, our teams have been speaking directly to the benefits of treating patients with Repatha.

We've recently concluded negotiations to improve patient access in the U.S. with several payers, including, but not limited to, CVS and Anthem. These payers presently represent greater than 65% of Repatha's commercial revenue. As these changes take effect in the second-half of this year, we expect the proportion of commercial plans requiring documentation and the utilization management criteria to be cut in half with the rest relying on simple physician attestation.

In exchange for simpler, UM criteria, we have increased our rebates which will result in a lower net price. We recognize that the higher rebates unfortunately don't always result in lower out-of-pocket cost for patients. Therefore, we continue to work with a wide range of stakeholders on continued improvement in access.

We are, however, encouraged by the fact that physicians have consistently recognized the benefit of treating patients with Repatha and have demonstrated a strong demand for the drug even when faced with severe restrictions on reimbursement. Our priority remains reaching the large population of high-risk cardiovascular patients.

Now on to Aimovig, the first and only therapy specifically designed to prevent migraine by targeting and blocking the CGRP receptor. Patients and physicians share our excitement for this new therapy. And, as you know, we set up a hub to assist patients to gain early access to the product while we complete negotiations with payers. This program provides a free two-month trial of Aimovig.

We have, in fact, received a large bolus of requests from the Headache Centers of Excellence reflecting the pent-up demand for this innovative new therapy. We're busy working through these requests and expect to see the prescriptions coming through over the coming weeks.

Should a patient not be approved by the insurance during this two-month period, we have a bridging program during their negotiations to ensure that patients are not denied drug. Negotiations with payers are progressing well and we have successfully completed contracts to attain coverage for just under 30% of lives already.

We're also excited that we've launched our first biosimilar, KANJINTI, a biosimilar version of Herceptin in Europe. Biosimilars represent an important growth driver for Amgen and so far the market is behaving as we anticipated.

So, in closing, we continue to transition our portfolio, exemplified by volume-driven growth. I'm pleased with the execution and the consistency of performance in 2018. I'm excited about the opportunities in front of us. Let me close by thanking all the Amgen staff that work so hard to get these important products to patients and for a strong first half of 2018.

Let me now hand you over to Sean. Sean?

Sean E. Harper {BIO 16272195 <GO>}

Thanks, Tony, and good afternoon, all. I'll begin today with our neuroscience collaboration with Novartis. Tony spoke about our U.S. launch of Aimovig and the difference it's already making for migraine patients.

In addition to the U.S. approval in May, our partnership announced a CHMP positive opinion in the EU last month. And I'm pleased to announce that we recently submitted a Supplemental Biologic License Application in the United States for our 140 milligram SureClick autoinjector. We look forward to working closely with FDA to make this available to patients as soon as possible.

Also, in migraine, we expect the data from our proof-of-concept in dose-finding Phase 2 study of our PAC1 antibody for migraine prevention, AMG 301, to be available by the end of the year and presentation at a medical meeting in 2019. There have been a number of recent developments in Alzheimer's disease clinical programs in our industry, so I thought it would be useful to highlight our partnership's ongoing beta secretase inhibitor program and why we have such confidence in our approach.

AMG 520 or CNP520 is a potent and selective small molecule inhibitor of BACE1, a target with strong genetic human validation from deCODE that is part of our neuroscience collaboration with Novartis. We're taking a differentiated approach with this clinical program and are currently enrolling two Phase 3 studies.

In Alzheimer's disease, amyloid precursor protein cleavage products such as Abeta begin accumulating decades before symptoms present. And by the time a patient is symptomatic, Abeta accumulation has reached a plateau and significant neurodegeneration and subsequent inflammation have already occurred.

Therefore, we've always felt that potential treatments should be administered as early as is feasible in trials attempting to demonstrate disease modification. So our partnership in collaboration with the Banner Institute (sic) [Alzheimer's Institute] (00:29:16) is focused on a population of pre-symptomatic cognitively normal subjects who based on their APOE genotype and age are very highly predisposed to developing cognitive impairment.

One study is enrolling approximately 1,300 APOE4 homozygotes, that is subjects with two copies of the APOE4 risk allele and a second study is enrolling approximately 2,000 subjects, either APOE4 homozygotes or heterozygotes which have one APOE risk allele and evidence of brain amyloid accumulation.

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While we're studying a genetically defined population, it's a large and representative one, as approximately 60% of patients who develop Alzheimer's disease have at least one of these predisposing disease alleles. We haven't been surprised by how the Alzheimer's clinical landscape has played out of late and the recent disappointments and potential signals of efficacy have not changed our overall conviction around our program, particularly that a small molecule BACE1 inhibitor administered pre-symptomatically is likely to be the best approach to address this pathway and disease.

In oncology, I'm happy to report we've completed enrollment in two Phase 3 studies, our study of KYPROLIS plus DARZALEX and dexamethasone versus KYPROLIS and dexamethasone alone in relapsed or refractory multiple myeloma, and our IMLYGIC combination study with KEYTRUDA in unresectable metastatic melanoma.

Turning to our early-stage oncology pipeline, we've advanced a number of programs into clinical testing as reflected on slide 26. And by the end of this year, we expect initial Phase 1 data from our BCMA BiTE, AMG 420, in multiple myeloma and our CD33 BiTE, AMG 330, in AML. We look forward to additional data from other BiTE programs over the next year or two, including both liquid and solid tumors.

We've also deprioritized AMG 224, our BCMA antibody-drug conjugate, based on early data reads from our AMG 224 and AMG 420 programs that support our view that our BiTE technology may be superior to current ADC technologies. Finally, on Nplate, we recently submitted an application in the U.S. for pediatric immune thrombocytopenia.

In other regulatory news beyond the KYPROLIS update that Tony discussed, we received a Repatha label update incorporating our cardiovascular outcomes data and full approval for BLINCYTO in the EU and Prolia was approved for the treatment of glucocorticoid-induced osteoporosis in both the U.S. and EU.

Also, in our bone franchise, we resubmitted our EVENITY Biologics License Application for the treatment of osteoporosis in postmenopausal women at high risk for fracture. Finally, in our biosimilars development programs, in addition to our KANJINTI approval that Tony discussed, we received Phase 3 data from ABP 710, our biosimilar of Remicade in rheumatoid arthritis, that we believe demonstrates similarity to a referenced product.

In closing, as always, I'd like to thank our staff for continuing to deliver for patients. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Sean. Before we turn the call over to Q&A, Sean, if you'd like to say a few words as I guess this is your swan song earnings call. Why don't you feel free to share your thoughts? And then we'll invite Dave Reese to say a few words and then open up for questions.

Sean E. Harper {BIO 16272195 <GO>}

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Right. Well, this was, of course, an exceedingly difficult life decision for me given the wonderful experience I've had over more than 16 years at Amgen. I love the mission, the people, the science and technology, and all of these are the best they've ever been, not to mention the relationships I have based on mutual trust and respect with you, Bob, and many other Amgen leaders and staff.

That said, it's rare in our industry to have the opportunity to personally hire from academia and develop over more than a dozen years such a capable individual as David Reese as a successor for Head of R&D. As you all know, succession for this particular role can be very challenging. Dave is truly ready and just, as importantly, after 21 years in the industry, I'm ready for a change, likely to early biotech company creation here in this local area of California.

Dave is a medical oncologist who was on faculty at UCLA, when I recruited him to Amgen and he served in a variety of increasingly senior roles since his hire in 2005. These have included late-stage clinical development, discovery research and as our Head of Translational Sciences and oncology programs. In this last role, he's introduced all of our current pipelines into the – molecules into the clinic.

Many of you know Dave from his presence in our investor events. If not, you're going to really enjoy getting to know him. He has my full confidence and that of my team as the next Head of R&D for Amgen. I'll be staying around through the end of the year to ensure a smooth transition.

Finally, I'd like to thank everyone at Amgen and in the investment community for the support I've received over the years. It's been a privilege to be part of the evolution of this great American company and to have such high-quality interactions with our investors and analysts.

Dave, welcome to earnings call-land. Why don't you make a few comments?

David M. Reese {BIO 19782623 <GO>}

Well, thank you, Sean, and thank you for your partnership. It's certainly been a highlight of my career over the last 13 years. I'd like to emphasize that we're dedicated to our core mission of advancing science for the benefit of patients. We'll continue to focus on developing medicines that produce large effect sizes in serious diseases where there is significant unmet medical need.

I've been a part of the R&D leadership team for some time as Sean mentioned. And I also believe that the commitment that we've made to using human genetics to understand the origins of disease and to suggest therapeutic interventions is the right choice and in fact will become increasingly important in our drug discovery enterprise.

Likewise, I'm convinced the platforms such as our BiTE technology, and other therapeutic modalities have the potential to deliver transformative medicines. Having led our

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Translational Sciences efforts for some time, I cannot be more excited about our preclinical and clinical pipelines.

At the same time, it's undeniable that we've entered a period of remarkable technological ferment leading to both a deeper understanding of disease, and providing a wide array of new technologies that will change how we do science at the bench and advance molecules in the clinic. In light of this, I'm extraordinarily enthusiastic about the opportunities in front of us and I look forward to keeping Amgen at the forefront of this rapidly-changing industry.

I also very much look forward to working with all of you in the investment community as we focus on creating value through delivering our pipeline. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thanks, Dave. Let's open it up for questions now and we'll ask our operator just to remind you all of the procedures for doing that. Ian, over to you.

Q&A

Operator

Our first question comes from the line of Ying Huang from Bank of America Merrill Lynch.

Q - Ying Huang {BIO 16664520 <GO>}

Hey. Good afternoon. Thanks for taking my question. Congrats on the quarter and congrats to both, Tony and Sean. So first one I have a high level question. You guys bought back $3.2 billion stock in second quarter in addition to the $10 billion buyback in first quarter. And then there's another plan to do a $3 billion to $5 billion in second half. Does this suggest anything about your strategic thinking about M&A transactions, given the large buyback?

And then, secondly, maybe I want to see if you have any comments on the potential entry of Neulasta biosimilar in the second half. We saw Mylan priced at 33% discount on list price level. So what's the assumption on the second half run rate for Neulasta? And what's your defense strategy on Neulasta? Thank you.

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

Okay. There's quite a lot there, Ying. Let's break it into two-parts. Start with David Meline in response to your question on capital allocation. Then we'll ask Tony just to reiterate what he said in the call.

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

Yeah. So on capital allocation, I think, we've been quite clear in the past and we haven't changed our point of view, which is how we create value as an enterprise is investing in

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innovative medicines either internally through our own R&D efforts and also we're very active looking for opportunities externally to add to the portfolio. And so we'll continue to do that.

What's also true is I think we all know we have a tremendous capability for cash generation, and we have a large amount of excess cash following tax reform. And we are committed to return excess cash through time to shareholders. So I wouldn't read our ongoing repurchase activities to be anything other than following on that commitment and I would definitely not read that we're backing off from our commitment to continue to add to our pipeline and our portfolio.

FINAL

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

So as regards the Neulasta biosimilar, I mean clearly we have been competing in the marketplace with NEUPOGEN and biosimilars for a number of years now. The team stands ready and able to compete. We have a long legacy and history of reliable and consistency of quality supply. We have spent quite a bit of time converting the market to the Onpro device, which is a unique and innovative device which is beneficial for both clinical practice and for patients themselves. And I think there's quite a difference in the marketplace between the list price of these drugs and the ASP price.

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

Okay. Let's go to the next question.

Operator

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

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

Thanks for the question. And I guess, Sean, this might be your last call so I wanted to ask you a question. And that was you highlighted Alzheimer's and perhaps you could opine, obviously, on your view since you are running different studies in APOE carriers and non-carriers, whether there is truly a difference there and whether there's a difference in progression and opine on the debate, of course, this week.

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

Well, Michael, I think that we've been able to utilize data that we've accumulated in Iceland through deCODE who, as you know, have done some of the really seminal breakthrough genetics and epidemiology and in Alzheimer's to understand the rate of cognitive decline that occurs in patients who have 01 or 2 of the APOE4 alleles. And that plus age allows one to make some estimates of when people who are cognitively normal will begin to develop some cognitive impairment in the context of a disease-modifying trial.

So we've had the advantage of that information, and that's what led us with Novartis to move toward this kind of a genetic stratification of the population. And we again expect

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because we are looking at this type of enriched population that we'll be able to conduct in a feasible way these trials which otherwise it would be very difficult to conduct if you were taking patients who were cognitively normal and didn't have these high risks for conversion in the reasonably near future, try to engage in a clinical trial.

So it is a differentiated approach and I think an important one. And as I stressed before, it's not like a little proof-of-concept experiment in some tiny subset of patients with a genetic risk factor. This is 60% of the people who present with Alzheimer's disease have one or two APOE risk alleles.

FINAL

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

Thank you. Next question?

Operator

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

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

Hey. Good afternoon. Thanks for taking the question. So before my question let me say congratulations to Sean and Tony on their tenure and good luck as they move on and welcome to Dave. So, Tony, I was hoping a question for you. You mentioned a little bit about Aimovig. I was hoping if you could provide some insight into two factors. So we're obviously seeing the scripts but we don't really have a good idea of the translation of those scripts for free drug into revenue.

So I don't know if you're willing to just give us any thoughts around how we should be thinking about the script trajectory versus your ability to generate revenue from them. And then second item is you talked about having about 30% of the lives with coverage already. Could you just talk a little bit about what's the utilization management criteria that you've been able to negotiate for that? And do you think that's suggestive of the UM that we should expect for the rest of the plan? Thanks.

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

Okay. Sure, Matthew. So I want to start by saying I think from what I've seen anecdotally from both physicians and from patients, the response to Aimovig in the marketplace is beyond our expectations, right. So patients are really finding this to be a definitive difference in the way of managing their migraines. We knew we'd have a little bit of an issue in the beginning as we sort of put the contracts into place. So we created the hub together with Novartis to ensure all patients referred into the hub first to allow them access if they didn't already have coverage to the two-month free program.

Right now, the majority of our business is in free drug, but we are rapidly converting that business to paid prescriptions. And you'll see as the bolus comes through the hub, there's been quite a dramatic change in the number of patients that happened in the last week or so. And we expect this to get back to a steady state in the next three or four weeks or so.

In terms of those organizations who were visionary enough to move rapidly to give access to patients who have been struggling with this devastating disease for a long time, the UM criteria has been pretty clear. We always assume the drug will be used as a second line when patients have failed on existing generic therapies and that's where it is, but all the plans at the moment only require physician at a station, right? So, no documentation, just a physician stating very clearly the patient has already tried some other products.

FINAL

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

Okay.

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

Thank you. Let's go to the next question.

Operator

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

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

Thanks. Got a question on co-pay accumulators. So I think last quarter, Tony, I think you indicated that you don't anticipate seeing any impact in the first half but we're now in the thick of Q3 and from most modeling of these types of plans it looks like much of the impact is likely to be in the summer. So I guess maybe can you describe – and also, one of your big competitors actually lowered guidance for one of their drugs as a result of impact here. Can you maybe just talk about the dynamic impacting Enbrel in particular? And I know there's a few countermeasures that you and other folks in the industry have talked about taking but maybe give an update as to how effective those countermeasures are and where things stand with this thing? Thanks.

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

Okay. Sure. So I'm not going to talk about what the countermeasures are that we've put into place. They're clearly competitive. But I have looked very closely at the potential impact of accumulator programs on Enbrel both in the first quarter where I saw minimal to nothing and again for the second quarter where I saw minimal to nothing and I'm not forecasting much in the third quarter beyond.

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

Okay. Thanks. Let's go to the next question.

Operator

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

Q - Umer Raffat {BIO 16743519 <GO>}

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Hi. Thanks so much for taking my question. I figured I'll ask both Tony and Sean a question each. So, perhaps first, Sean, maybe just a little confusion on your response on one of the prior questions on AMG 520. I guess what I'm asking is why not enroll non-carriers? Do you think they'll perform better and it'll be harder to tease out a signal? Just want to understand why not have it in your Phase 3 program?

And then, Tony, my question to you was just to clarify how Neulasta's economics work the way it's structured currently in the face of biosimilars? And specifically what I was looking to understand was, A, is any part of Onpro reimbursed via Part D as in David? And then also the economics, how they work for 340Bs versus clinics, and whether some part of market could be rebated more or could be more defendable, that kind of thing? Thank you.

FINAL

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

Okay. A lot of questions there. We'll try to take those one at a time.

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

Right. So with respect to the strategy we're using, so the way to think about it is that we're focused on testing people before it's potentially too late to be able to show disease modification. And so we believe that means that people have to be cognitively normal on an intense battery of cognitive testing. But if you imagine bringing people in who don't have a predisposing genetic driver to have them be very likely to develop the cognitive impairment in the relatively near future, you're going to be doing this study forever.

So what we decided to do was basically enrich for people who have both a certain age and the APOE status that they were likely to have enough events of people going from cognitively normal to cognitively impaired during the course of a trial that won't take forever. And given that this represents 60% of people with Alzheimer's disease, it seems like a pretty reasonable strategy to me.

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

So as regards Neulasta, Umer, all of Neulasta's Part B. Nothing is in Part D. From a reimbursement perspective, Part B is obviously under ASP plus. ASP depends on what your prices are today and what they'll evolve to be in a few quarters time. As Amgen, as a company, we've always presented our position very strongly to both the environment and to CMS and the government that we prefer a level playing field between our sales and biosimilars in the future and allow normal competitive factors in the marketplace to allow us to compete equally.

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

Ian, let's take the next question.

Operator

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

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Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the questions, and best of luck to Sean and Tony on next steps and congrats to Dave. Maybe first just for Tony on Repatha. Was wondering what percent of lives now have the eased utilization management criteria. And with the new treatment guidelines expected later this year do you think that'll have a further impact on access? And then maybe just for Sean on AMG 301 you mentioned the PAC1 antibody. What are you hoping to see from this Phase 2 trial and if it's positive could you move right into Phase 3? Thank you.

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

Okay. So again a couple questions there, Repatha, the utilization management question and then how guidelines may affect.

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

So as I said, about 65% of our business at the moment is going to move towards at a station only. And in terms of total evolution of the commercial business that's probably between 25% and 40% of the total lives available. I think as we continue to negotiate the other plans we will get better utilization management criteria. I do believe we're going to get better access. The drug is proving to be something that physicians and cardiologists are prescribing consistently continually and the demand from patients is still there.

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

Yeah. And, Terence, for AMG 301, our PAC1 antibody receptor antagonist, we're doing something very similar to what we did with Aimovig where the proof-of-concept trial also includes the dose ranging, all predicated on some dermal blood flow assays that were done in healthy subjects to pinion the dose ranging. So if we're successful in demonstrating proof-of-concept, hopefully we also would have enough dose information to be able to proceed directly into Phase 3 as we were able to do with Aimovig, but, of course, we'll see. This is a novel pathway that needs to be validated in humans through this experiment.

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

Okay. Let's go to the next question.

Operator

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

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

Thank you very much and repeat the congratulations to Tony and to Sean. One quick question, perhaps for Bob on rebates. Could you give us a sense of what impact elimination of the Safe Harbor for rebating would have on Amgen's product access and price? And then I hate to sort of pursue this Alzheimer's question again, but, Sean, could you talk as you're sort of looking at leaving Amgen, what are the barriers to exploring all

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the sensible combination ideas that might be out there in Alzheimer's given all the frustration that the industry has had with single product trials?

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

Okay, Geoff. Maybe I'll answer your rebate question in two parts. I'll start, and then, Tony, you can jump in. So big picture, Geoff, as you know, the discussion about rebates is underway. The administration has asked for perspectives, and we've participated with our industry colleagues in sharing our thoughts about this.

We think that the administration is focusing on an important topic here, which is rebates and the impact that the rebate structure in our industry has on patient affordability. So we welcome an opportunity to be able to share our industry perspectives with decision makers in the government, and that process is underway. It's a little bit premature I think to talk about what the specifics of your question were on our business, but I'll invite Tony to share his thoughts.

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

So the only thing I could add to what Bob was saying is that clearly in competitive markets your rebates tend to be higher. And so the gap between your list price and your net price tends to get quite large, none of which allows patients to benefit from, of course, because they're paying co-pays, co-insurance or deductibles based on the list price. If the rebates went away, by definition your list prices would get closer to net prices, and patients would be able to access drug better.

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

And maybe one last thought – sorry, Geoff – and then we'll kick to Sean. Rebates and the structure that exists today evolved over many decades. It's hard to imagine what the impact of unraveling that would be if that unraveling occurred quickly. But, again, we're part of the discussion. We look forward to trying to figure out whether there isn't a better way for patients than what's in place today. Sean, why don't you...

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

Yeah. It's a great question, Geoff. I think that what I would say is that it's difficult given the costs and complexity and duration of these kind of trials to imagine going directly into combination without having demonstrated some efficacy and safety of the individual interventions.

And I think there is a very strong logic behind combination and the disease because we know from the human genetics that one problem is APP processing and the generation of fragments like Abeta. And that another problem is the way in which the glial cells in the brain handle the subsequent cell detritus and death and inflammation. And that's pretty clear from the genetics which has largely been elucidated by deCODE.

And so we think that we'll get there and that there will be combination therapy. But we probably need to see one of the individual components validated. And then you'll see

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people adding on to that therapy to try and see a more dramatic impact on disease progression.

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

Okay. Let's go to the next question.

Operator

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

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

Robyn, are you there? Okay. Ian, let's go to the next one.

Operator

Very well. And our next question is from the line of Geoff Meacham from Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Hey, guys. Thanks for the question, and I also wanted to offer congrats to Sean and to Tony. Just a question on healthcare policy. I know there's been a lot of talk about – with respect to biosimilars, interchangeability, and, Tony, want to get your perspective on maybe how close we are on that. And then the other issue is Part B to Part D conversions, or the demo project, kind of what your thoughts are on that. Thanks.

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

Okay. Maybe we'll ask Sean to talk about the appropriateness of interchangeability from a regulatory standpoint first, Geoff, and then, Tony, feel free to add any thoughts you have.

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

Yeah. I think obviously there are two aspects to this. There's the regulatory piece which varies from country to country. In the U.S., as you probably know, the agency has provided reasonably clear guidance around what's necessary to achieve the interchangeability, but that hasn't really been put into practice yet. People are doing trials that are designed to meet that standard.

No one has had an approval based on it yet, so there's a learning curve there. But that will be an important goal that some companies will pursue with their products. Then there's the question of whether there may be, if you will, interchangeability policies that will exist at the level of payers, and who can potentially do whatever they want independent of the regulatory component. That, Tony, maybe you could comment on.

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

Sure. So, I mean, as we said, NEUPOGEN to us is probably the best example of the existing system allowing biosimilars to access the marketplace. After three years, they

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hold the majority market share and, therefore, we continue to put forward our proposal that the market be left as is, that we keep the playing field level, that we allow the normal competitive framework of the marketplace to take place.

Q - Geoff Meacham {BIO 21252662 <GO>}

And talk about B to D.

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

Okay. I'm not sure exactly what you're getting at, Geoff, but obviously one of the things that's being discussed in Washington is whether it makes sense to consider the movement of certain drugs from Part B to D. And, again, there are early stages of discussions about what that would look like and for which products it would be irrelevant. So premature I think to speculate about whose products would be included in that over what time and what impact.

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

Okay. Ian, let's go to the next one.

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 my question. Also let me add my congratulations to Sean and Tony on the retirements as well as to David on his well-deserved promotion. So a question is for Sean. I wanted to ask about BCMA, and kind of what you see as the bar in your ongoing Phase 1 trials. And are you looking at your products more as monotherapy assets or as part of existing combinations down the road?

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

Yeah. I think this antigen is going to likely prove to be fairly transformative in the disease. And the question becomes the modality that you go after it with. As I mentioned, we're less impressed with what we're seeing with the ADCs and the BiTE technology appears to be capable of generating early data, small numbers of patients, very dramatic results.

Whether you gain anything from a cell-based therapy directly against this antigen? Nobody knows because there's no – not even a way to do an indirect comparison at this point, let alone any kind of direct comparison. So it'll be really interesting. I think, of course, initially, we'll be studying it as a monotherapy in patients who are late stage and have undergone many rounds of attempts to treat the disease. But one could easily imagine a therapy like this entering all lines of therapy and including attempts to cure the disease in the first-line settings. Dave, you may want to comment further as -

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

Yeah, no, it's a very good question and, of course, we would anticipate the initial forays to be as monotherapy but there are a variety of potential biologic combinations that make sense. And we will plan to also aggressively develop those over time. As Sean mentioned earlier, we're hoping to be able to present publicly sometime later in the year on some of the first clinical data from these programs.

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

Okay. Let's move on.

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. A quick one on the EVENITY resubmission. I was wondering just how you were thinking about this internally. There was obviously some hope at least on the Street that the independent blinded re-review would suggest some kind of missed adjudication of events, which may really help the resubmission.

And then, secondly on Neulasta, just wanted to get your perspective on sort of the strength of the Onpro defense if a hospital protocol has changed. I know a lot of time and effort went into getting Onpro onto hospital protocols. I was just hoping to get your perspective as to how large of a barrier this is. For instance, how challenging this could be to be changed to Mylan's generic?

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

Thanks, Kennen. Why don't we have Sean answer the first question and, Tony, if you'd take the second question?

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

Yeah. So with respect to EVENITY, we did a very comprehensive scouring of the clinical databases and then re-adjudicated all of the events that were originally identified plus any that have been identified subsequently. The good news is that it showed that our research platform is very robust, because when we redid this we saw pretty much the same thing we did the last time when we did it originally.

The bad news is that it didn't really change the dataset for the potential safety signal. It is the opinion and this is just an opinion of the people involved both at Harvard and here at Amgen that the most likely explanation for the finding in the alendronate-controlled trial is chance. We think that's most likely. However, that's not going to be good enough to mean that you're not going to have a need to warn patients about a potential risk. And I'd say we think we're sort of back where we were before we did the exercise.

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

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Okay. And then to answer your question on Neulasta Onpro. So, to remind you again that all the institutions are working as hard as anyone else is to improve on the efficiencies of their processes. Most of the large teaching institutions took about 12 to 18 months to change their clinical practice, because it does apparently take some time to change clinical practice in a large institution.

The benefit of this one is, of course, is it changes the entire protocol about how you treat a patient, how many times a patient has to come back to the institution, how many times the oncology pharmacist has to be remixing, how many times the oncology nurse has to be infusing, and how many times the oncologist has to be there which is all on top of the fact that a lot of patients live far from the hospital and have a problem to come back the next-day when they're suffering from the side effects of high dose chemo.

So what we've delivered is not just a unique opportunity to give better value to patients who can spend more time at home, who are going to have the drug administered at home but we've also taken out a huge amount of inefficiency in the institutions which allows the nurses, the oncologists, and the pharmacist to go and do something else. So one assumes that the value we bring is more than just the drug itself. It's truly an augmented value and we believe that's fairly sticking.

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

Ian, let's take the next question. And just a quick reminder that if you can please limit yourself to one question, so (01:04:35). Let's go to the next one.

Operator

And our next question is from the line of Phillip Nadeau from Cowen & Company.

Q - Phil Nadeau {BIO 4838409 <GO>}

Good evening. Thanks for taking my question. Just one on Repatha. In the prepared remarks, you mentioned that price was going down because of the agreements that have recently been signed. Can you talk a little bit about the time course of that decline in price? When did it start? Did it start in Q2 or is it starting on July 1 and when will price stabilize again? Thanks.

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

So the list price hasn't changed. Some of the rebates by contract have changed. Some of the newer contracts become effective July 1 and we're clearly having to be competitive in the marketplace to maintain these contracts.

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

Okay. Ian, next question.

Operator

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

Q - Carter Gould {BIO 20035589 <GO>}

Great. Thanks for taking the question and congrats to Sean and Tony. I guess for Sean or David, coming back to the BCMA question. How should we be thinking about 420 relative to 701? Is there any differentiation other than the half-life format and then sort of is 420 just sort of proof of principle and then the strategy would be the switch to 701? Thank you.

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

David, why don't you?

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

Yeah. No. Thanks for the question and it's a good one. 420 as you may know advanced into the clinic earlier than 701. And so our intent at this time is to continue advancing both molecules until such time as we've generated datasets definitive enough for us to make a decision. All things being equal, of course, we'll take forward the half-life extended molecule.

Operator

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

Q - Aharon Gal

Let me just add my congratulations to both Sean and Tony for their time with Amgen. As we're talking about biosimilar let me just ask something there. First, Tony, I was wondering about Herceptin subQ in Europe since you're launching the molecule. Do you think that segment of the market will be protected from biosimilar competition or do you think this is accessible? And then in the United States, I noticed you've signed a lot of agreements with various providers around oncology. And I was wondering do those agreements provide economical advantages for those providers to continue to use Neulasta over the biosimilar over the duration of the agreement.

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

Okay. So any innovative SKU to any product, of course, makes the entry of the biosimilar a little bit more difficult. It doesn't make it impossible, so we're watching all those segments in Europe as we speak right now. And then as regards Neulasta and our customers in the U.S., we have fairly strong relationships with our customers, and we have continued to work hard to maintain and to expand those good relationships, yes.

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

Ian, let's take the next question.

Operator

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And our next question is from the line of Jim Birchenough from Wells Fargo Securities.

Q - Jim Birchenough {BIO 5068439 <GO>}

Yeah. Hi, guys. Thanks for letting me in, and congrats, again, to Sean and Tony. I'm just wondering if you'd be willing to give any further detail on patients in the hub for Aimovig, whether you'd quantify those patients and give us a better sense of how many patients may be queued up in this bolus that may be coming. Thanks.

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

So we haven't made that public yet. We're trying to make sure that we understand how unique each of those patients are, coming in, and that they are appropriate patients. I would say that, as you watch the evolution of the prescriptions coming out of that, you'll start getting a feel of the size of the bolus.

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

So, Ian, as it's well past 6:00 p.m. on the East Coast, why don't we take two last questions?

Operator

Very well. Our next question is from the line of Salim Syed from Mizuho.

Q - Salim Syed {BIO 16887281 <GO>}

Yeah. Hi, guys. And I'll throw my congrats as well to Sean and Tony and welcome to David. Just one on Aimovig probably for Tony. Tony, I was wondering if you can speak to – when we're thinking about Aimovig longer-term, so past this bolus here, what are the potential bottlenecks that you're seeing. Do you think that this is an area where you'll have to get reimbursement at the PCP level in order to not have a bottleneck in the system? And also the neurologists that are treating, do they have additional capacity to take in additional patients? Thank you.

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

So there are about 20 headache specialty centers around the country at the moment, and the volume of patients they can take in depends on how much they expand over time or not. But it's a fairly large number of patients coming through them. And then, there are another couple of thousand neurologists who clearly are prescribers. But I do believe that the role of primary care physicians down the road becomes important. They do see patients and their ability to refer patients who are appropriate for a drug like Aimovig would be critical for the long-term value of this drug, yes.

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

Ian, let's take one last question.

Operator

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And our last question is from the line of Brian Skorney from Robert W. Baird.

Q - Brian P. Skorney {BIO 15993204 <GO>}

Hey, guys. Thanks for fitting me in. I just wanted to ask a question on the pipeline on AMG 301 for migraine prevention. I was wondering if you can just help us understand the role that you guys see of PAC1 versus CGRP. And if successful, how do you kind of envision these being used, separately or a possibility for a combination down the line? Thanks.

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

Yeah, I guess what I would say – this is Sean – is that the thing I'd stress is that these appear to be rather independent neural pathways in the system. And so if it works, if PAC1 inhibition works, one would expect that it's not likely that it's going to be kind of redundant to CGRP. So you could imagine situations in which patients who are poor responders to CGRP inhibition might respond to PAC1 or that the two together might give better efficacy, assuming that was tolerable. But that will all have to be figured out in the clinic, and we're just at the first step of trying to understand whether, as monotherapy, we can see the efficacy of the PAC1 pathway in the first place.

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

Okay. Ian, well, thanks. Let me just say a couple of quick remarks. Obviously, we're encouraged by the strong start we've enjoyed to the first half of 2018 and hope our investors share our optimism for the long-term prospects of the business through the growth that we expect from our new and recently-launched products as well as our biosimilars and innovative pipeline.

And, finally, I would be remiss if I didn't just take a moment to thank our staff for their continuing focus on our mission, which is to serve patients with innovative medicines that make the big difference for serious disease. So thank you to all our staff for their focus, the results of which you see in our report through the first six months. Look forward to talking to all of you in October. Thank you.

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

Thanks, all, for your participation. If we didn't get to your question, feel free to call us. The IR team will be standing by for several hours. Thanks again.

Operator

Ladies and gentlemen, we thank you for joining us for Amgen's second quarter 2018 financial results conference call. You may now disconnect.

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