Q2 2017 Earnings Call

Company Participants

- Anthony C. Hooper, Executive Vice President, Global Commercial Operations
- Arvind 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

- Aaron Gal, Senior Analyst
- Alethia Young, Analyst
- Andrew Peters, Analyst
- Carter Gould, Analyst
- Cory W. Kasimov, Analyst
- Eric Schmidt, Analyst
- Geoff Meacham, Analyst
- Geoffrey C. Porges, Analyst
- Jim Birchenough, Analyst
- M. Ian Somaiya, Analyst
- Matthew K. Harrison, Analyst
- Michael J. Yee, Analyst
- Robyn Karnauskas, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Ying Huang, Analyst

MANAGEMENT DISCUSSION SECTION

Operator

My name is Skinner and I'll be your conference facilitator today for Amgen's Second Quarter 2017 Financial Results Conference Call. I would now like to introduce Arvind Sood, Vice President of Investor Relations. Mr. Sood, you may now begin.

Arvind Sood {BIO 4246286 <GO>}

Thank you, Skinner. Good afternoon everybody. Thanks for taking the time to participate in our conference call today to review our results for the second quarter. So before we begin, I would like to acknowledge those who are new in their coverage or have changed jobs recently, including Michael Yee, who is now at Jefferies; Andrew Peters at Deutsche Bank; and Matt Phipps at William Blair. Each of us look forward to look working with you.

Okay. So let's go ahead and get started with the business at hand. Consistent with the theme that we discussed at the beginning of the year, we delivered a quarter with strong volume growth, volume driven growth of our newer products, which of course will be key for a long-term growth strategy.

So leading our call today is our Chairman and CEO, Bob Bradway, who will provide a brief strategic update followed by our CFO, David Meline, who will review our financial results for the second quarter and our outlook for the remainder of 2017. Our head of Global Commercial Operations, Tony Hooper, will then discuss our product performance during the quarter, followed by our head of R&D, Sean Harper, who will provide a pipeline update. We will be using slides for our presentation today, which have been posted on our website and a link was sent to you separately by email.

We plan on using non-GAAP financial measures in today's presentation to provide information which may be useful in 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 today are forward-looking statements and our 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.

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Arvind, and let me thank all of you for joining our call. Halfway through the year, we remain on track to achieve our objectives for 2017 as well as our longer-term objectives. Our second quarter financial performance was enabled by strong volume-driven growth for our newer products including Prolia, KYPROLIS and Repatha, as well as our other more recently launched drugs. This is encouraging as we continue to believe that such volume-driven growth is a key ingredient for long-term success in this industry.

Our transformation efforts are enabling us to make significant investments in our pipeline and new product launches while still delivering near-term operating leverage. And you see that reflected in our 9% operating income growth and our 15% earnings per share growth this quarter. Our margin trends also reflect the success of our ongoing transformation.

We continue to generate strong cash flows, enabling us to return significant cash to shareholders including almost $2 billion in the second quarter alone in share repurchases and dividends. Strong cash flows, combined with a strong balance sheet, give us the strategic flexibility we want to invest in external innovation. We're continually looking at opportunities in our chosen therapeutic categories, yet we remain disciplined in our approach to looking for investments that will enable our shareholders to prosper.

Turning to our product highlights, I want to start with our cardiovascular business and Repatha, which we expect to be a significant contributor to our long-term volume-driven growth. Our focus right now is on improving Repatha patient access in the U.S. and around the world, and with our outcomes data in hand, we're making progress. I was pleased to see the swift updates to cholesterol treatment guidelines and recommendations from four leading professional societies interested in atherosclerosis and expect more to come. This change in professional opinion is an important precursor for growth in the market.

Additionally, our recent discussions with U.S. payers about Repatha and the need to improve the utilization management process have been constructive, again reflecting the strength of our data. Finally, we submitted our outcomes data to regulators this quarter and look forward to being able to incorporate them into our label following regulatory review.

Within oncology, I want to highlight a few recent notable milestones. First in multiple myeloma, we completed two pivotal studies showing an overall survival benefit for KYPROLIS patients with relapsed disease, underscoring our confidence in this molecule as the new standard of care for these patients. And similarly, in relapsed and refractory acute lymphoblastic leukemia, BLINCYTO demonstrated an overall survival benefit versus standard of care chemotherapy. I would remind you that BLINCYTO is the first and only bispecific T-cell engager to have done that. Overall survival is the gold standard when it comes to oncology drug development and we were encouraged to be able to show that patients live longer when treated with KYPROLIS and BLINCYTO.

In neuroscience, we're getting closer to being able to make a meaningful impact in the lives of migraine patients. We submitted erenumab for which we have the brand name Aimovig to U.S. regulators in the second quarter. We have the lead position in this exciting new class of medicines, combining our commercial strengths in specialty biologics, with Novartis' established infrastructure in neuroscience, we think positions us to win in this segment.

Our biosimilars programs continue to advance nicely and the quality of our work here was on display once again in the recent FDA panel review of our biosimilar to Avastin.

The outlook for the company remains strong. With growth from newer products and effective lifecycle management of our legacy products, we're confident in our position and looking forward to the second half of the year.

Let me now turn to David to review the financial performance of the business.

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. We were very pleased with our consistent revenue and earnings growth in the second quarter as our transformation efforts continue to enable investment in our core business, while also delivering operating leverage in a period of portfolio transition and in a competitive environment.

Turning to the financial results on page 6 of the slide deck, worldwide revenues at $5.8 billion in the second quarter grew 2% year-over-year. This quarter we also saw product sales at $5.6 billion, growing 2% on a year-over-year as well, as strong unit growth demand for our newer products outweighed declines in the 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 $236 million grew 10% versus the second quarter of 2016, driven by higher IBRANCE royalty revenue offset partially by decreased Nexavar royalty revenue.

Changes in foreign exchange had a 1% negative impact to total revenue and product sales in the quarter on a year-over-year basis. Non-GAAP operating income at $3.1 billion grew 9% from the prior year. Non-GAAP operating margin improved 3.8 points to 55.2% for the quarter, reflecting positive revenue performance, continued favorable expense impacts from our transformation initiatives across all operating expense categories and the expiry of the Enbrel residual royalty payment in Q4 of 2016.

On a full-year basis, we expect another year of strong operating margins driven by tight operational expense management. We expect to see our typical trend of higher operating expenses during the second half of the year.

On a non-GAAP basis, cost of sales as a percent of product sales improved by 0.8 points to 12.7% driven by reduced royalties. Research and development expenses at $851 million were down 3% year-over-year, driven by lower spending required to support certain later stage clinical programs and continued benefits from our transformation initiatives and process improvement efforts. R&D as a percent of sales was 15.3% in the second quarter. We expect research and development as a percent of product sales to approach 2016 levels in the second half of the year.

SG&A expenses decreased 7% on a year-over-year basis due to the expiry of the Enbrel residual royalty payment, partially offset by increased investments in product launches. In aggregate, non-GAAP operating expenses decreased 5% year-over-year and remain on track to meet or exceed our 2018 commitment of $1.5 billion in transformation savings, while investing to build the business globally, support new product launches and investing in the long-term pipeline for the business.

Other income and expenses were a net $156 million expense in Q2. This is favorable by $20 million on a year-over-year basis, primarily driven by higher cash balances. The non-GAAP tax rate was 17.4% for the quarter, a 1.2 point decrease versus the second quarter of

2016. This decrease reflects discrete benefits associated with the settlement of certain state and federal tax matters and favorable changes in the geographic mix of earnings, offset partially by a prior-year benefit associated with tax incentives. Non-GAAP net income increased 12% and non-GAAP earnings per share increased 15% year-over-year for the second quarter to $3.27 per share.

Turning next to cash flow and the balance sheet on page 7, free cash flow was $2.1 billion for the quarter compared to free cash flow of $2.5 billion in the second quarter of 2016, driven by timing impacts of income tax payments to the IRS. We continue to provide significant cash returns to shareholders, consistent with our commitments as we deployed $1 billion to repurchase 6.2 million shares at an average of $162 per share and are on track to achieve total share repurchase for this year in the range of $2.5 billion to $3.5 billion as previously communicated.

Additionally, our second quarter dividend of $1.15 per share is an increase of 15% over last year. This reflects our balanced approach to capital allocation, with significant investment in innovation in support of long-term growth of the business, as well as return of cash to shareholders.

We continue to maintain financial and strategic flexibility as a result of our strengthening balance sheet position. Cash and investments total $39.2 billion, an increase of $4.2 billion from the second quarter of last year. This increase reflects continued solid net cash flow generation. Our debt balance stands at $35.1 billion as of June 30, carrying a weighted average interest rate of 3.7% and an average maturity of 13 years.

Turning to the outlook for the business for 2017 on page 8. Overall, our revised 2017 revenue guidance is $22.5 billion to $23 billion. Our first 2017 volume and price performance was in line with our plans, as we experienced a solid contribution from our newer products while managing the impact of competition against the balance of the portfolio.

This range also reflects the potential impact during the remainder of 2017 from the outcome of Repatha litigation and potential for improved access for appropriate patients as a result of the positive Repatha outcomes data and professional society guidelines and recommendation updates. Our guidance assumes no new U.S. biosimilar competition in 2017.

With regard to our non-GAAP earnings per share guidance, we are raising and narrowing the outlook to $12.15 to $12.65 per share, reflecting our overall solid first half 2017 performance and continued operational expense management. Further, we are confirming our non-GAAP tax guidance at 18.5% to 19.5%. We continue to expect capital expenditures of approximately $700 million this year.

Finally, consistent with our 2017 outlook, we remain confident that we will meet or exceed the commitments we provided for the 2014 to 2018 period including double digit non-GAAP EPS growth, non-GAAP operating margin improvement from 38% to 52% to 54%,

$1.5 billion of transformation savings and return to shareholders of at least 60% of non-GAAP net income on average during the period.

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

Anthony C. Hooper {BIO 6284080 <GO>}

Thank you, David, and you'll find the sales details starting on slide number 10. We delivered a strong solid quarter with sales increasing 2% year-over-year. Prolia and our more recently launched brands including Repatha and KYPROLIS continue to deliver strong volume growth. We are focused on their near-term growth and realizing their long-term potential as the product portfolio continues to transom.

For the quarter, sales in the U.S. increased 2% year-over-year while sales outside the U.S. increased 8% excluding the impact of foreign exchange or 3% including. Internationally we had double-digit volume growth led by our European business.

Let me begin first with Prolia. Prolia sales increased 15% with an 18% volume growth year-over-year, with share gains in both the U.S. and our international markets. Prolia continues to offer a unique opportunity to both post-menopausal osteoporosis patients as well as Amgen. There are currently about 3.5 million patients on Prolia globally relatively equally distributed across the regions, about 1 million in the U.S., about 1.6 million in Europe and the rest of the world about 1 million.

Elderly patients who suffer bone fractures often become bedridden and face potential loss of their independence. This places an enormous economic burden on society and less than half the diagnosed patients are treated, raising the need for improved education and treatment guidelines. This is what we as a company are focusing on next.

Prolia's average share of treated patients is around 20%, both in the U.S. and globally. However, there are some countries such as Australia, Switzerland and Ireland, where better diagnosis and treatment rates for osteoporosis have led to Prolia having 50% share or better. These are countries that truly understand the societal cost of non-intervention. Prolia has a strong clinical profile with a proven ability to reduce risk of fractures. Combined with solid long-term safety data spanning over 10 years and a convenient twice per year administration schedule, Prolia will remain an important growth driver and we will continue to target our commercial efforts on improving diagnosis, treatment rates and duration in order to drive access to a greater number of these patients.

KYPROLIS grew 23% year-over-year, led by our successful launch efforts across existing and new markets outside the United States. Uptake continues to be robust across the launch markets with a 20% sequential volume growth. As Bob mentioned, KYPROLIS has developed two sets of exciting overall survival data in relapsed multiple myeloma patients this year. Earlier in the year in the head-to-head ENDEAVOR study against VELCADE, we demonstrated that the KRYPOLIS arm reduced the risk of death by 21% and improved overall survival by about eight months compared to the VELCADE arm. Just recently, the ASPIRE study demonstrated that adding KYPROLIS to REVLIMID and dexamethasone also

reduced the risk of death by 21% and improves survival by about eight months. It is clear. Multiple myeloma patients live longer when treated with KYPROLIS.

With these two new sets of overall survival data, our message to physicians is simple and powerful. When multiple myeloma relapses, don't put your patient's survival at risk. KYPROLIS-based regimens KRd and Kd reduce the risk of death by 21% versus Rd and Vd and extended overall survival by 7.9 and 7.6 months respectively. This data will also help community oncologists better understand the risk/benefit ratio of profile of KYPROLIS versus other options.

XGEVA grew 4% year-over-year, mostly due to volume. We look forward to having the positive multiple myeloma study data added to our label in 2018, which will expand the eligible patient population and provide a new growth opportunity for XGEVA.

For Nplate and Vectibix, we continue to see strong volume growth in both brands. Vectibix has now over 50% share of the U.S. EGFR segment. Our recent label update, which includes expanded RAS testing, demonstrates Amgen's ongoing commitment to using cutting edge science and technology to target treatments to patients most likely to benefit.

Turning now to Neulasta. We continue to drive adoption of Neulasta Onpro, exiting the second quarter with about 55% share of Neulasta sales. The treatment and convenience benefits to patients and providers is clear, as penetration continues to improve in patients undergoing myelosuppressive chemotherapy regimens.

I'd point out, however, as we look at the cancer therapy in total, PD1s and other new novel therapies are causing a low single digit decline in the usage of myelosuppressive agents. We've also seen a small share loss internationally and we believe these factors contributed to the year-over-year decline of about 5%. The quarter-over-quarter decline of 10% was primarily due to heavier purchasing by certain end customers and favorable accounting adjustments in the first quarter. We expect the trend in myelosuppressive regimens to continue for the remainder of the year.

I'd point out, however, that in spite of decreased use of myelosuppressive regimens, there has been an increase in the number of hospital admissions for febrile neutropenia and we continue to focus on improving penetration for the benefit of patients and for the reduction of unnecessary hospitalization costs. Looking forward, I'd remind you that the fourth quarter of 2016 also included a single $38 million purchase from the U.S. government.

NEUPOGEN declined 30% year-over-year. The impact of short-acting biosimilar competition on NEUPOGEN in the U.S. was in line with prior trends. We exited the second quarter holding 44% share for the short-acting segment and importantly have maintained pricing discipline over the three-plus years since NEUPOGEN first faced competition in the U.S. We expect the competitive dynamic to continue through the rest of 2017.

Enbrel sales declined 1% year-over-year but increased 24% on a quarter-over-quarter basis. In the first quarter, you'll recall that market volume growth rates in both rheumatology and dermatology segments had contracted from recent levels. As we expected, in the second quarter, market volume growth improved in both segments. We expect year-over-year segment growth trends to approximate these recent levels for the balance of the year. Sequentially, our unit share was relatively stable in both rheumatology and dermatology, declining less than 1 percentage point to 31% in rheumatology and 15% in dermatology.

Changes in net selling price had a positive impact on Enbrel's sequential growth. Recall that quarter one was negatively impacted by increased commercial co-pay assistance. As calculated on a full year basis, we continue to expect year-over-year impact of changes in net selling price to be negligible. We estimate that we exited the second quarter with a balance of about $140 million of excess end-user inventory. We expect a portion of this excess inventory to deplete through the remaining of the year.

In summary, we saw improvement in the underlying segment performance this quarter versus the prior quarter and our share trajectory continues as previously projected. Enbrel has a strong track record of safety and efficacy in treating patients with rheumatoid arthritis and psoriasis. We continue to believe the long-term dynamics are intact and continue to invest in Enbrel to remain competitive in these growing segments.

Aranesp grew 6% year-over-year, primarily from volume growth, which includes a benefit from some timing of tenders in certain markets outside the U.S. versus the prior year. With EPOGEN, we've been executing our lifecycle management strategy by successfully transitioning much of the dialysis business to Aranesp and extending our supply contract with DaVita through 2022. The transition to Aranesp is largely complete and the second quarter year-over-year decline in EPOGEN is primarily due to lower net prices as a result of the DaVita agreement. We believe that for now our EPOGEN volumes have stabilized.

Sensipar year-over-year growth of 10% was mainly due to net selling price and to a lesser extent unit growth. We continue to await CMS guidance on the reimbursement mechanism for Parsabiv. Parsabiv launch is underway in Europe with seven markets so far and three more expected by year-end.

In conclusion, let me turn to Repatha. We continue to extend our market leadership across the U.S. and Europe. We now hold 58% share of the PCSK9 segment in both markets, with sequential growth points of 4% in the U.S. and 2 points in Europe. More importantly in the U.S., new-to-brand patient share averaged 70% in the second quarter. Since March, and the presentation of the positive Repatha outcomes data, we have been engaging with payers to improve their utilization of management criteria and processes to improve access for appropriate patients. Payers and PBMs acknowledge the benefit to patients demonstrated by the outcomes data and are evaluating changes to their processes.

We continue to believe that Repatha will grow steadily as guidelines and clinical pathways are revised and the outcome data are in our label. We look forward to the publication of the final update of the ACC Expert Consensus Decision Pathway, an important reference

for physicians. Cardiovascular disease continues to be the number one cause of death and disability in the world. Repatha has the potential to help millions of patients around the world dealing with this grievous illness.

Let me close by thanking all the Amgen staff who worked so hard and tirelessly to get important products to patients around the world.

I'll now provide you (26:00) to Dr. Sean Harper. Sean?

Sean E. Harper {BIO 16272195 <GO>}

Thanks, Tony, and good afternoon. I'll begin my comments today with an update on our cardiovascular efforts. In Q2 we submitted our Repatha outcomes data to global regulators and we look forward to working with them to include this important update to the prescribing information. I have also been very encouraged to see multiple professional societies updating their expert consensus documents and guidelines on the use of PCSK9 inhibitors including the U.S. National Lipid Association, the American Association of Clinical Endocrinologists and the European Society of Cardiology and European Atherosclerosis Society, clearly reflecting the importance of our Repatha outcomes data.

In addition, a draft version of the 2017 update of the ACC Expert Consensus Decision Pathway on non-statin therapies for LDL cholesterol lowering has recently been made available for public comment. These decision pathways are intended, among other things, to provide guidance to clinicians in areas where clinical evidence is new and evolving. While the document is still in draft form, we find the concepts within to well reflect the excellent safety profile and efficacy of Repatha and to suggest evidence-based utilization in appropriate patient populations. We expect the final publication of this document in Q3 of this year.

Beyond Repatha, we've advanced our ASGR1 inhibitor into the clinic in the form of an antibody. As it is just over a year since we first published the strong genetic association of ASGR1 variance with cardiovascular disease in The New England Journal of Medicine, a rapid movement into the clinic demonstrates the speed at which we're able to move programs forward when we have human validation of the sort that deCODE Genetics can provide to ultimately improve R&D productivity.

We also have additional modalities directed against this target under pre-clinical investigation. Our omecamtiv mecarbil Phase 3 outcome study in heart failure continues to enroll briskly, demonstrating the interest in an innovative new add-on therapy in an area in which significant unmet need still exists. And finally, we're looking forward to the presentation of the anacetrapib REVEAL study by Merck to help to inform our plans for our own CETP inhibitor, AMG 899.

Turning to oncology, we recently received our second positive overall survival result with KYPROLIS, this time from the ASPIRE study. We clearly demonstrated KYPROLIS' superiority to VELCADE with improved overall survival in the ENDEAVOR study of

KYPROLIS plus dexamethasone versus VELCADE plus dexamethasone and now we've demonstrated positive survival benefit from KYPROLIS plus REVLIMID plus dexamethasone versus REVLIMID plus dexamethasone in the ASPIRE study. In each case, KYPROLIS reduced the risk of death by 21% and improved survival by approximately eight months, a very meaningful clinical result that reinforces the role for KYPROLIS in driving deep and durable responses. We have already submitted the ENDEAVOR overall survival data to regulators for inclusion in the labels and we are preparing the ASPIRE data for submission as well. And lastly on KYPROLIS, our Phase 3 study in combination with DARZALEX in relapsed or refractory multiple myeloma began enrolling patients in the second quarter.

At ASCO, we had the opportunity to present Phase 2 data from our combination study of IMLYGIC and YERVOY in metastatic melanoma, where we saw an approximate doubling of the response rate compared to YERVOY alone with no unexpected toxicities. This was an important proof of concept for combining the complementary mechanisms of an oncolytic viral immunotherapy and a checkpoint inhibitor to enhance antitumor effects. There is significant interest in exploring IMLYGIC with other checkpoint inhibitors in a variety of tumor types.

In regulatory news, we received a February 2018 PDUFA date for our XGEVA submission for the prevention of skeletal-related events in multiple myeloma patients. We also received full approval for BLINCYTO in the U.S. The approval expands the indication of BLINCYTO for the treatment of relapsed or refractory ALL in adults and now children and included overall survival data and an indication for Philadelphia chromosome-positive forms of the disease. Also within our BiTE platform, we are advancing AMG 673, our half-life extended anti-CD33 BiTE into the clinic with first in human testing in AML patients to begin soon.

And lastly, we received a label update for Vectibix to more precisely molecularly define a population with wild-type RAS for treatment in colorectal cancer.

In our bone health therapeutic area, as expected, we have received a complete response letter for EVENITY from the FDA and will be responding with data from the ARCH study and the BRIDGE study in men with osteoporosis. Along with our colleagues at UCB, we're currently in the process of reviewing the detailed ARCH data with experts. This will be a Class II resubmission in the U.S., which carries a six-month review timeline. We believe there are patients for whom the benefit/risk of EVENITY would be favorable and we will work with regulators on a path forward.

In our neuroscience collaboration with Novartis, we've submitted erenumab, now known as Aimovig, to global regulators for the prevention of migraine and have received a PDUFA date of May 17, 2018. We recently presented data from our Aimovig program at U.S. and EU medical conferences, and the feedback on the efficacy and safety profile continues to be very positive.

In our beta secretase program for Alzheimer's disease, we're expanding the development of CNP520 to individuals who carry one copy of the ApoE4 allele and also have evidence

of brain amyloid accumulation. This will be assessed in an approximately 2,000 subject trial that will be starting soon, and combined with the ongoing Phase 3 study evaluating CNP520 and ApoE4 homozygotes, will constitute a robust data set in an at-risk population. Given how early beta amyloid starts to accumulate in the course of the disease, we feel that a therapy like a BACE1 inhibitor should be administered as early as is feasible. This, combined with the strong genetic validation for specifically targeting BACE via deCODE's work, gives us great confidence in our approach.

And finally, in our biosimilars program, we received a unanimous vote from an FDA advisory committee in favor of approval of ABP 215, our biosimilar Avastin, which has a user fee action date in September of this year.

As always, I want to thank our staff for continuing to deliver on these important milestones for the benefit of patients. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Sean. And Skinner, let's open the line up for questions, and please remind our callers about the process for asking this afternoon.

Q&A

Operator

Absolutely. Our first question comes from Matthew Harrison from Morgan Stanley.

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

Great. Thanks, everybody, and good afternoon. If I could just ask a clarifying question here on Enbrel, that would be helpful. So I believe you said in the fourth quarter you had a $150 million inventory build and then, I can't remember, I think you either said you had a $20 million or $30 million burn-off in the first quarter. Now you've said you're back at $140 million. So can you just review for us the sequential pattern here? And did you have an inventory build quarter over quarter? And I guess should we expect all of this $140 million to burn off in the second half of the year or how do you expect that to play out? Thanks very much.

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

Sure. Thanks, Matthew. Ask Tony to respond.

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

Matt, it's Tony. So let me get back to discussing the inventory. So inventory, as we said, we report at a point in time. So it's either on March 31 or it is June 30. So it's an endpoint. What we have in hand is we know exactly what the revenue numbers are in terms of ex-factory sales. We also understand what our in-market demand is based on the IMS retail prescriptions, which are about 90% accurate and 10% predicted. We also understand

exactly what is held by the wholesalers because of our contracts with them and the triangulation between how much has been sold from wholesalers to end users minus the demand leaves us with a number which we then extrapolate as being the end-user inventory.

So clearly what happens is, at the beginning of the quarter, there's a drawdown of that inventory, which we did see in April-May this year, and then there appeared to be a build towards the end of June. So what I'm saying is we ended the quarter with an excess of about $140 million of inventory, which I would expect to burn off the majority of that during the rest of the year.

A - Arvind Sood {BIO 4246286 <GO>}

Skinner, let's take the next question.

Operator

Our next question comes from Eric Schmidt from Cowen & Company.

Q - Eric Schmidt {BIO 1505721 <GO>}

Thanks for the question, and congrats on a solid quarter. Maybe for Sean on these ACC Decision Pathway document that's going to be coming out here shortly. Can you just talk about what the impact of the decision pathway is relative to, I don't know, the actual treatment guidelines, which I think the ACC expects to put out in 2018? And also, if you think there's going to be an immediate or relatively near-term impact for the decision pathways document, what payers have to maybe do to comply? Thanks.

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

Yes. It's a great question. I mean I think that, in my experience with these documents, the guideline process is one which is quite complex, involves a systematic review of the world's literature by a very large group of international experts and has to kind of occur on a cadence of every two to three years. And also, the result is, if you've ever looked at one of these guidelines, it's a long complex technical document designed for people who are really expert in the field. Because of that cadence, and because of the need to produce something that is more usable to the practicing clinician, these pathway documents emerged, and they are important reference documents for physicians to think about how to deal with patients who come in and present themselves.

And this is the first time, to my knowledge, that one of these pathway documents has been updated outside of its normal schedule and that's because the pathway documents, in part, are designed to deal with just this situation where new important clinical information, particularly the quality of information that's come from both our outcomes trial as well as the Pfizer outcomes trial with PCSK9 have come on the scene and publications have become available. So it's an important step. This is a document that is used quite a bit in clinical decision making, and generally speaking but not always, these kind of changes that you see in these documents then roll in and become incorporated in

the formal guidelines which will come out, as you say, probably 2018, late 2018 is our best knowledge.

In terms of immediate impact, I'd say it's a little bit hard to judge. I think there's an accumulating weight of evidence that the professional societies around the world, including very important ones in the U.S. like the Lipid Society and the endocrine societies and now ACC are beginning to converge in their opinions around the importance of LDL lowering and the impact that one sees, both the safety profile as well as the efficacy of using Repatha in particular. And so I do expect that payers will responsibly look at these guidelines and recommendations and begin to try to make it possible for the doctors who practice in their plans to practice in a way that's consistent with these professional recommendations.

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

And Eric, why don't we ask Tony to share a few thoughts as well on the payer perspective in your question.

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

So I mean, it's clear to us, Eric, that in our discussion with the payers, they do pay very careful attention to position papers and the guidelines coming from these bodies. And the National Lipid Association is a subdivision of the AHA. So it's clear that they're making those decisions on that regard. The ACC, of course, has always been the grand-daddy of guidelines and people will pay definitive attention and look at how they will be actually servicing patients aligned with these position papers or pathways that the ACC are put into place. So we're working extensively with them at the moment. As Sean says, as the weight of evidence continues to build around the importance of delivering Repatha to patients who do have this particular disease.

Operator

Our next question comes from Ying Huang from Bank of America Merrill Lynch.

Q - Ying Huang {BIO 16664520 <GO>}

Hi. Good afternoon. Thanks for taking my questions. My first one has to do with the balance sheet. You have a $39 billion cash on balance sheet. If you guys don't have any plans to consummate M&A transactions or repay the debt, many investors are just wondering whether you have any plans to repurchase a significant portion of the float for the shares. And then maybe for Sean, when might you know whether FDA would require a cardiovascular safety study for romosozumab? And if so, would you continue the development or not for romosozumab? Thank you.

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

Okay. Ying, why don't I take the first question, invite David to add any color if he'd like and then, Sean, you can briefly answer the romo question. On, with respect to the balance sheet, I think again you're aware that our business is generating significant cash flows. We have a track record of wanting to use that cash flow to pay dividends to our shareholders,

a rapidly growing dividend as well as to buy back stock and to invest in the business. So we're optimistic about the outlook for the business. As I say, continue to generate strong cash flow. We have a strong balance sheet and we'll look at ways of deploying that capital as appropriate through time. And, David, maybe you'd like to update where we are with respect to the capital commitments that we've made to our shareholders.

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

Yes. So I would just add to that two things. One is that we continue with the plan as I said to return 60% of net income through 2018 to shareholders and I think that is certainly something we'll execute on going forward. And I think the second point, as many know, the vast majority of the cash that we're holding does sit offshore and we don't see right now that it would be appropriate to repatriate it under the current U.S. tax system. So obviously as and when they make progress on tax reform and make it more reasonable to consider repatriation, would we then take a look and start providing some commentary on how we might deploy that.

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

Yeah, and with respect to romosozumab, I think it's just too early in the process to comment meaningfully on whether additional studies would be appropriate and whether they would be a good investment for our shareholders and UCB's shareholders. We have to go through a process that's going to take some time to discuss these results formally with regulators.

Operator

Our next question comes from Terence Flynn from Goldman Sachs.

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. Maybe a two-part for me. Just wondering following the romo safety signal, if your BD priorities have changed at all either with respect to size, stage or disease areas of interest. And then on the guidance, just wondering if you can talk about the changes on the revenue side, particularly lowering at the top end, what the driver or drivers of that was. Thanks.

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

We'll do this in two parts as well then. With respect to romo and the impact on our BD thinking, I don't think it has any direct impact, Terence, on how we're looking at the opportunities of business development. David, do you want to talk a little bit more about guidance?

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

Sure. In terms of guidance, if you might recall when we entered the year, we provided revenue guidance that was broader than traditionally we would have, because of in particular the uncertainties around the evolution of the sales of Repatha, which related to this question of the outcomes trial being published as well as the ongoing litigation that's

taking place. And so now as we sit at midyear and look at the trajectory of the business, the good news for us is the revenue is evolving as we'd set out for the company through the year and indeed the earnings performance is quite good and we've raised again our EPS for the year.

So really, what we're doing now is we're narrowing the guidance to reflect the fact that as we look to the balance of the year, we don't have the most positive upside that might have occurred if there had been an early decision on the litigation. We're awaiting the outcome of that and then we're also reflecting the trajectory which we're encouraged by the uptake of Repatha which we think will continue to accelerate. And so the guidance simply reflects the best estimate we have right now.

Operator

Our next question comes from the line of Michael Yee from Jefferies.

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

Thanks so much for the question. My question is in relation to your longer-term guidance and your margin guidance for 52% to 54%. You're at the higher end of that and next year you're not necessarily going to face so much biosimilar competition. So can you talk about where and when you could think about reassessing that? And importantly, if you think that these margins can be sustained or managed even in the face of potential future biosimilar risk? Thanks so much.

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

Sure. Yeah, so I would say first of all on – you're correct on our margin performance. We've been pleased with how it's evolved for the company given that we set that goal out at a time we were delivering 38% operating margin. So it was quite a big task for the company, but you've seen it evolve very nicely. And I think importantly for us during that time, we've also stood up a very significant cardiovascular franchise. We're in the process today of investing in preparation of our first launch in the neurology sector. We've been building out and are on track with our portfolio of biosimilars and we've added several hundred million dollars a year of structural cost to a international network as we built out globally. So not only are we seeing margin improvement, but also we'd been building a base for the company which is going to be very important for our sustainability going forward.

In terms of as and when we would then look forward and what do we think about margins for the company, I would say we're approaching now the end of the period that we gave guidance through 2018. So obviously, within this next year, year-and-a-half, we'll have a look and start providing some additional views of the future for the company. But at least as we sit here today, we feel very good about not only the performance of the company and the prospects but also the sustainability of that profitability.

Operator

Our next question comes from Geoffrey Porges from Leerink Partners LLC.

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

Thank you very much, and congratulations everybody on a solid quarter. I just wanted to have a little discussion on Aimovig or hear your thoughts on it. You've said that you're likely to be first, and I know you can't really comment on pricing, but certainly the PCSK9 experience was sobering for all of us in terms of the payer response. And I'm just wondering how your discussions with payers are going. What sort of step edits you would expect for people to get access to Aimovig and should we be expecting pricing that's more at the Prolia end of the spectrum or more at the Repatha end of the spectrum? Thanks.

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

So, Geoff, it's Tony. I mean, one, we've never given pricing guidance prior to a launch. Aimovig is going into a patient population that are uniquely different from a symptomatic perspective, right. So we estimate about 3.4 million patients presently on prophylactic treatment for migraine, both episodic and chronic, which is a crippling disease resulting in mothers not being able to be mothers, or employees not being able to do their work. And our discussions have been with payers from a clinical perspective at this particular stage as we move things forward. And there's a huge unmet need, and we're busy developing our pharmaco-economic value-based pricing models for this particular disease. It's going to be a competitive market. That we understand. But our pricing will be made as we get closer to the launch time.

Operator

Our next question comes from Ian Somaiya from BMO Capital Markets.

Q - M. Ian Somaiya

Thanks for taking my questions, and congratulations on the solid quarter. I was just trying to better understand the drivers of Repatha until we get to the publication of the ACC treatment guidelines at the end of next year. Specifically, just two different, two sub groups that the payers and physicians have a lot of interest in, seeing results for diabetic, smokers. And then just separately at the time of the ACC presentation, the follow-up was roughly 2.2 years. Was wondering when we could see follow-up or data following up patients for greater than three years.

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

Okay. Why don't we do this in two parts. Tony, why don't you talk a little bit about what we expect to see between now and when we have the outcomes data in the label, what the drivers are. And then, Sean, you can address the follow-up question.

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

So when we look at the actual usage in the marketplace, right, there are sort of three patient segments that are pathing to us that are clearly indicated inside the label, and aware physicians are starting to understand they're important to treat, right. These are patients who have ASCVD, who've had two events in the last 24 months, clearly high-risk patients or what we call higher high-risk patients. They are those who have ACS who have

had an event in the last year or so with ASCVD. And then there's the FH population. And that's a fairly large population, and we've seen the majority of our patients coming from that group at the moment. If you look at the NRx data, which is really looking at the new-to-brand prescriptions in terms of new patient capture, you are seeing that we are gaining market share there and gaining traction consistency in terms of getting patients.

When you look inside the data and you see that our abandonment rate by commercial patients has gone down to about 24%, it is clear that we are assisting patients who can't afford their co-pay or their deductible. So we're getting a higher access to patients there. So we see a continued usage and expansion by existing physicians. We are capturing about between 300 and 400 new prescribers per month, so the prescriber base is growing as we go forward. The new guidelines are starting to take a little bit of traction. Physicians understand. We look forward to the ACC presentations. So that's where we see the growth of our business right now.

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

And with respect to the insights into the data on diabetics and smokers, there were a very substantial portion of Type 2 diabetics in FOURIER, and about 30% of the population were smokers. And essentially when you looked at those subgroups in comparison to the whole study, the data were virtually identical. So there we did see, as you might expect, with LDL lowering, as has been seen with statins, that it has the sort of uniform effect across these type of clinical populations.

Obviously, the controlled portion of the FOURIER study is complete, but there is – I think you are referring to long-term extension kind of data that is available. As you might recall, we had over four years of long-term extension data, treatment data, at the time of presentation of FOURIER published at that time in one of the major journals. And we have a long-term extension of approximately 5,000 patients from FOURIER as well who will run out for an additional number of years, perhaps up to 10. We'll figure that out as we go along. But that is designed to be a leading indicator of any safety issues that might not have presented themselves in the window of the FOURIER study, which was, as you point out, just 2.2 years.

Operator

And our next question comes from Geoffrey Meacham from Barclays.

Q - Geoff Meacham {BIO 21252662 <GO>}

Afternoon, guys. Thanks for taking the question. I have one on Repatha for either Sean or Tony. And I guess the question is more in demand trends post-ACC in this year. I'm just trying to get a sense for when payer policy and guidelines become more favorable? If you guys would expect any hurdles at the actual prescriber level at the cardiovascular – at the treating physician level or if patient persistence rates over time have really changed materially? Thanks.

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

So, Geoff, let me take that one as best I can in the moment. So just to remind you, that the outcomes data was presented at the ACC in March. We are not promoting that data at the moment. We are clearly awaiting the FDA decision to include the data in our label, at which stage we will start being able to promote that data into the marketplace itself.

We are working consistently with the payers at the moment in terms of reevaluating and challenging some of the utilization management criteria, challenging some of the onerous processes that are in place and actually working with the professional bodies themselves so they become involved in ensuring they can get access to their patients. We have seen a high level of willingness from the payers and the PBMs to relook at their utilization management criteria to ensure that the processes are reasonable.

The cohorts are probably a bit too small to be able to really understand patient persistency at the moment, so what we are tracking is new patient capture early on, and as you know, you can see that quite easily from the IMS data. And that continues to grow as well as the growth trial as (55:06) we go forward. We do believe that once the FDA ratifies the data and puts it in the label, we'll be in a much better position to see an opening of access through the payers.

Operator

Our next question comes from Cory Kasimov from JPMorgan.

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

Hey. Good afternoon, guys, and thank you for taking my question. I wanted to follow up on erenumab. And on their call this morning, Lilly mentioned that they that haven't seen any competitive CGRP data that they view as better than what they've generated. So I'm wondering if you can talk a little bit about how you see this market and how you maybe plan to potentially differentiate erenumab or Aimovig in the study as you begin to get a better feel for the various profiles of other agents in the class? Or is this something that really just comes down to first to market and potentially price, as you were asked about before? Thanks.

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

Okay. So let me start doing a little bit of an answer there if I can, and perhaps Sean can add around the clinical data. Right, so just to go back, my comment to Geoff earlier on, around the unmet need, the more we dig into this market, the more you realize that not only patients but specialist physicians themselves have been absolutely frustrated for decades because of the inability to actually prescribe a migraine drug for a migraine. They've used substitutes. They've used drugs that have caused huge side effects, and patients are unhappy with them. So as we've talked to patients, patient bloggers, patient groups about their needs, it's clear the unmet need continues to be large.

Every specialist I've spoken to who looked at the Aimovig data has been impressed by the data, has seen a dramatic potential for change in what this will do for patients on their day-to-day lives. We do believe that we will be first to market. We have submitted first. We intend coming to market first. We have a partnership with Novartis who have an existing

strong relationship with the neurologists, a lot of them who treat migraine. And we expect to be using their skills, competencies and relationships to set us up and to move fast and quickly into the marketplace.

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

And my only additional comment would be that because the other agents are not receptor antagonists and are ligand directed, they're less potent, and the amount of antibody required to achieve the clinical effect is considerably higher. This results in things like loading doses or IV administration or multiple large volume sub-Q administrations required at the same time, and none of those are positives for patients. So we know we can get erenumab to a monthly single small-volume well-tolerated auto injection. I don't know that that's possible with these other agents. The data as it appears to me at this point doesn't suggest that.

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

Okay. Skinner, let's move on. We've got I know quite a few questions still lined up to go, and we're pressing up against the top of the hour. But we'll do our best to get to the remaining questions. Let's go ahead.

Operator

Absolutely. Our next question comes from Robyn Karnauskas from Citi.

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Thank you. So given the pushback so far with the payers in the cardiovascular space that you've seen with Repatha, like how are you thinking about the bar for developing your CETP inhibitor? And what threshold do you want to see with the Merck data that will make you feel more positive about the prospect of the class?

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

I think we're focused, Robyn, on that medical need and trying to figure out whether that aid class of agents has a role to play. But Sean, I'll let you talk about the specifics. And obviously we need to believe that we can earn a return on any further investment there for our shareholders. Do you want to talk about the clinical piece?

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

Yes. No, I mean, I think that it's the case that if we were to see as we did with the PCSK9s that have been assessed in outcomes trials, a linear relationship as has occurred with statins between LDL lowering and event-rate risk, and the agents are lowering LDL in the range of 30% to 35%, 40%, that an oral agent that could do that as an add-on to statins would be a meaningful drug to have in the armamentarium.

It's obviously not going to deliver the kind of LDL reductions you can achieve with the PCSK9 antibody, but because the drugs are oral and so on, we feel they play a role. What remains to be seen is whether these agents, based on their LDL lowering capacity, and

the Merck drug will be the first that I think will answer this question more definitively. Whether we see that relationship or whether we're seeing some fractional effect of that relationship, and that the effect on cardiovascular risk is marginal, in which case obviously we'd be much less excited about pursuing this. So I think it much depends on the details of the reveal data.

Operator

Our next question comes from Umer Raffat from Evercore ISI.

Q - Umer Raffat {BIO 16743519 <GO>}

Hi. Thank you so much for taking my question. Just to focus on the PCSK9 a bit. In a scenario where there's no meaningful inflection for Repatha post-guideline updates, would you potentially consider the idea of a pricing reset? And then also, do you think Novartis CANTOS data impacts PCSK9 opportunity at all? Was very curious to have your take on it.

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

Umer, this is Tony. I think a lack of inflection would be a terrible tragedy for those patients who suffer from this disease and who will either be suffering an early untimely heart attack or stroke. The price we came to market with was clearly aligned with an understanding about the rebate that would be required in the marketplace to gain a competitive position. When you look at the data we presented at the ACC in March this year, we clearly talked about the pharmaco-economic value of this product, how PCSK9 within the class, and reconfirmed that our net price to payers is presently very much in the range of a pharmaco-economic price. We continue to believe that this drug brings value. When you look at the second year data, that you're reducing heart attacks by 35%, reducing stroke by 24%, 27%. It's an enormous crack in this disease that takes lives on a untimely basis. So we will continue to drive it forward, and to ensure that the value we bring is distinct and beneficial in the marketplace.

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

And with the IL-1 beta data from the Novartis trial, I think we just have to wait to see the data to understand, but I don't expect that to have a direct impact on lipid-lowering approaches.

A - Arvind Sood {BIO 4246286 <GO>}

Skinner?

Operator

And our next question comes from Salim Syed from Mizuho Securities.

Q - Salim Syed {BIO 16887281 <GO>}

Hey, guys. Thanks for taking my question. I have one on biosimilars. So you guys have 10 now in development I believe and you've seen success with the first three, HUMIRA, Herceptin and Avastin. Can you just remind us what is your situation with manufacturing capacity? Do you have capacity for all of these? Or will you need to expand and what's the path that if you'd have to go outside and use a CMO or would you build it yourself? Thank you.

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

Salim, we're in good shape with respect to our biosimilars. And one of the reasons we committed to this as a growth opportunity for the company was our belief that we do large-scale manufacturing of proteins very well. So we're deploying our process, development and manufacturing skills and we're in good shape for our programs.

Operator

Our next question comes from Alethia Young from Credit Suisse.

Q - Alethia Young {BIO 17451976 <GO>}

Hey, guys. Thanks for taking my question. Just one for Sean. Maybe if you can talk about some of the earlier things in your oncology pipeline, and how you are developing IO and do you think you need some of the more traditional assets like PD-1 or any of the other ones, OX40, that people are going after? Thanks.

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

Yes. I mean I think right now we're very interested in our BiTE platform. We've made a strategic decision to focus primarily in biospecific T cell engaging, not ADCs, and we do have a limited but important effort, of course, in collaboration with Kite on CAR T cells. The BiTE platform is moving along quite significantly and because of the timing, if you think back to when we acquired the technology and how long it takes, we have a big wave of these molecules directed at hematologic and solid tumors moving into the clinic over the next 18 months or so.

We have, of course, the half-life extension technology that we've added to the majority of these at this point. So that is very important. As you point out, there'll be the opportunity to combine them in many cases with checkpoint inhibition. From a R&D perspective, we've had no trouble at all getting partners to do these experiments with us, providing the PD-1 and often sharing the actual cost of the trials with us. So that's not been an issue.

And then the other area we're still very excited about is T-Vec, particularly now as we begin to explore hepatic injection, different tumor types in combination with checkpoint inhibition. It opens up a range of tumor types to explore, including those that don't respond well to checkpoint inhibitors without a immunization strategy.

And then last one I'd mention is our CSF-1 antibody is in combination right now with Merck's PD-1 and we're very excited about that program as well. So in terms of pure immuno-oncology, those would be the ones that I'd highlight.

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

I think the big picture, Alethia, is that we see a lot of excess capacity, as I think it's two dozen, maybe even 25 different PD-1, PD-L1s that are competing now for space in oncology. So we're unlikely to jump in. We're watching the space carefully, but it looks to me like there's a lot of excess capacity right now in that area. Let's go to the next question

Operator

Our next question comes from Ronny Gal from Bernstein.

Q - Aaron Gal {BIO 15022045 <GO>}

Good evening, and thank you for squeezing me in. Just a question on the 340B program. When talking to folks at onco channel (1:05:58), they're talking about expanding their outpatient services out of disproportional share (1:06:02) hospitals. Could you just comment about how big this is for your business? What do you see the trend line? And what do you expect the impact would be of the CMS proposal to reduce the reimbursement rate?

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

Ronny, it's Tony. I don't have those exact numbers with me. We can get back to you, but obviously a lot of our oncology business is in the institution which falls under 340B and we watch that versus carefully. It has grown quite dramatically in the last three, four years or so, but I think it's sort of under 20% of our total business would be 340B.

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

Closer to 10% of the business, Ronny, and the trade associations, as you know, bio and pharma have been very focused on this, and I think it's a program that got launched with noble intentions, but it's one that's subject to some abuse. And so there's, as you know, some oversight focus in this area right now in Capitol Hill, including looking at whether the discounts are being appropriately applied to the patients that are most in need of them, et cetera. So I'd say stay tuned. This is an area that's likely to be evolving here over the coming legislative calendar.

Operator

Our next question comes from Jim Birchenough from Wells Fargo Securities LLC.

Q - Jim Birchenough {BIO 5068439 <GO>}

Yeah, hi guys. Thanks for taking the question. You've mentioned value-based pricing a few times with regards to the CGRP category and Repatha. Could you maybe talk about what you're hearing from payers in terms of how set up they are for that kind of model? And in migraine specifically, could you see some sort of contracts that are based on a certain level of migraine reduction? Thanks.

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

So, Jim, the value-based process is defining the value of a product based on the threshold you set for a quality of life you saved. It's a process used by most health technology assessment companies around the world, such as the UK, Canada and Australia. It's an evolution of a process in the U.S. at the moment and we feel quite robust and confident in our ability to establish that type of range of value for a product. We discuss that with the payers on an ongoing basis.

I think what you might be referring to is a bit of our risk-share contract we've actually put into place. And those are interesting ones too, where we have product deliver a distinctive value and we're prepared to put our money where our mouth is with those particular products. Some payers have taken us up, such as Harvard Pilgrim. Others are trying to work at how do they track that, monitor that as they go forward. But I would imagine going forward, it has to be something that becomes more and more popular.

A - Arvind Sood {BIO 4246286 <GO>}

Yeah, Skinner, let's take two last questions after which Bob will make some concluding comments.

Operator

Yes, sir. Our next-to-last question comes from Andrew Peters from Deutsche Bank.

Q - Andrew Peters {BIO 20622504 <GO>}

Hey, guys. Thanks for squeezing me in. Quick one for me, just wanted to see if you've seen an inflection in the rate of Repatha rejections or approvals since FOURIER. And do you think that's really the biggest driver of kind of the share increases that you've seen against alirocumab or is it something else that you see in the market? Thanks.

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

If you turn to page 23 of your slide deck, that's of course a chart that I look at often, which shows a distinctive movement of our market share since the outcomes data was delivered at the ACC in March. Clearly people understanding the value of this drug in terms of long-term treatment. So we have in the interim also worked hard as I said earlier to try and reduce the impact on patients who have large commercial co-pays or large commercial deductions. And we're working consistently with payers to try and make the utilization management criteria as well as the process to get access to drug more reasonable to ensure appropriate patients get access.

Operator

And our final question comes from Carter Gould from UBS Equities.

Q - Carter Gould {BIO 20035589 <GO>}

Good afternoon, guys. Thanks for fitting me in. For Tony, maybe just taking a different direction, can you help frame for us the magnitude of the incremental commercial

opportunity for moving XGEVA into myeloma? And any nuances we should keep in mind in looking at peak penetration in the U.S. first year? Thank you.

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

You guys can see the size of the multiple myeloma market based on the patient numbers themselves. So there's a distinctive population that exists over there. It's a population that presently isn't in our label and therefore we have not been able to promote on that particular patient group. And we look forward to doing it early in or whenever we get in a label in 2018.

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

February PDUFA date and, Sean, you might just want to remind Andrew and others of the benefits we believe that XGEVA will provide those patients with multiple myeloma.

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

Yes. I mean, as you probably are aware, virtually all myeloma patients, because of the secreted protein that characterizes the disease filters into the kidney, have varying degrees of renal insufficiency and have to have dose reductions or simply can't tolerate drugs like zoledronic acids. So there is an obvious need for a product that doesn't have renal clearance such as denosumab. However, in our original applications with denosumab, we had a subgroup of patients in one of the trials of multiple myeloma where it appeared as though there could be a harm signal on overall survival. It was a subgroup analysis that was unlikely to be real. We've of course demonstrated it wasn't real by doing this large trial that we've filed. And once we have the indication and can promote it and so on, I think the utilization that's been hampered by that concern about impact on the actual disease process will be alleviated and it should be a great advance for patients with multiple myeloma to have more access to denosumab.

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

Okay. Carter, thanks for that question. Thank you all for joining the call. I also want to thank our worldwide staff who are busy successfully executing on our strategy and operating the business right now really effectively while both delivering for patients and shareholders. So I hope you can see from our results that we're positioned for the changing competitive environment with the benefit of a new product cycle set to drive volume growth and a strong balance sheet that we intend to deploy to create value for our shareholders. We see both of these as key to sustaining long-term growth with Amgen.

So thanks very much for joining us. We look forward to talking to you after the third quarter.

A - Arvind Sood {BIO 4246286 <GO>}

Thanks, everybody. We appreciate your participation and look forward to connecting both off line and after hours. Thanks again.

Operator

Ladies and gentlemen, this concludes Amgen's Second Quarter 2017 Financial Results Conference Call. You may now disconnect.