Q3 2017 Earnings Call

Company Participants

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

Other Participants

- Aharon Gal, Analyst
- Alethia Young, Analyst
- Andrew Peters, Analyst
- Carter Gould, Analyst
- Christopher Raymond, Analyst
- Cory W. Kasimov, Analyst
- Eric Schmidt, Analyst
- Geoffrey C. Porges, Analyst
- Geoffrey Meacham, Analyst
- Jim Birchenough, Analyst
- Kennen Mackay, 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 Ian, and I will be your conference facilitator today for Amgen's Third 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 K. Sood {BIO 4246286 <GO>}

Okay. Thanks, Ian. Good afternoon everybody. Thanks for calling in to review and discuss our business performance for the third quarter. Consistent with the tradition that we have now established, I would like to acknowledge those who are new in their coverage or have changed firms recently, including Chris Raymond, who recently joined Piper Jaffray; Laura Chico of Raymond James and Kennen Mackay of RBC. Each of us are very much looking forward to working with you.

Turning to our quarterly performance and keeping with the theme that we articulated at the beginning of the year of growing volumes, our growth products are all benefiting from solid unit volume growth, which is a key component of our long-term growth strategy of effectively transitioning from mature products to the more recently launched products.

To discuss this, together with other topics, our Chairman and CEO Bob Bradway will lead the call today, followed by our CFO David Meline, who will review our financial results for the third quarter and our revised and tightened outlook for the remainder of 2017. Our Head of Global Commercial Operations, Tony Hooper, will review our product performance during the quarter, followed by our Head of R&D, Sean Harper, who will provide a pipeline update.

In addition to posting slides that we plan to use for presentation today on our website, we have also posted an updated statement on progress we're making with our manufacturing facilities in Puerto Rico following the aftermath of Hurricane Maria.

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, and also on the Investor Relations section of our website.

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. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thank you, Arvind. Our operating results through the first nine months of the year highlight that we are effectively managing our business during a period of transition as our recently launched products begin to gain traction around the world. Based on our ability to effectively manage costs, we've been able to raise our earnings outlook for the full year 2017, even while absorbing the costs of Hurricane Maria and continuing to direct investments towards long-term growth.

As I've said before, growing volumes will be key to driving future revenue growth. Our growth brands, including Prolia, Repatha, KYPROLIS and BLINCYTO are all exhibiting solid unit volume growth. I'd like to highlight Prolia in particular. Prolia is a unique asset in the bone health area and has an extremely strong value proposition. As you can see in our results, it continues to generate strong volume growth. Osteoporosis remains an under-diagnosed and under-treated disease with serious consequences and we will continue to educate physicians and patients on the established clinical profile of Prolia and the obvious benefits of preventing fractures.

I remain optimistic that Repatha will become a significant product for Amgen as it also brings a compelling value proposition to patients. Repatha's cardiovascular outcomes data are under priority review by the FDA, as you're aware, and this underscores the significant unmet medical need in cardiovascular disease.

These data have already been incorporated by global professional societies into treatment guidelines and pathways, including the recent update from the American College of Cardiology. As I've said before, cardiovascular disease is the leading cause of death around the world and it's a disease that costs over $600 billion a year in the U.S. alone. Improving patient access to Repatha remains a top priority for our team.

Looking ahead to next year, we expect to begin tackling another significant unmet medical need in migraine. We're pleased to be pioneering the new CGRP class of medicines. We continue to receive positive feedback on Aimovig and patients and physicians are excited by the prospects of a new, safe and effective preventative therapy. And that's exactly what we expect to deliver with Aimovig.

Given our core capabilities in biologics, I think biosimilars will become an important growth driver for us as we continue to make progress in this area. As has become increasingly apparent, achieving biosimilarity is challenging, and our expertise in biologics development and manufacturing is a clear differentiator.

This quarter, we received our second biosimilar approval with MVASI, a biosimilar to Avastin. We've also submitted our biosimilar to Herceptin to regulators for review. And importantly, we gained clarity around the launch timelines for AMGEVITA, our HUMIRA biosimilar, including an opportunity to launch in Europe starting next year.

We expect our biosimilars business to be an attractive source of revenue growth for us and one from which we expect to earn a strong return on investment for our shareholders.

We're taking steps to develop our pipeline to sustain long-term growth. In addition to pursuing Phase 3 trials for omecamtiv mecarbil in heart failure, and of course CNP520 for Alzheimer's disease, we're excited about moving Tezepelumab into Phase 3 for asthma. We have a leading position in the TSLP area and we're excited about the prospects of treating a broader population of asthmatics than other biologics on the market or in development. Sean will address this in more detail shortly.

Let me just say a few words about our manufacturing operations in Puerto Rico following the recent direct hit of Hurricane Maria on the island. Amgen has more than 2,000 staff members in Puerto Rico and I'm delighted to report that all of our staff are accounted for and nearly all of our staff are now back at work. In fact, just five weeks after experiencing what was a 100-year storm, we have substantially resumed operations, serving patients in Puerto Rico and around the world.

While we did experience some damage in Puerto Rico, generally speaking, our facilities weathered the storm well and are in relatively good shape. As we've said before, we expect no impact to product supply for patients around the world, a real tribute to our team on the island and to all those at Amgen who've been working together to help us manage through these challenging circumstances.

We appreciate the FDA's focus on Puerto Rico while the island recovers, and we've also been reaching out to many other pharmaceutical and medical device companies on the island to see if there are things that we can do collectively to help Puerto Rico get back on its feet as quickly as possible. We will continue to provide updates on this situation as appropriate.

Before I turn to David, let me just say that all-in-all, we feel we're in a strong position. We feel that we've positioned the company for the moment that we find ourselves in, as reflected in a balance sheet which is very strong, as reflected in the cash flows that you see in our business and as reflected in our ongoing tight control of expenses.

As we look to the future, we feel we have improved clarity on our opportunities for 2018 and beyond, with the inclusion obviously of Repatha outcomes data in our label, which we think is set to happen in a matter of weeks; the prospect, as I've already mentioned, of launching our first-in-class migraine therapy Aimovig; clarity around prospective launch of Parsabiv in the U.S. for patients with kidney disease; two new opportunities for our denosumab franchise including for glucocorticoid-induced osteoporosis for Prolia and for multiple myeloma for XGEVA.

We're also encouraged to have clarity now around our biosimilar franchise with, as I said a moment ago, a clear path for launching AMGEVITA internationally in 2018. And finally, following on our great success with Onpro for Neulasta, we're excited to be introducing our new AutoTouch injector for Enbrel as well.

With that, let me turn to David.

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. We are pleased with our solid overall results and earnings growth in the third quarter as our transformation efforts continued to enable investment in our core business, while also delivering operating leverage in a period of portfolio transition.

I also want to take a moment to provide an update from a financial perspective on our Hurricane Maria recovery efforts at our Puerto Rican manufacturing facilities. First off, I

want to recognize the staff for their tireless efforts which have ensured our patients a stable supply of Amgen's medicines even in the face of devastating personal loss and disruption across the island.

As Bob mentioned, while we did experience some damage, all things considered, we weathered the storm in relatively good shape. Consistent with our approach to all other aspects of our business, we hold ourselves accountable for managing a disciplined and effective recovery effort.

We incurred $67 million of pre-tax expenses, or $0.07 a share in non-GAAP earnings in the third quarter related to inventory, idle facilities, repairs and support for our Puerto Rican staff. In the fourth quarter, the company expects our manufacturing facility recovery effort to drive pre-tax expenses in the range of $75 million to $100 million or $0.08 to $0.11 a share. At this time, we do not expect the recovery to have a significant impact on our full-year 2018 results. We will provide further detail when we share our 2018 guidance in January. We're working with our insurance providers but these estimates do not yet include insurance recoveries.

Turning to the financial results on page 6 of the slide deck. Worldwide revenues at $5.8 billion in the third quarter are flat year-over-year, excluding the impact of foreign exchange, and are 1% lower on a reported basis including FX. This quarter we saw worldwide product sales at $5.5 billion, also flat year-over-year, excluding the impact of foreign exchange, and 1% lower on a reported basis including FX. Strong unit demand growth for our newer products was offset by declines in our mature brands.

Other revenues at $320 million grew 8% versus the third quarter of 2016, driven by higher IBRANCE royalty revenue. Non-GAAP operating income at $3 billion grew 4% from the prior year. Non-GAAP operating margin improved by 2.7 points to 55.6% for the quarter, reflecting continued favorable expense impacts from our transformation initiatives across all operating expense categories and the expiry of the Enbrel residual royalty payment.

As in prior years, our operating margin is expected to be lower in the fourth quarter of the year, driven by the timing of expenses with the compare this year being especially challenged due to the $75 million to $100 million of incremental charges related to our hurricane recovery efforts. We will also pass the one year mark since the expiry of the Enbrel residual royalty payment at the end of October.

On a non-GAAP basis, cost of sales as a percent of product sales increased by 0.5 points to 13.5%, driven primarily by the impact of Hurricane Maria on our Puerto Rican operations, offset partially by manufacturing efficiencies and reduced royalties. Research and development expenses at $858 million were down 11% year-over-year, driven by several upfront payments for in-licensing transactions in Q3 of 2016, lower spending required to support certain later stage clinical programs, and continued benefits from transformation initiatives and process improvement efforts.

SG&A expenses decreased 6% 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, reflecting additional 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 $58 million expense in Q3. This is favorable by $51 million on a year-over-year basis, primarily driven by higher cash balances and gains from our venture investment portfolio.

The non-GAAP tax rate was 19.4% for the quarter, a 0.5 point increase versus the third quarter of 2016. This increase was primarily due to adjustments to certain federal tax credits and deductions, offset partially by favorable changes in the geographic mix of earnings.

Non-GAAP net income increased 5% and non-GAAP earnings per share increased 8% year-over-year for the third quarter to $3.27 per share.

Turning next to cash flow on the balance sheet on page 7. Free cash flow was $3.3 billion for the quarter compared to free cash flow of $2.5 billion in the third quarter of 2016, driven by improved collections and lower cash expenditures.

We continue to provide significant cash returns to shareholders, consistent with our commitments as we deployed $0.8 billion to repurchase 4.4 million shares at an average of $177 per share and are on track to achieve our total share repurchases for this year in the range of $2.5 billion to $3.5 billion.

Additionally, our third 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 the 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 totaled 41.4 billion, an increase of 3.4 billion from the third quarter of last year. This increase reflects continued solid net cash flow generation. Our debt balance stands at $35.8 billion as of September 30, carrying a weighted average interest rate of 3.7% and leverage maturity of 12 years.

Turning to the outlook for the business for the remainder of 2017 on page 8. Overall, our revised 2017 guidance range for revenue is $22.7 billion to $23 billion versus previous guidance of $22.5 billion to $23 billion. With regard to our non-GAAP earnings per share guidance, we are raising and narrowing the outlook to $12.50 to $12.70 per share. Our improved 2017 guidance reflects our continued conviction in our strategy as well as business performance over the first three quarters of the year.

As a reminder, we expect to see an increase in operating expenses in Q4 versus Q3, reflecting the typical pattern for the business. Also included in this guidance is an

incremental $75 million to $100 million of expenses related to Hurricane Maria recovery in the fourth quarter.

Further, we are revising our non-GAAP tax guidance to 18% to 19% versus prior guidance of 18.5% to 19.5%. We continue to expect capital expenditures of approximately $700 million this year.

In summary, our 2017 performance remains on track as we continue to invest to grow the business while transforming to a more efficient operating model. We will provide 2018 guidance on our January call.

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

Anthony C. Hooper {BIO 6284080 <GO>}

Thank you, David, and good afternoon folks. You'll find the details of revenue starting on slide number 10 of your deck. Strong and continued volume growth by Prolia and our more recently launched brands like Repatha, KYPROLIS and BLINCYTO helped offset declines in our mature brands. Excluding the impact of foreign exchange, sales growth was flat year-over-year as reported sales declined 1%. The U.S. declined 2% year-over-year, and sales outside the U.S. grew 5%, excluding the impact of foreign exchange, driven by a robust 8% volume growth.

Let me start with Prolia. Prolia continues to deliver exceptional performance after being on the market for over seven years. Prolia grew 22% year-over-year with double digit volume growth in all markets, primarily from share gains. Quarter-on-quarter, we saw a slight decline, which follows the typical pattern for Prolia in the first and the third quarters.

Prolia, as Bob said, is a unique asset with a very strong value proposition. There remains a large underserved osteoporotic population at risk for fracture. These fractures often cause loss of independence for patients and place a large burden on caregivers and society. We remain focused on improving diagnosis and treatment rates in order to bring Prolia to more of these patients in need.

With share around 20% in most markets, there continues to be a lot of room for Prolia to grow and we are investing accordingly. As I mentioned before, there are some countries such as Australia, Switzerland and Ireland with better diagnosis and treatment rates for osteoporosis where Prolia has a 50% share or better. These are countries that truly understand the societal costs of nonintervention.

KYPROLIS grew 13% year-over-year in a competitive multiple myeloma segment with several new entrants. Outside the U.S., we continue to see strong growth from both existing and new markets. KYPROLIS is a unique product in a competitive position having two compelling sets of overall survival data in relapsed multiple myeloma patients.

Our most recent market share data in the U.S. shows an improvement in new patient share in second line setting. This is an important leading indicator for sales growth into future quarters. KYPROLIS also continues to have a prominent position in the NCCN Guidelines for all lines of therapy.

XGEVA declined 2% year-over-year, primarily due to a shift in timing of purchases from some larger end customers. We believe XGEVA's positioned for growth in 2018 with the addition of a multiple myeloma indication.

Neulasta declined 6% year-over-year due to a shift in timing of purchases by some larger end customers as well as a small decline in the number of myelosuppressive chemotherapy regimens.

The Onpro kit grew share to 56% of Neulasta units and we expect to continue to drive additional Onpro adoption into 2018. Our most recent in-market data shows that Onpro drives better adherence to therapy, which leads to lowering of rates of febrile neutropenia, and in fact lower rates of hospitalization. Simply put, Onpro is a better value to the healthcare system and this is an important point of potential differentiation for the future.

With NEUPOGEN, the impact of short-acting biosimilar competition was consistent with prior trends. We exited the quarter with 41% share of the short-acting segment and we have continued to maintain pricing discipline despite the competitive pressures NEUPOGEN has faced over the last several years.

Enbrel sales declined 6% year-over-year, in line with prescription trends. We expect these prescription trends to continue into 2018. Segment growth year-over-year was in line with last quarter across both rheumatology and dermatology segments, confirming the rebound from the slower growth seen in quarter one.

Enbrel lost less than 1 point of share in both segments in this quarter, consistent with prior trends. Quarter three saw a low single digit year-over-year decline in net selling price. Overall, we expect there to be a very slight year-over-year decline in net selling price for the full year 2017. Most formulary decisions for 2018 have now been finalized and we expect the net selling price trends of 2017 to continue into 2018.

You may recall that we noticed some potential excess end-user inventory at the end of quarter two. End-user inventory levels are estimated by deducting the value of prescriptions from the value of wholesaler shipments to end customers. Based on this data, we did not see a depletion in the third quarter. And if prior fourth quarter patterns hold, we would not expect a depletion in the fourth quarter either. We continue to make investments to maximize Enbrel's long-term value such as the imminent launch of our Enbrel AutoTouch, a reusable auto injector that is ergonomically designed to meet the needs of rheumatoid arthritis patients.

Lastly, we look forward to extending our information franchise into Europe next year with the launch of AMGEVITA, our biosimilar to HUMIRA.

Aranesp saw modest declines of 3% year-over-year. We had a small unfavorable impact from foreign exchange and unit volume declined slightly globally.

EPOGEN declined 21% year-over-year. The primary driver was lower net selling prices, in line with quarter one and quarter two as a result of our extended DaVita agreement. In the third quarter, we did not see any underlying changes in the EPOGEN business, did have some unfavorable inventory changes which added to the year-over-year decline.

Sensipar increased 10% year-over-year, primarily due to net selling price. We've now launched Parsabiv in over 10 countries in Europe and our partner ONO has had a very successful launch in Japan. We're preparing to launch in the U.S. when CMS reimbursement code for Parsabiv becomes effective on January 1, 2018.

Now to Repatha. Our cardiovascular team continued its strong competitive execution, reaching 60% of total prescription share in the U.S. and 57% in the EU. In the U.S., new to brand share, which in my mind is a forecast of future sales, in the U.S. reached 74%. Sequentially, our Rxs grew by 20% in the U.S., however, sequential sales growth was tempered by changes in inventory and accounting adjustments that benefited the second quarter.

We continue to work hard with payers to improve access for appropriate patients. And we look forward to the FDA's priority review of Repatha's cardiovascular outcomes data, which will allow us to start promoting Repatha's ability to reduce heart attacks and strokes with both physicians and patients in December this year. Cardiovascular disease continues to be the number one cause of death and disability in the world and it's a top priority of Amgen to ensure that appropriate patients have access to Repatha.

So in conclusion, we are focused on a strong finish to 2017. As we prepare for numerous launches in 2018, which include our Repatha outcomes label, the Enbrel AutoTouch device, Aimovig for migraine, Parsabiv, the XGEVA multiple myeloma indication, as well as large opportunities from our biosimilar franchise.

Let me for a moment stop and say thank you to all the Amgen staff, who have worked so hard and tirelessly this quarter to get our important drugs to patients around the world.

And now let me pass you to Sean. Sean?

Sean E. Harper {BIO 16272195 <GO>}

Thanks, Tony, and good afternoon. I'll begin with our cardiovascular therapeutic area. On Repatha, we continue to work with regulators towards incorporating cardiovascular outcomes data on our label and we are looking forward to our PDUFA date of December 2. In September, the American College of Cardiology issued their updated expert consensus decision pathway for non-statin therapies based largely on our cardiovascular outcomes data. It's clear that if these recommendations were followed in the United States, millions of patients would be treated with PCSK9 inhibitors.

We also recently completed a Phase 3 Repatha LDL lowering study in diabetic patients, an important population at increased risk for cardiovascular disease. Repatha demonstrated efficacy and safety data consistent with that seen in our broader Repatha program and we'll be presenting the results at an upcoming medical meeting.

After reviewing the recently presented outcomes data from Merck's CETP inhibitor, anacetrapib, we feel the value of our CETP inhibitor, AMG 899, would be best realized through potential out-licensing opportunities, which we are exploring.

I'd also like to provide an update on one of our exciting Phase 1 cardiovascular programs, AMG 986. AMG 986 is a small molecule agonist of the apelin APJ receptor, which is associated with the body's biologic stress response to heart failure. Consistent with our strategy to pursue novel targets with human validation, administration of an endogenous peptide agonist of APJ has been shown to improve cardiac function in heart failure patients.

Preclinical data support clinical testing in the setting of heart failure with both preserved and reduced ejection fraction. We're actively enrolling healthy volunteers and heart failure patients in Phase 1 and appear to be in a significant leading position around this exciting axis.

Turning to inflammation and our TSLP antibody Tezepelumab, which we're developing in collaboration with AstraZeneca, the results of a large Phase 2b study in patients with uncontrolled asthma were recently published and presented to a very enthusiastic response.

TSLP is an upstream epithelial driver of inflammation in asthma and the data supported the potential to address a broader population of patients, essentially all comers, then targeting individual cytokines such as IL-413 or IL-5. We're currently working with our partner and regulators on the design of our Phase 3 asthma program and we'll provide updates as we progress.

Finally, results from a small exploratory short duration Phase 2a study of Tezepelumab as an add-on treatment to medium and high strength topical glucocorticoids in atopic dermatitis were recently posted. 111 patients with moderate to severe atopic dermatitis received 280 milligrams of Tezepelumab or placebo every other week for 12 weeks.

Statistical significance on the primary endpoint of 50% reduction in eczema area and severity index at 12 weeks was not achieved, though positive trends were observed across a number of disease activity endpoints, suggesting that Tezepelumab may deliver clinical benefit as add-on treatment to topical glucocorticoids. The evaluation of Tezepelumab in atopic dermatitis may require further study and we continue to consider this indication among others in our lifecycle development plan.

I'll begin my comments on our oncology efforts with KYPROLIS. In the second-line, a relapsed multiple myeloma setting, we now have an April 2018 PDUFA date for the

ENDEAVOR overall survival data, and we're busy preparing a submission for the ASPIRE overall survival data.

In the frontline, or newly diagnosed multiple myeloma, we're supporting high-quality evidence generation through randomized Amgen-supported studies, sponsored by investigators and large cooperative groups with a focus on the KRd regimen, KYPROLIS, Revlimid and dexamethasone.

We're particularly interested and excited about the potential of KYPROLIS plus DARZALEX and will begin to support KRd plus DARZALEX study along with Janssen in the frontline transplant-eligible population to build on the ongoing KD plus DARZALEX study we're running with Janssen in the relapsed or refractory setting. We believe the combination of these two highly potent therapies could significantly improve patient outcomes and drive patients into deep, durable remissions.

Lastly, on KYPROLIS, the Phase 3 A.R.R.O.W. study of KYPROLIS administered at 70 milligrams per meter squared weekly versus 27 milligrams per meters squared twice weekly in combination with dexamethasone met its progression-free survival primary endpoint at a pre-specified 75% interim analysis by demonstrating superior efficacy of the 70-milligram weekly regimen with similar safety findings.

Turning to our bispecific T cell engager programs, we recently announced the collaboration with CytomX to expand our immuno-oncology capabilities with an additional and complementary bispecific technology. As part of the agreement, we will co-develop a T cell engaging bispecific antibody against epithelial growth factor receptor, or EGFR, employing their Probody technology. And we've also have exclusive rights to develop up to three additional undisclosed targets.

In our BiTE platform, we have several extended half-life BiTEs moving into Phase 1: AMG 673, directed against CD33 for AML, AMG 596 against EGFR Variant III for glioblastoma and AMG 701 against BCMA for multiple myeloma. Importantly, we have also seen data recently that markedly increased our confidence that BiTEs can have impressive activity in solid tumors.

Turning to IMLYGIC, our oncolytic viral therapy, in collaboration with Toni Ribas at UCLA, we recently published positive clinical and impressive biomarker data from a Phase 1b melanoma study of IMLYGIC in combination with Keytruda, a checkpoint inhibitor. To the best of our knowledge, these were the first clinical data published in the journal Cell, and generated much enthusiasm among clinical investigators. These results, along with our other Phase 2 data, of both biomarker and clinical endpoints in combination with the belimumab, add to the growing body of evidence supporting the systemic effect of IMLYGIC and its considerable potential for combination with checkpoint inhibitors.

A word on Aranesp, after many years of intense effort, our final post-marketing requirement study on tumor progression and overall survival has read out. This was a prospective 2,500 patient double-blind placebo-controlled study to evaluate the safety and efficacy of Aranesp in anemic populations with advanced non-small cell lung cancer,

receiving multi-cycle chemotherapy. Recall that this was one of the tumor types that had suggested potential tumor progression effects in a small study.

The data monitoring committee determined that the primary endpoint would be met with near certainty and recommended that we stop the study early. After discussion with global regulators, we ended the study and the data indeed showed that the primary endpoint of non-inferiority of Aranesp to placebo in overall survival was successfully achieved as were the secondary endpoints of non-inferiority to progression-free survival and non-inferiority to objective tumor response. As expected, transfusions were lower in the Aranesp arm.

In bone health, our Prolia submission for the treatment of glucocorticoid-induced osteoporosis is under review with a May 2018 PDUFA action date. Results of the Phase 3 ARCH study with romosozumab, or EVENITY, compared to alendronate in postmenopausal women with osteoporosis were recently published and presented. We continue to believe from our interactions with experts in the field and regulators that there may be a patient population at high risk for fractures for whom EVENITY could provide a positive benefit risk and we're evaluating all of our Phase 3 clinical trial data to gain a comprehensive understanding of the cardiovascular safety results that were observed in ARCH, yet not observed in our placebo-controlled FRAME study.

In our neuroscience collaboration with Novartis, we recently presented the results from a unique dedicated study that demonstrated that Aimovig did not aggravate ischemia in patients with stable angina, contributing further to the growing body of evidence supporting the safety profile of CGRP receptor inhibition with Aimovig.

In our second migraine program, I am pleased to report we're currently enrolling migraine patients now in a Phase 2b study of our PAC1 antibody AMG 301. PAC1 inhibition is a novel approach to migraine prevention that is mechanistically differentiated from the CGRP pathway.

And finally, I'd like to highlight our second U.S. biosimilar approval, in this case, for all eligible indications of Avastin, and the U.S. submission of ABP 980, our biosimilar Herceptin. Achieving biosimilarity in the U.S. regulatory environment has turned out to be more challenging than many expected and our continued success is a testament to our unsurpassed biologics development and manufacturing capabilities.

As always, I'd like to thank all of the staff at Amgen that make it possible to wage war against the worst forms of disease. Bob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay, thank you, Sean. Ian, can we open up the lines for questions now and would you remind our callers of the process?

Q&A

Operator

Our first question is from Chris Raymond from Piper Jaffray.

Q - Christopher Raymond {BIO 4690861 <GO>}

Hey, thanks. Thanks for taking the question. So just a question on the Neulasta Onpro Kit, if you don't mind, I'm noticing that quarter-on-quarter share ticked up about 1%, it looks like, to 56%. I think that's a little bit of a leveling off from what you've seen in previous quarters. Just wondering if you could maybe comment on what you think a steady-state share would be for that presentation of the product ahead of any biosimilar Neulasta launch? Thanks.

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

So, Chris, this is Tony. Clearly, I'm not happy with 56%. If I look at the product value that this thing brings in terms of enhancing patients' ability to go home, the value to a large institution in terms of how they treat patients, we will continue to drive hard to increase that share beyond 56%.

Operator

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

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

Thank you very much and congratulations on the solid results. A question for David. Look, you highlighted the operating margin uptick in the quarter and then the potential step down in Q4. But as you look ahead, you must have gone through your sort of long-range planning exercise, David. How do things look in terms of your ability to maintain those operating margin as you change the mix of products and pivot over to partnerships and collaborations? Is this 55% looking sustainable to you, or should we be anticipating that there will be some reduction over the next few years?

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

Sure. So yeah, so if you recall, we set out a plan for the company a few years ago to get to 52% to 54% objective by 2018. And the good news for the company is we've been able to certainly move that forward and achieve that type of performance upwards to a year in advance of our original goal. So we've been quite pleased with our ability to deliver on that performance.

And I think importantly during the period, while we were accomplishing that, we've had record levels of investment in R&D. We've stood up a cardiovascular franchise. We're about to stand up a neuro franchise here next year, built the biosimilars business and increased our footprint from 50 to 100 countries.

So if I look at that performance and I look at our ability to continue to invest, I think it's quite encouraging. And while we haven't given guidance post 2018 yet, I think suffice to

say we feel very good about the sustainability of that type of margin performance for the company.

Operator

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

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

Great. Good afternoon. Thanks for taking the question. It's two parter for me on Repatha. I guess, maybe could you comment on what your view is on the market share for that product going forward? Obviously, you pointed to NBRxs that are quite high, though your competitor products obviously may remain on the market longer than you originally thought. And then any comments on how formularies for Repatha are shaping up into 2018? Thanks.

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

Okay, Matt, so Tony, let me respond there. So, the market share we've achieved to date has been in the presence of a competitor. So as I think about going forward, we will continue to be competitive. And I think getting more and more patients on Repatha is our objective, which we've been quite successful with. We are working extensively with payers at the moment in terms of improving potentially the utilization management criteria and working on trying to reduce the onerous bureaucracy that takes place and frustrates physicians at the moment. We look forward to being able to pull some of these things through potentially in 2018.

Operator

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

Q - Terence Flynn {BIO 15030404 <GO>}

Hi. Thanks for taking the question. I was just wondering, Bob, if you could just give us your view on tax reform as we head into 2018? I know there's a lot of moving pieces there, but do you anticipate that Puerto Rico would still be advantaged relative to the U.S.? And then on the capital allocation front, how do you think about the potential for use of capital if there is a repatriation allowed under the deal? Thank you.

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

Sure, Terence, thanks for the question. Obviously, we think tax reform makes sense for the country. We've been advocating for that for some time. We continue to advocate for it and continue to advocate for the need for that tax reform to reflect the reality in Puerto Rico which is that a number of organizations, including Amgen, have major investments in Puerto Rico that were made there to capitalize on the tax advantages created by U.S. laws.

So we're keen to see that as tax reforms plays out, the important role of manufacturing in the island is reflected and that the appropriate language is included in the tax reform to

continue to maintain the incentive for us and others to invest on the island. So we're watching the process closely, Terence and interested as no doubt all of you are to see exactly how the language will be written to address the needs in Puerto Rico.

And then more broadly on capital allocation, obviously we have a track record of returning significant capital to our shareholders and to the extent that tax reform happens and provides greater flexibility for us, we'll take that into account in our capital allocation plans. But as you know, from our track record over the last many years, we've been actively returning capital in the form of growing dividend and buyback and I'd expect us to continue that.

Operator

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

Q - Robyn Karnauskas {BIO 15238701 <GO>}

Hi, guys. Thank you. So, you tend to have had – one of the few people who have had a lot of success getting biosimilars approved and through. There's been a lot of other rejections or delays. And we have noted that NEUPOGEN really was impacted by biosimilars while Remicade was not. So I was just wondering if you could help us understand given what you seen in the biosimilar space, how to think about how you will launch your biosimilars. How do we think about the Remicade analogy and the NEUPOGEN analogy and how to model your biosimilar business?

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

Okay, Robyn, I'll ask Tony to comment on the specifics of how we're looking at going to market. But your general point is noted. It has proven difficult for our competitors to get biologics approved and biosimilars approved on time. And we're not fully surprised by that. We expected that there would be difficulties and we expected that the capabilities we had would be helpful for us to differentiate versus some of our competitors. And I think that's what's playing out. But I think the gist of your question about how we're planning to go to market is one for Tony to address.

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

Okay. So, Robyn, clearly we think that the market in the beginning will be a branded biosimilar market. And therefore, the value we bring as an organization about the quality and the continuity of our supply is really important. The relationships we have with large institution, with small community clinics is really going to be important as well. So we will focus very clearly upon our relationships of the past, our skills of the past, as well as the value of the product we bring to market.

Operator

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

Q - Ying Huang {BIO 16664520 <GO>}

Hi. Thanks for taking my question. I have one on Enbrel, maybe for Tony. So one, I'm curious on your comment that you do not expect further depletion of Enbrel inventory in Q4. And I was wondering why that could be. And then secondly, can you comment on 2018 net pricing trend for Enbrel now that we're kind of like late 2017 already?

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

Okay. Ying, so as I've said, the end-user inventory is a triangulation we do in an attempt to give you guys as much visibility as possible about what we know to allow you to run your models. But fundamentally, we do the calculation based on what the Rxs are in the marketplace, which I'm never 100%, minus what we know our wholesaler have sold to the end users and the balance we assume is an inventory build. When I look back five years, I've never seen an inventory burn in the fourth quarter, so we're making the assumption that there wouldn't be an inventory burn this fourth quarter as well.

As regards to 2018, as I said in my earlier comments, most of our contracts have been negotiated, although that doesn't mean that there won't be negotiations that continue going forward during 2018, but we do expect the net selling price for Enbrel, the trend you've seen in 2017, we expect that to continue to 2018.

Operator

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

Q - Eric Schmidt {BIO 1505721 <GO>}

Thanks for taking my question. It's on Sensipar and Parsabiv. I guess first, are we expecting generic Sensipars in March of next year, or were you able to extend pediatric exclusivity I think is what you were looking for another six months? And second, can Tony talk a little bit about the switching strategy to Parsabiv starting January 1? Thanks.

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

Yeah, so let me just take your question on Sensipar, and then Tony, you talk about Parsabiv. We have litigation, as you know, Eric, underway, regarding the pediatric extension, so I don't want to comment on that while the litigation is pending. But Tony, why don't you talk about Parsabiv.

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

So we are bringing Parsabiv to market based on the clinical data we have at present, right. So by definition, secondary HPT is a very difficult thing to treat and adherence is a real problem. I think we have about 150,000 patients on the drug at the moment which is only about a 26% penetration. The head-to-head data we have shown great levels of efficacy of Parsabiv and without doubt in our mind, we will see a better level of adherence as physicians are back in control.

All feedback we have had to date from nephrologists in the marketplace has been very good. They are looking forward to having this drug available. So whether it's a switch or

replacement or usage during a treatment period will be dependent upon the physician or the dialysis unit in terms of their guidelines.

Operator

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

Q - Umer Raffat {BIO 16743519 <GO>}

Hi guys. Thanks so much for taking my questions. I actually had a strategy question today, if I may. And I'm curious, has there been any consideration or deliberation internally on possibly extending the Novartis partnership to include the CV franchise also? And I'm just thinking out loud about Novartis' increased presence in cardiology with ENTRESTO as well as their new CANTOS data. I wasn't sure if this something that has been dealt with previously, and/or how you'd think about pushes and pulls on a possible setup like this? I mean it doesn't have to be necessarily a 50/50, but just perhaps thinking about margins and taking advantage of their presence now. Thank you.

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

With respect to our partnership with Novartis, we're very happy with how we're collaborating with each other. And neuroscience, as you know, we were really attracted to their BACE program because we liked the clinical experiment that's being run there. We believe strongly in BACE and we believe that the appropriate way to test it is by getting to patients early, and together that's what we're doing. And they liked our CGRP program and our commitment to migraine, so that we think we have a good partnership there.

We have pioneered a lot of new ground in the cardiovascular space and we're excited about our intellectual property there, excited about what we see in the pipeline and so we're content to continue to own all of that franchise certainly in atherosclerosis. And as you know, we have partnerships already in heart failure. So we're generally optimistic and upbeat about what we see happening in cardiovascular. And as David said, we've fully invested in the standing up of that franchise.

Operator

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

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

Hey, great. Thanks for the question. I know that you're prepared to give I'm sure 2018 guidance in due time, but many years ago you gave longer-term guidance. As you think ahead over the next few years, which I think the Street remains uncertain about, what are the push and pulls that you think need to happen to be able to have visibility to provide that, or should we stay tuned? How do we think about that? Because that seems to be something I think that's weighing on people.

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

Yeah, Michael, as David said in his remarks, we would expect – we'd normally give guidance in January for 2018, so we'd expect to do that. As David also said in his remarks, we've made great progress on achieving the objectives that we established for 2018. In some areas, obviously we're moving more quickly to achieve those objectives than we had expected, so we're looking at the options to what makes sense when we get to providing the next batch of guidance and talking to our shareholders about that.

Operator

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

Q - Geoffrey Meacham {BIO 21252662 <GO>}

Hey, guys, thanks a lot for the question. A real quick one. Sean, on the migraine program, maybe just can you go into a little bit more on 301, what you'd be looking for in a Phase 2 above and beyond what you see with erenumab? I'm just trying to think about kind of cost/benefit and risk/benefit?

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

Yeah, thanks for the question. I think initially, we have a form of human validation for this pathway and that if the ligand for this receptor is infused into migrainers, they experience migraine, and this is what was seen with CGRP as well. And we also have a pharmacodynamic assay that we look at in Phase 1, which is very similar to what we did with erenumab, where we know that we're covering the target and peripheral tissues.

So the next step for this is to achieve clinical proof-of-concept for the pathway and in terms of the ability to prevent migraine and to understand the dose that's required for that. And then I believe that we need to begin to understand, since these are such different neural circuits in the brain, whether there is a situation in which we can see additive or synergistic activity between PAC1 inhibition and CGRP inhibition, where there are certain patients who respond to one but not the other, or whether we can get again a kind of a synergistic effect in patients who do already respond to CGRP inhibition.

So I think that's all work that remains and we of course have the option to pursue that either through fixed dose type combinations, but we also have a bispecific program where we're actually able to inhibit both these targets in a single molecule. And that's all work that's going to be done, as we've mentioned, collaboratively here at Amgen but in collaboration with Novartis.

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, which is on erenumab as well, or Aimovig. I wanted to ask about the progress of your prelaunch activities, how they're going and the early reception you're seeing on the part of physicians and especially

payers in terms of the level of enthusiasm for the class in general and this product in particular. And maybe how are the responsibilities towards these activities being divided by you and Novartis? Thanks.

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

So this is Tony. Thanks, Cory. I just came back from the International Headache Conference (sic) [International Headache Congress], which was in Vancouver, where I was meeting with a group of key opinion leaders and individuals who run headache clinics together with me with my counterpart from Novartis, Paul Hudson. So he and I, we're working this together. So as we think strategically, the two organizations are doing a lot of strategic thinking together.

We both jointly agree that we probably saw more enthusiasm from this set of neuro physicians than we've ever seen in many other physicians in other congresses. People are talking about this is the first time they are being able to potentially prescribe a migraine drug for migraine patients in two decades. So I came away feeling much more positive about the scientific understanding, the clinical need and the large population that is waiting for this.

The work we've done at the moment with migraine bloggers and patients who are suffering from migraine has also been very beneficial. We understand much better now the patient's journey, the importance of the work we have to do with patients and their willingness to work with us to spread this good message once we have our drug approved. Obviously, we continue to work with payers in strategic discussions, but we haven't made any final decisions around pricing as we go forward.

Operator

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

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys. Thanks for taking my question. Another one for you, Tony, on the migraine. I guess, can you maybe talk about parallel learnings from PCSK9 since they are kind of similarly big, and like how to think about the migraine market in light of what the payers could do and strategies you have there? Thanks.

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

Sure, Alethia. So I think first of all, the magnitude of the market is different, right? In the U.S., we estimate about 3.5 million patients right now are being treated for prophylactic treatment of migraine. A lot of those patients fail. A lot of those patients go off treatment because of side effects. A lot of those patients find the treatment is not effective. I think we believe that we will clearly be positioned for patients who failed existing therapy.

And last but not least, I think patients are much more aware of the disease. This is a symptomatic disease. When you have a migraine, you're very much aware of it. So I think

patient mobilization in terms of their voice around the need to have access to drug is going to be important.

The value these drugs bring to the marketplace too, when you think about how debilitating migraine really is in terms of stopping people from going to work, preventing people from being mothers or caregivers, there is huge value to society to allow these people to get back their independence and to become normal citizens again.

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

Ian, before you go to the next question, let me just note that we're getting up towards the top of the hour, but I gather there are a few questions still queued up, so just wanted to alert the listeners that we'll go a little longer than usual. Go ahead to the next question.

Operator

Certainly. Our next question is from the line of Ronny Gal from Bernstein.

Q - Aharon Gal

Good evening, and thank you for fitting me in. Two questions. First, CMS seems to be contemplating a single J-code for biosimilars innovative product. How do you guys feel about it? Would that help or help the biosimilar market? And second, one of your peers appears to be pushing up the pricing band for oncolytics. What is your take on this as the current investment in oncolytics justifies gradually raising the price band on those products?

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

Yeah. Okay. So two questions there, Ronny. I'm not sure we're going to want to talk about pricing. But with respect to J-codes, this is an important issue that we've been active in trying to help legislators understand. So Tony, go ahead.

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

Right. So we clearly believe that having a single J-code is not what you want, right? If you believe that a biosimilar has to be a decision made by a physician, you want clarity around each single product has to be able to reflect in the marketplace. So we're working hard to ensure that we have actual J-code by product as we go forward. On the pricing one, I'm not quite sure what the competition is doing and that's their decision.

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

We launched our oncolytic antiviral product or viral therapy with a very, we think, compelling value proposition, as you perhaps recall, Ronny. So we were trying to help institutions and patients understand that we were willing to cap their exposure from a price perspective. And I think that's been well received in the marketplace.

Operator

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

Q - Kennen Mackay {BIO 18821382 <GO>}

Thanks so much for taking our question. And, Arvind, thank you for the recognition of our initiation and, Bob, it's a huge relief to hear that your Puerto Rico staff is safe and accounted for here.

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

Thanks, Kennen.

Q - Kennen Mackay {BIO 18821382 <GO>}

I actually had one quick question on Hurricane Maria. David, you'd mentioned the $67 million in one-time quarterly damage associated with the Hurricane was partially due to inventory. And was just curious if this was inventory lost in Puerto Rico. And had also been looking at the product slides Tony had in the slide deck, and it looks like there were inventory drawdowns across the board with the exception of Sensipar. Is that a function of hurricane disruption, or is that just sort of quarterly reflection there? Thank you.

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

Sure. So it is true, what happened as a result of the hurricane is we had some product that was in process that it turned out was contaminated and so we had to scrap that product. So that was the inventory impact which was a portion of the $67 million of cost for the company. In terms of other disruption within the context of Puerto Rico, we have ample inventory for such interruptions, and so it hasn't impacted obviously our ability to supply. And Tony will probably comment, but I think as to the second part of the question, that's your normal dynamics of the seasonality, right?

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

Yeah, I don't think any of the inventory movement had anything to do with the hurricane. Most of the discrepancies were as a result of contracts ending early and buying in that took place in the second quarter which would normally happen in the third quarter. There was sufficient inventory both in our supply chain here as well as in the wholesaler supply chain during this period.

Operator

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

Q - Andrew Peters {BIO 20622504 <GO>}

Hey guys, thanks for squeezing me in. And I guess just another biosimilar one. So regarding the overall portfolio, while regulatory timelines appear relatively straightforward, I'm wondering if you can provide a little bit more context regarding potential launch timing. I know it's kind of on a case-by-case basis relative to I guess legal negotiations, et cetera. Just wanted to understand if you have any sense of where we are

in the process for the various products and how you think about timing overall to coming to market? Thanks.

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

Well, Andrew, I guess the premise that it's relatively straightforward to develop these is one that people are struggling with in the industry. But as I said earlier, I think we expected that some of our competitors would struggle to achieve biosimilarity and we would observe that that's been playing out. So far we've been fortunate to be able to advance molecules that have passed the test with not just regulators here in the U.S., but globally, and we're committed to continue to try to do that.

Obviously the first step along the journey is getting our products approved. We have now, as you know, two of them, AMGEVITA and MVASI, which is our biosimilar to Avastin. And we now have clarity around our launch plans for AMGEVITA and we're excited about that. We have ongoing litigation with respect to MVASI, so I think it's probably inappropriate to talk about that now.

But generally, I think that since in the U.S. anyway, this pathway is still so new, there probably are still some regulatory paths to be made more clear. And I think certainly on the intellectual property front, there's still more work to be done in the field before we can all start to predict launch timetables accurately. So I'd like to resist trying to do that on this call, but I would remind you that we continue to be transparent about where our products are when they enter pivotal Phase 3 trials and when we file them with regulators and we'll continue to do that.

Operator

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

Q - Salim Syed {BIO 16887281 <GO>}

Yeah, hi guys. Congrats on the quarter. I had a question on Repatha. So we're getting the ODYSSEY outcomes data early 2018. And if we get the scenario here where the data looks optically better, right, because of the longer duration trial, but it still falls along the CTC (01:04:10) line, how do you guys view that? Is that a good because it grows the market you think, or a bad, because that's competitor data. I was just curious what your thoughts are there. Thank you.

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

Sounds like you're trying to draw us into a discussion of hypotheticals there, Salim. I think, Sean, if you feel you want to be drawn to that, fire away. But I hope you'll take a moment just to reiterate what we've learned about our products in the outcomes trial.

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

Yeah well, I mean, my view would be that we've already seen with bococizumab, although they had their immunogenicity issues, which caused the molecule not to be able to be

commercialized. We've already seen two PCSK9 inhibitors clearly fall along the CTCC (01:04:57) line.

And so is it good for the science and for the field to have a third outcomes result? Sure, I mean, the reason there's so much confidence in statins, for example, is we have a couple dozen outcomes trials that all more or less show the same thing. And I think, so from a scientific perspective, I think it will reinforce a number of the issues. And so in that way, I look forward to seeing the additional data. Tony, obviously.

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

I think if you were at the ESC recently when we presented some of the subcuts of the Repatha outcomes data and we looked at the cohort where you had patients who entered at LDLs below 70 and how as you drove LDL down to levels way below 70, you actually got a higher reduction in myocardial infarction and reduction in stroke, and our data alone showing up to about a 33% reduction in MI. I can't understand why you wouldn't want to do anything other than drive LDL down as low as you can. So our drug does that, other drugs don't.

Operator

And our next question is from the line of Ian Somaiya from BMO Capital Markets.

Q - M. Ian Somaiya

Thanks for taking my question. Just wanted to follow up on one of the earlier questions on Puerto Rico. Can you just give us a sense for your ability to continue to sort of manufacture in Puerto Rico? Is that based on resumption on some semblance of normalcy? And when would that need to occur? Or can you continue to manufacture based on sort of the contingency plans that you have in place?

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

Yeah, we have very robust contingency plans in place, Ian, and we're up and running. We're virtually all of our activities are up and running. We have astonishingly almost all of our 2,000 staff are back at work despite enormous disruptions in their personal lives. They're back at work making product for patients around the world. So we're, I must say, we're humbled and incredibly proud of what we've seen from our staff down there over the last five weeks. So we're up and running.

We are dependent on our own sources of power right now and we're looking forward to the island getting the electrical grid restored. We're looking forward to the communications grid getting restored, looking forward to a reliable water supply. We think we're in pretty good shape there at the moment though and the roads. And gradually, things are getting back to normal for the families who work at companies like Amgen. But the good news is we're up and running.

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

Yeah. No, that's right. As of this week, all of the plants that where we have demand requirements are fully ramped up and are producing. So, and that's very recently that's happened, but we don't see any, as I said earlier, we don't see any risk of disruption of supply. And I think importantly, we're back up and running and feel very good about that. And the one thing that's not as convenient is the fact we're running on our own power and we look forward to that being restored. But that's doesn't create any risk of our ability to produce. So yeah, so it's come out very well, I'd say.

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

Hey Ian, being sensitive to the fact that it's past 6:00 PM on the East Coast, why don't we take two more questions.

Operator

Certainly, sir. 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 fitting me in. I guess just a strategic question and given your focus on bispecific T-cell engagers in BLINCYTO, and given the acquisition of Kite by Gilead and your relationship with Kite as well, can you maybe speak to your interest in the cell therapy area to complement what you're doing with bispecifics? Thanks.

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

Yeah, good. Thanks for the question. I think we do have an interest in cell-based therapies and we're very happy that we have the collaboration with Kite, now Gilead, around the six targets that we set up in that original deal. And we're learning a lot there and we're progressing those programs.

I think our perspective remains, as we've looked at the technologies that the bispecific T-cell engaging approach, both in hematologic malignancies and increasingly in solid tumors, particularly in combination with checkpoint inhibitors, is appearing to be a very powerful technology. And these are off-the-shelf products that can be administered virtually immediately to patients and may offer a benefit/risk profile that would allow them to be used in earlier lines of therapy than in the current benefit/risk profile for CAR-T therapies, for example, tends to limit them to later stages of situations where patients are rather deep into the relapsed and refractory phases of their disease.

I also think that we have a significant opportunity here now that we have the sense from accumulating data in our own hands and seeing what's going on out in the rest of the industry of the opportunity for BiTEs to have activity in solid tumors. And so I think we have a very large number of programs that we are pushing through the pipeline right now against both hematologic and solid tumor products.

I think cell-based therapies do have a role and that role will probably increase over time as some of the technology matures. And it may be possible to use them in earlier lines of

therapy, as I mentioned. And we're tracking that closely. But right now, for the immediate kind of foreseeable three to five year period, we remain very enthusiastic about the bispecific T-cell engaging platform, particularly now with the half-life extended protein engineering.

Operator

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

Q - Carter Gould {BIO 20035589 <GO>}

Thanks for squeezing me in guys, and congrats on the quarter. One for Sean, real quick. How should we think about AMG 986 development in the context of omecamtiv? Should it be perceived more as a backup or complementary? And if there's any sort of just natural patient segmentation that might follow from the mechanism for these two assets, that would be helpful. Thank you.

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

Yeah, it's a great question. I mean, this is really a completely different mechanism of action than myosin activation. And while they're both targeting patients with heart failure, that's kind of where the obvious similarities end. I would say that what's been particularly exciting with apelin is the fact that we're seeing not only enhanced contractility, so systolic effect, but we're actually seeing enhancement of cardiac relaxation or diastolic effect. And that is unique in our knowledge to this particular mechanism.

So it allows us to consider pursuing add-on therapy presumably to standard-of-care in the reduced ejection fraction setting as we are doing with omecamtiv mecarbil in our experiment right now in Phase 3, which by the way, is enrolling extremely well. And, but also to explore the situation where there is absolutely no registered therapy available for the heart failure with preserved ejection fraction population, which is a very large population and is currently very underserved. So it's still reasonably early days in the clinic, Phase 1, but this is one of the more exciting programs we have in the cardiovascular arena.

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

Okay, well thank you, Sean. I think we probably should break now but let me just say a couple quick thoughts in conclusion. First, I hope you can see that we're executing on our strategy and that we've put the company in a strong position for dealing with the realities of the environment that exist in our industry today. I'm pleased with our efforts to drive growth products as well as with the lifecycle management of our mature brands.

And I wanted just end by thanking our staff globally and particularly once more our colleagues in Puerto Rico for driving results and delivering for patients.

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

Great. Thanks, Bob. And I would like to thank all of you for your participation. Of course, if you have any follow-on questions, comments, that you would like to discuss, feel free to reach out to me and my team. We'll be around for several hours. Thanks again.

Operator

Ladies and gentlemen, this concludes Amgen's third quarter 2017 financial results conference call. You may now disconnect.