Q2 2019 Earnings Call

Company Participants

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

Other Participants

- Alethia Young, Analyst
- Chris Raymond, Analyst
- Do Kim, Analyst
- Evan Seigerman, Analyst
- Geoffrey Porges, Analyst
- Jay Olson, Analyst
- Kennen MacKay, Analyst
- Matthew Harrison, Analyst
- Michael Yee, Analyst
- Mohit Bansal, Analyst
- Ronny Gal, Analyst
- Salim Syed, Analyst
- Terence Flynn, Analyst
- Umer Raffat, Analyst
- Yaron Werber, Analyst

Presentation

Operator

My name is Ian and I will be your conference facilitator today for Amgen Second Quarter 2019 Financial Results Conference Call. All lines have been placed on mute to prevent any background noise. There will be a question-and-answer session at the conclusion of the last speaker's prepared remarks. In order to ensure that everyone has a chance to participate, we would like to request that you limit yourself to asking one question during the Q&A session. (Operator Instructions)

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

Arvind Sood {BIO 4246286 <GO>}

Okay. Thanks, Ian. Good afternoon everybody, and thanks for joining us to discuss our second quarter results. As I have done in the past, I would like to extend a special welcome to those, who are new in their coverage of our Company and this quarter it's Mohit Bansal of Citi, so welcome Mohit.

I think our performance in the second quarter can be best characterized as continued execution, while staying focused on sustained long-term growth. Leading the discussion today will be our Chairman and CEO, Bob Bradway, who will provide a strategic perspective on our business, particularly within the backdrop of a fast changing business environment. Our CFO David Meline will then review our financial results for the second quarter and provide an updated guidance. Our Head of Global Commercial Operations, Murdo Gordon will review our product performance, followed by our Head of R&D, Dave Reese, who will provide a pipeline update.

As we have done in the past, we will use slides to guide our discussion today, and you should have received the link separately. Just a reminder that we will use non-GAAP financial measures in today's presentation, and some of the statements will be forward-looking statements. Our 10-K and the 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 thank all of you for joining us. Halfway through the year, we are making clear progress and delivering on our strategy for a long-term growth. And that core of the strategy, of course, our innovative, first-in-class medicines, addressing serious diseases globally. While our strategy embraces medicines like BLINCYTO, which is our bispecific T cell engager, for example, with its large effect size in a specialty market, our strategy also explicitly addresses diseases, where the unmet need is measured in many millions of patients. Over time we think this balance is going to be essential and expect that increasing global price pressures will highlight the importance of products that can deliver sustained growth through volume gains rather than annual price increases.

Prolia is a great example of this. Now more than 10 years after launch, it once again posted double-digit volume growth this quarter and its long-term prospects remain bright, as there are still millions of women at high risk of fracture, who are not yet on a preventative therapy like Prolia. The recent launch of EVENITY will enable us to extend our industry leadership in bone health and bring more options to position seeking to address the global epidemic of osteoporosis. More generally Prolia points the way for other products in our portfolio like Repatha, Aimovig and potentially tezepelumab.

Let me touch briefly on Repatha. I think all of us know that cardiovascular disease is a leading health problem globally. The numbers are so large that some seem to have been numbed or rolled into a sense of complacency about them. But that's changing, partly because after decades of decreasing morbidity and mortality, the trends have worsened and the death rate from heart attack and stroke is now actually increasing in the US and internationally.

We know one of the reasons for this is that LDL levels are too high in too many people. We believe Repatha offers a solution to that problem for many people, and given demographics health systems cannot continue to ignore the meaningful uptick in cardiovascular events and deaths. It will only get worse without more widespread use of innovative medicines that address atherosclerotic disease.

We see increasing recognition of this here and abroad, and of course, we're seeking to do our part, including taking actions as we did last year in a competitive context to lower the out-of-pocket costs for patients to use this therapy. We will continue to advocate for high-risk patients and those who recognize the urgency of getting in front of the growing problem of heart disease in our society.

With Aimovig our first-in-class CGRP medicine, we're transforming the treatment of migraine. Like Prolia and Repatha it addresses a chronic debilitating disease afflicting millions of people worldwide. We recently presented important new data at the American Headache Society Meeting demonstrating that Aimovig's efficacy improves over time. We expect this medicine to be of increasing importance to migraine sufferers and a key growth driver for years to come.

Turning to our growing hematology and oncology products. We posted 10% growth for KYPROLIS, XGEVA, Nplate, Vectibix, IMLYGIC and BLINCYTO, which together are annualizing at more than $5 billion revenues. We see more growth ahead from these medicines. Our confidence in BLINCYTO was bolstered by the compelling five-year survival data we reported in MRD-positive ALL patients. Based on this and other data emerging from our BiTE platform, our confidence in that therapy is high.

The demand for innovative medicines is growing rapidly outside the US and the larger European markets. Looking at demographic trends, we expect this to continue for some time. That's why we have made international expansion, an important part of our strategy. We are beginning to see measurable returns from our efforts. Internationally our volumes were up 18% in the second quarter, and if you look at markets, where we were historically absent like Japan and China, you can also see the benefits of our strategy coming to light.

Japan was the first country to approve EVENITY globally and was our first market launch. We're very pleased with the uptake there. Similarly BLINCYTO is performing well in Japan and overall, we are encouraged by the performance of our Amgen-Astellas Biopharma partnership. China, though it is still early days for Amgen, represents another attractive long-term growth opportunity for us and we are encouraged by the progress in advancing our medicines for that market with the early launches of Repatha and XGEVA.

At Amgen, whenever we talk about delivering in the long-term, we are always clear that you only get to deliver in the long term, if you succeed in the short and medium term. Our results in Q2 show that we're doing that. With pressure following patent expirations across a number of our products, we maintained strong operating margins, attractive returns on our capital and ongoing steady return of cash to our shareholders in dividends and buybacks. Our stewardship of the business is also reflected in our competitive market share performance, across our mature and recently-launched portfolio of products. We will be staying closely focused on execution and productivity, as we seek to invest in the long-term opportunities that will enable us to reestablish our long-term track record of growth.

Our long-term opportunities include many novel first-in-class therapies across all phases of our pipeline. One of these of course is AMG 510, our KRASG12C inhibitor, which has generated significant interest and continues to move very rapidly through the clinic. We anticipate many important data readouts across the portfolio over the next 12 months, as we advanced therapies against cancer, cardiovascular disease, respiratory disease and other inflammatory disorders.

Additionally, I'd like to note in Q2, we bolstered our industry-leading human genetics capability with our collaboration with Intermountain Healthcare and we added a new important research platform through our acquisition of new evolution. Dave Reese will share more information about our pipeline as well as these collaborations, when he talks about research and development in a moment.

Now, let me share a couple of thoughts with you on the drug pricing debate here in the United States, noting first that the environment remains fluid. The Administration and Congress, as you know are considering various proposals, but it's too early to speculate on whether there will be any changes, and if there are any, what the impact of that might be, given that the process is still playing out.

I know the Senate Finance Committee bill in particular has attracted attention and is an important example of this focus, but many provisions in the bill remain controversial and will likely be modified before advancing. Amgen's particularly focused on ensuring that patients benefit more directly from any savings that are generated by legislation that's advancing and we think that in general, more can be done to help patients, who bear at presence anyway a disproportionate share of drug costs through out-of-pocket expenses. And we will continue to engage in a thoughtful dialog with the Administration and Congress on drug pricing issues and we are committed to find ways to drive change that's still promotes innovation and respects market-based initiatives that will help address financials -- the financials and societal burden of some of the world's most serious diseases.

One solution to alleviate some of the financial and societal burden is through the introduction of biosimilars. Last year we launched our first biosimilars in Europe, KANJINTI, our biosimilar to Herceptin and AMGEVITA, our biosimilar to Humira. A couple of weeks ago, we launched KANJINTI and MVASI, our biosimilar to Avastin in the U.S. We believe biosimilars will play an increasingly important role in helping to address issues of

access and affordability in the U.S. and around the world and we are excited to be a leader in this emerging space.

I'll end by highlighting that we continue to generate strong cash flow, continue to invest in R&D aggressively and prudently return excess capital to shareholders. We are in a strong position to grow our business organically and externally, but we will remain disciplined in business development opportunities. As I stated earlier, Amgen is executing well and we remain excited about our long-term outlook.

I'll turn the call over now to David Meline, who will review our financial performance. David?

David W. Meline {BIO 6397419 <GO>}

Okay. Thanks, Bob. Overall, we are pleased with our strong performance in the second quarter, as investments in support of our newer products delivered volume driven growth in year-over-year EPS growth in the second quarter.

Turning to the financial results on Page Six of the slide deck. Worldwide revenues at $5.9 billion in the second quarter, declined 3% year-over-year. Worldwide product sales at $5.6 billion in the second quarter, declined 2% year-over-year, as growth for our newer products was slightly outpaced by declines in our mature brands, impacted by increasing competition due to patent expirations.

Other revenues at $97 million declined $83 million year-over-year due to a prior year milestone payment. We continue to expect full year other revenues of about $1.1 billion. Non-GAAP operating income was $3 billion and declined 5% from prior year. Non-GAAP operating margin was 53% for the second quarter. As in prior years, our operating margin is expected to be lower in the second half of the year, driven by the timing of expenses.

Consistent with our plan, second quarter non-GAAP operating expenses decreased 1% year-over-year as we continue to make incremental investments to drive growth and maximize shareholder value, while benefiting from our permanent productivity capability. As communicated earlier this year, we continue to expect full year 2019 operating expense on an absolute basis to be flat versus 2018.

On a non-GAAP basis, cost of sales as a percent of product sales was relatively flat year-over-year at 13.2%. We anticipate 2019 full-year cost of sales on an absolute basis to be flat to slightly up depending on volume and continuing to reflect our industry-leading performance.

Second quarter research and development expenses of $906 million were 7% higher year-over-year due to increased investments in support of our early and late stage oncology programs. Research and development expense as a percent of product sales was 16.3%. For the full year, we continue to expect R&D spend trajectory on an absolute basis to increase in single-digit percentage terms, as our pipeline advances.

SG&A expenses decreased 6% on a year-over-year basis primarily driven by reduced discretionary general and administrative expenses and cost management discipline. We expect that for the full year SG&A expense on an absolute basis will decline year-over-year.

Other income and expenses were a net $114 million expense in Q2. This is favorable by $71 million on a year-over-year basis, primarily driven by prior year investment portfolio liquidation losses, as well as continued good performance for our Amgen venture's portfolio.

The non-GAAP tax rate was 15.3% for the quarter, a 1.1 point [ph] increase versus the second quarter of 2018, primarily due to a prior-year tax benefit associated with intercompany sales under U.S. corporate tax reform. Non-GAAP net income decreased 4% and non-GAAP earnings per share increased 4% year-over-year for the second quarter to $3.97 per share.

Turning next to cash flow and the balance sheet on Page Seven. Free cash flow for the second quarter of 2019 was $1.3 billion. This was lower than second quarter last year, as this year's result was negatively impacted by an advance tax deposit payment. Consistent with our principles, we continue to provide significant cash returns to shareholders. In Q2, we deployed $2.3 billion to repurchase 13.1 million shares at an average price of $180 per share. We plan to repurchase an incremental 1 billion to 2 billion of our shares in Q3. Additionally, our second quarter dividend increased to $1.45 per share, an increase of 10% over last year.

Cash and investments totaled $21.8 billion, a decrease of approximately $7.6 billion from the second quarter of last year, primarily due to share repurchases and debt repayments. Our debt balance stands at $30.6 billion as of June 30th, a reduction of approximately $3.9 billion from a year ago, as we continue to pay down our debt as it matures.

Turning to the outlook for the business for 2019 on Page Eight. We remain on track with our plans to continue to invest to advance our pipeline, including our oncology programs, build out our global presence and drive long-term volume growth, while delivering solid business performance. Today we are revising our 2019 guidance, which reflects our solid Q2 performance and the outlook for the second half of the year.

Our revised revenue guidance is $22.4 billion to $22.9 billion versus previous guidance of $22.0 billion and $22.9 billion. This continues to reflect the range of evolving competitive dynamics associated with Neulasta and other legacy products. With regard to our non-GAAP earnings per share guidance, we are revising the outlook to $13.75 to $14.30 a share versus previous guidance of $13.25 to $14.30. Further, we are maintaining our non-GAAP tax rate guidance of 14% to 15%. We continue to expect capital expenditures of approximately $700 million this year.

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

Murdo Gordon {BIO 18450783 <GO>}

Thanks David, and good afternoon everyone. You will find product sales information starting on Slide 10. In the second quarter of 2019, we continue to grow volumes across our newer portfolio, while competing effectively with our more mature brands.

Moving to second quarter results. Let me start with Repatha on Slide 12. Q2 sales grew by 3% year-over-year, as we continue to hold leading share of the PCSK9 class in this competitive market. Worldwide unit growth was 59% year-over-year with 66% unit growth in the United States. In the first half of the year, over 50,000 new patients were prescribed Repatha in the U.S., which was close to 585% increase versus the same period last year. The PCSK9 class has shown steady quarter-over-quarter growth, which we expect to continue throughout the second half of 2019, as we continue to make it our priority to improve access and affordability for patients.

For Medicare patients, our 60% list price reduction materially improves affordability and key to that patient affordability is access to Repatha at a low fixed co-pay tier. And while the lower list price version is now available to approximately 70% of seniors, we continue to be disappointed the payers have restricted low fixed co-pay coverage to 7% of Medicare patients. So, as we go through the bidding cycle for 2020, we're very focused on improving this number.

Further on the commercial access front, we've recently obtained coverage at ESI, which will help to expand access to close to 22 million patients. Recently a study published in Circulation demonstrated that high-risk individuals had a 16% increased risk of a cardiovascular event during the 11.5 month study period, when their PCSK9 treatment was rejected by their insurance plan.

The findings reinforce the need for continued engagement from all stakeholders, from healthcare professionals to payers, to plans and to government agencies to improve access and patient affordability, so that patients, who need Repatha, can get Repatha. With regard to pricing, the blended net price for Repatha in the U.S. declined in Q2 2019 versus the previous year due to contracts that took effect last July and the introduction of the lower list price SKU last October.

Sequentially, net selling price was roughly flat. We are committed to driving adoption of the lower list price SKU and our current plan is to discontinue the original list price SKU in the beginning of 2020. With these actions in our efforts to open up access for Medicare patients at a low fixed co-pay, we expect that we will see a positive impact on volume and reported net sales growth over the long term.

Next onto Prolia on Slide 13. Prolia continued its strong performance with sales increasing 14% year-over-year, driven by 15% volume growth. Given a seasonality quarters two and four deliver higher sales versus quarters one and three. We continue to increase our investments in Prolia to drive penetration in this under-treated population and have seen double-digit year-over-year new patient growth in the U.S.

Along with EVENITY, our innovative bone-building therapy, we are focused on addressing this global epidemic and increasing diagnosis and treatment for postmenopausal osteoporosis patients. EVENITY has convenient once-monthly physician administered dosing for 12 months and strengthens Amgen's leading position in bone health. Through our joint venture with Astellas, we launched in Japan and in March sold $25 million in Q2. The U.S. launch in partnership with UCB commenced in April and early feedback has been positive.

Now onto Aimovig on Slide 15. Versus Q1, sales increased 41%. We hold the leading share of the CGRP market and continue to see improvement in our conversion of free to paid patients exiting Q2 at 74% paid. That increase in the percentage of paid volume was a significant driver of quarter-over-quarter sales growth. Penetration in the overall market is currently low considering 4 million migraine patients in the U.S. are eligible for CGRP treatment. However, we remain optimistic a 7,000 patients a weak start a CGRP therapy and to-date 225,000 patients have been prescribed Aimovig with 1 million prescriptions filled.

Additionally, the number of prescribers is consistently increasing as 27,000 physicians have now prescribed Aimovig since launch, with close to 10,000 primary care prescribers among them. We expect net price to remain relatively stable going forward, as most patients have converted from free to paid and an increasing percentage of patients are covered under discounted contracts versus painful list price.

We launched a single convenient monthly Aimovig 140 milligram auto-injector replacing the 2 by 70 milligram presentation. Coupled with a further expansion into retail, we believe there is a small one-time increase in the amount of product in the channel in the quarter to prepare for this demand. We are confident that Aimovig will continue to grow and contribute to the strength of Amgen's innovative portfolio.

Moving to our hematology and oncology business, the portfolio of XGEVA, KYPROLIS, Nplate, Vectibix, BLINCYTO and IMLYGIC collectively totaled $1.3 billion in the quarter, growing 10% year-over-year.

For more detail on the larger brands, let's start with XGEVA on Slide 17. In Q2, XGEVA grew 10% year-over-year primarily from volume. In the U.S. shares approximately 60% and we're seeing rapid growth in multiple myeloma patients, while also growing the number of treated solid tumor patients.

KYPROLIS grew 2% year-on-year, driven primarily by 13% volume growth in the U.S. Recall that in the second quarter of last year, our international business recognized $27 million in clinical trial purchases and when normalizing for clinical trial purchases across periods, the underlying worldwide business grew 8%.

Moving to Enbrel. Sales increased 5% year-over-year, driven primarily by net selling price benefits. Overall, we expect volume trends to continue and anticipate a slight benefit from net selling price on a full year basis.

Next to Neulasta on Slide 20. Overall, the competitive dynamic is playing out, as we expected on a global basis. In Q2, Neulasta sales declined 25% year-over-year with a 24% decline in the U.S. Exit share of Neulasta in the U.S. was just under 80% in the long-acting segment with absolute units of Onpro stable on a quarter-over-quarter basis, as many providers and their patients continue to appreciate the benefits of Onpro. This performance reflects the confidence that our customers have in the reliability and quality of our supply. The decline in U.S. Neulasta units continues to come primarily from our prefilled syringe reflecting a competitive biosimilar market. Regarding our international business, Neulasta declined 31% due to increasing competition.

Switching to nephrology starting on Slide 21. Q2 EPOGEN sales declined to 11% due to lower net selling price. This quarter also benefited from approximately $15 million of large one-time end customer purchases and $13 million in favorable changes to accounting estimates. Given our contractual pricing commitments with DaVita, net price will continue to decline for Epogen in 2019.

Aranesp declined 8% year-over-year in Q2 driven by lower volume due to increased competition. We expect Aranesp sales to continue to decline at a faster rate in 2019 versus 2018, with both long-acting and short-acting competition in the U.S.

Parsabiv continues to experience solid growth more than doubling sales on a year-over-year basis. Independent and midsize dialysis providers utilize Parsabiv for a majority of their calcimimetics patients, while FMC and DaVita are increasing their adoption.

Turning to Sensipar. As a result of some at-risk small molecule generic launches, you can see on Slide 24, that Q2 sales declined by approximately $300 million year-over-year. We believe that inventory of generic Sensipar remains in the market. Given ongoing legal proceedings, there remains uncertainty about the magnitude of future U.S. Sensipar sales.

I would like to highlight the strong performance of our biosimilar products. Our launches of KANJINTI, our biosimilar to Herceptin and AMGEVITA, our biosimilar to Humira, outside the U.S. are progressing in line with our expectations, annualizing at greater than $300 million. We also recently launched our first ever biosimilars in the U.S. with KANJINTI and MVASI, our biosimilar to Avastin.

We are encouraged that our experience -- our experience in the dynamics of both innovator and biosimilar molecules and our expertise in world-class biologic manufacturing will benefit us greatly and shaping in advancing this important market for patients and payers.

In summary, I am pleased to see that our careful planning for the evolution of our product portfolio is progressing nicely. I continue to believe we are well positioned to deliver volume growth in the future, as we launch and grow new products, deliver value with biosimilar products and defend our mature brands. We are prepared for the challenges that faces and continue to drive toward providing patients with high-quality innovative and biosimilar products in markets across the globe.

Now let me turn it over to Dave Reese.

David M. Reese {BIO 19782623 <GO>}

Thanks Murdo, and good afternoon everyone. It's been a year since I assumed leadership of the R&D organization, and I wanted to take a moment to reflect on our progress. Two of the core challenges facing any R&D group are improving success rates and decreasing the drug development cycle time. To address these challenges, we have created a research organization that is tightly integrated triple-threat capabilities, namely one; human genetics as a foundation; two, a core strengthen in biology; and three, world-class molecular engineering. We have made tangible progress on all fronts, and I would like to highlight some recent announcements to build on this.

The acquisition of deCODE genetics gave us the industry-leading human genetics platform and we have expanded that capability. Today, there are about 1.6 million participants in the deCODE database. Last month, we announced the collaboration with Intermountain Health, a leading integrated delivery network here in the U.S., which will increase our sample size by up to a 0.5 million over the next five years.

This unique collaboration will give participants access to important genetic information as appropriate allow the leaders of Intermountain to use genetics to improve population health and enhance our target discovery and development efforts. The platform we have put in place will solidify our lead in use of human genetics for years to come.

Another investment in our innovation engine was the acquisition of Nuevolution now completed. We would like to welcome our new colleagues in Copenhagen and look forward to integrating their world-class expertise in DNA-encoded library and other technologies into our research platform. These technologies enhance our small molecule capabilities and our ability to engineer molecules that induce targeted protein degradation on which we will place a major emphasis going forward.

Turning to our therapeutic areas. In cardiovascular disease, we have completed enrollment in our omecamtiv mecarbil Phase 3 outcome study. At over 8,000 patients GALACTIC-HF is one of the largest heart failure clinical studies ever conducted and speaks to the emphasis, we have placed on building a clinical trials platform that can deliver rapid efficient study execution. This is an event-driven study and we will provide updates on expected timing as events accumulate.

With AMG 890, our Lp(a) small interfering RNA program, we are now enrolling patients with known elevated Lp(a) based on the data in healthy human volunteers and anticipate launching the next phase of development in the first half of next year.

In inflammation enrollment in our tezepelumab Phase 3 asthma study continues on schedule with data expected next year. We are also advancing AMG 570 a bispecific antibody-peptide conjugate that targets ICOS -ligand and BAFF in to Phase 2 for the treatment of systemic lupus erythematosus. I will have more to say on AMG 570 as the program progresses.

In our migraine portfolio, we recently presented additional long-term Aimovig data at the American Academy of Neurology and American Headache Society meetings that demonstrate sustained reductions in monthly migraine days. Aimovig is the only CGRP inhibitor with four-year clinical data in migraine, with 77% of Aimovig patients achieving at least a 50% response, more than half achieving at least 75% response and one-third achieving 100% response in monthly migraine day reduction. No new safety signals were detected over the extended treatment period.

In bone health, EVENITY is now approved in Japan and the U.S., as Murdo discussed and we also recently received approval in other countries, including Canada, Australia and South Korea. We were disappointed by the negative opinion for EVENITY and Europe by CHMP, UCB has submitted a written notice to the European Medicines Agency requesting reexamination of the CHMP opinion and we will support UCB in this endeavor. We strongly believe that EVENITY is an important treatment option in patients with postmenopausal osteoporosis, who are at high risk of fracture.

Turning to oncology. I'll begin with AMG 510, our KRAS G12C inhibitor. After nearly four decades of research in the pursuit of KRAS inhibitor, the response from the medical community to our first in human data at ASCO was simply overwhelming. We reported a 50% response rate in non-small cell lung cancer and very encouraging stable disease data in colorectal cancer with the tolerable adverse event profile.

Today I am pleased to report that we now have formal tumor responses in colorectal and appendiceal cancer patients and the program is moving forward rapidly. We have completed enrollment in our monotherapy expansion cohort and are also now enrolling non-small cell lung cancer patients in the PD-1 combination arm. We will also begin enrollment of lung cancer patients in the coming days in the potentially registration enabling Phase 2 monotherapy portion of the program, and we'll provide an update of our progress in lung cancer at the 2019 World Conference on Lung Cancer in early September.

I would highlight that we are coming up on just one year since initially entering the clinic in August of 2018. We remain extraordinarily enthusiastic about the promise of AMG 510 and continue to aggressively prosecute the development program.

Turning to our BiTE platform. We presented the first solid tumor data from a BiTE molecule at ASCO with AMG 212, our prostate-specific membrane antigen BiTE molecule for castrate-resistant prostate cancer. The initial data were very encouraging and we are currently in dose escalation with an extended half-life BiTE molecule AMG 160.

At ASCO, we also provided an update on our BCMA program with our canonical BiTE molecule AMG 420 showing durability out beyond a year in some multiple myeloma patients. AMG 701 our half-life extended BCMA BiTE molecule continues to advance nicely through dose escalation and we expect to present the initial first in human data at a medical meeting next spring depending on data availability.

Before I leave oncology, I would note that we have paused our DLL3 and FLT3 CAR T programs in the Kite collaboration. We continue to have a keen interest in cellular therapies. However, in light of our growing confidence in the BiTE platform, we will maintain our immediate strategic focus on the BiTE molecules and direct our efforts in cellular therapy towards developing new generation technologies likely through collaborations.

Briefly in biosimilars, we received FDA approval for KANJINTI for all approved indications of Herceptin. The non-Hodgkin's lymphoma study of ABP 798, our biosimilar Rituxan is completed dosing and we expect to have the data in-house by the end of Q3. And finally, the FDA review of ABP 710, our biosimilar REMICADE continues to progress toward the PDUFA target action date in December. Rob?

Robert A. Bradway {BIO 1850760 <GO>}

Okay. Thanks, David. Ian, now let's turn to questions and out of respect for the fact that we started an hour later than usual, we'll try to move briskly through this. So, if you could please remind our callers of the procedure for questions, we can get started.

Questions And Answers

Operator

(Operator Instructions) Our first question from the line of Ronny Gal from Bernstein. Ronny?

Q - Ronny Gal {BIO 15022045 <GO>}

Good morning and good afternoon everybody. Congratulations on a nice quarter and thanks for the -- thanks for the question. Biosimilars, I'd like to ask one on the attacking and defending side. First, congratulations on the launch of the two biosimilars in United States. For KANJINTI, you have only the 420 mg and another 150 mg yet.

Can you give us a timeline for when you think, going to get the lower dose in and do you think it will have an impact on the initial uptake? And on the defendant side, looking at Neulasta, would you be able to share with us kind of like the trends in the clinic non-340B hospitals and 340B hospitals, where is the adoption of biosimilars right now?

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

Okay. Ronny, thanks for the question. We'll take it in two parts. Murdo, do you have the answer to the first question on the 150?

A - Murdo Gordon {BIO 18450783 <GO>}

Yes. So, I don't have the exact timing for you Ronny, but we're not seeing a whole lot of resistance in the market initially to the conversations we're having with payers, hospitals

and providers. We're seeing good response to KANJINTI and MVASI and we feel good about our ability to compete with the presentations we have in the market right now.

And then on Neulasta, we continue to see the effects of biosimilar competition as we had anticipated. We are seeing an uptick of biosimilars in the 340B channel. We're also seeing a stronger performance of biosimilars in business that we have not contracted. So again, that is -- as we would have expected, but we're also seeing strong performance of Onpro on a unit basis quarter-over-quarter holding in majority of accounts. And that's something that we had hoped to see by now and we're feeling good that continues to happen.

And overall, I think it's recognized in the market that the ability for Amgen to supply high quality, reliability on our overall long-acting filgrastim business is being appreciated and continuing to support that franchise.

Operator

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

Q - Chris Raymond {BIO 4690861 <GO>}

Hey, thanks for taking the question. Just on AMG 510, so kind of keen on your commentary on the tumor responses in CRC. So, I wonder if you could maybe give some clarity here, are these new patients that were enrolled in (inaudible) maybe the 960 milligram dose or were these -- and I know you had an option for patients to have intra-patient updosing. So, any color there in terms of who responded would be great.

And then maybe a second part of that question that also on the registration trial, starting this year. I know you said it's in lung, but just kind of wondering if you could give some color on the design in the setting and what constitutes maybe a control in third-line lung that would be great. Thanks.

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

Yeah, sure. With regard to colorectal, the majority of patients that we're reporting going forward will have been treated at 960 milligrams. As you may recall, at ASCO, we only had I think one patient at that point, who is on that dose level. And so, we will provide updates in that particular indication as we accumulate data towards the end of the year and the first part of next year, when we have enough patients at the target dose to get a real sense of the clinical activity.

In terms of potential registration plans, we would assume that lung cancer will be the lead indication going forward. As I mentioned in the coming days, we will be enrolling in the Phase 2 portion of that program. We're moving very, very rapidly and we'll provide updates on that particular pathway as we go forward. But I would say we've had productive discussions with regulatory authorities and have a good sense of the pathways moving forward.

Operator

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

Q - Matthew Harrison {BIO 17603148 <GO>}

Great. Thanks for taking my question. I guess another pipeline question for me. Can you just clarify on the half-life extended BiTE, what your view on the data that we may see in the fall? And what that data needs to look like versus the canonical BiTEs that you've reported so far in terms of efficacy and safety to move those programs ahead? Thanks.

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

Yeah. I think Matt as we've said in the past, in general, we will prefer the half-life extended program, all things being equal, meaning seeing efficacy and safety profiles that are comparable to what one would expect with a short half-life or first generation BiTE. Based on emerging data, I think we're getting increasing confidence in the half-life extended program, when we look forward to sharing those data across both hematologic malignancies and solid tumors as we go forward.

Operator

And our next question is from line of Evan Seigerman from Credit Suisse. Evan?

Q - Evan Seigerman {BIO 18922817 <GO>}

Hi all, thanks for taking the question. So, on your recent biosimilar launches in the United States, how do you really compete with the innovator of molecules? And I guess what structural changes do you need to just see in the U.S. healthcare system to encourage more use of biosimilars? And what's your view on the broad use of rebates to protect branded biologics in light of biosimilar competition? So, there is a few in there?

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

Yeah, there is a few questions in there. But we'll take these in part Evan.

Q - Evan Seigerman {BIO 18922817 <GO>}

Thank you.

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

First go head Murdo.

A - Murdo Gordon {BIO 18450783 <GO>}

Yerah, Evan thank you. I mean the gist of your question seem to surround the viability of the biosimilar market in the U.S. and I think in two parts. We are seeing a very healthy competitive biosimilar market evolve. We're experiencing competition on Neulasta and

we anticipate being able to compete effectively with our new biosimilar launches with both MVASI and KANJINTI.

I think competitively where Amgen differentiates is, in the fact that we have four decades of high-quality, reliable supply in the market. We are able to offer physician and patient educational services and reimbursement support. And we're also able to cover many of these customers, who will be making treatment decisions using our biosimilars, given our strong history and experience in the oncology sector.

I also think that the dynamics on pricing and competition, while fluid are less of a barrier than they once were and I think that we will continue to see deeper and deeper penetration of biosimilars against originator products in the U.S. in the future. And I will just remind you that we have many years of experience now outside of the U.S. in Europe in biosimilars, and I think the market in Europe started slow and has since become a very mature, very attractive market for biosimilars manufacturers.

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

I'd just add there Evan from a policy perspective, there are some in the industry, who are advocating for changes that would favor biosimilars over the innovator molecules. We are not among them. We think that what the country needs is a long-term, vibrant, competitive marketplace for biosimilars. And our fear would be anything that tilts the playing field to biosimilars might perversely have the long-term effect of diminishing the competitive opportunity in the U.S. And we want to avoid what has happened, for example, in the small molecule generic industry in the U.S., where there are unfortunate market abuses relating to the fact that there are single companies left with the license to manufacture individual generic products.

So, we think that for the long run what the country needs is a vibrant competitive market for biosimilars, produced safely and reliably by competitors that can earn a fair return for their effort and we think we'll be able to do that without having to have policies that tilt the playing field in favor of those biosimilar molecules.

A - Murdo Gordon {BIO 18450783 <GO>}

Thanks. And if I can just jump in to close out Ronny Gal's earlier question, the FDA action date on KANJINTI 150 milligram SKU is October 28, 2019.

Operator

And our next question is from the line of Yaron Werber from Cowen. Yaron?

Q - Yaron Werber {BIO 19486720 <GO>}

Great, thank you. And David, I have a follow-up also on 510, a little bit, in two parts. Maybe the first one the -- what can you share with us on solubility or formulation of the compound? We understand that solubility is better in the gastric acidity, a little bit lower in the intestinal. So, what do you see there? And is there anything special on the formulation? And then on the CRC side, as you contemplate combo as the next-stage

now that you're seeing single agent activity, are you thinking a PD-1 combo or is that going to be a TKI combo next? Thank you.

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

Sure. So, let me take both of those questions in turn Yaron. In terms of solubility, I would say, broadly, we've been very happy with the pharmacokinetic and pharmacodynamic profile of the drug. And again to remind everyone with a covalent inhibitor, the key is really to maintain exposures above a target level for a period of time that is adequate to poison the target through a dosing interval. And based on what we've seen in the clinic to-date now across several dozen patients, gives us the confidence that we've got a very attractive pharmacokinetic profile.

In terms of colorectal cancer, obviously combinations will be of great interest going forward, I would say, potentially both with immunotherapeutic agents and additional targeted therapies and as that program moves forward, we'll provide additional guidance a little later in the year and early into next year.

Operator

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

Q - Geoffrey Porges {BIO 3112036 <GO>}

Thank you very much. I appreciate taking the question. And I'll try and confine myself to three sub-parts. I guess the main question that we are being still asked is about the Sandoz litigation. And I think we all expected that we would get a result from the district court by now. And I'm sure you can't really comment, but could you talk hypothetically perhaps about what your fallbacks might be, if unexpectedly your issued patent was overturned? Should we be anticipating that there is the risk of rapid erosion of Enbrel, sort of along the Neulasta trajectory, or could you kind of give us some thoughts, Bob, on how the outlook is for that?

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

Sure. Geoff, I understand that you're anxious for an answer from the courts and, of course, are we. We are, as you know, confident in the intellectual property surrounding Enbrel. So, we're -- we don't know any more than you do about when we will expect that -- when we should expect that decision. But if for whatever reason that decision were to surprise us and go against us, as you can imagine we would appeal that because again we feel that we have robust intellectual property for the molecule and we intend for that intellectual property be respected. So, I think as to the hypothetical question about competition for Enbrel, we will defer discussing that Geoff at this time. Thanks.

Operator

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

Q - Umer Raffat {BIO 16743519 <GO>}

Hi, thanks so much for taking my questions. I had one question with three parts. It's all just clarification. So, thank you for that update on KRAS with -- and you mentioned formal tumor responses. I wanted to ask, just clarify, A, are these resist responses number one? Number two; can you confirm if it's more than one response in colorectal, or are you counting one colorectal and one appendiceal? And finally, also, at what dose level? Thank you very much.

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

Yeah, so taking those three parts in turn, yes, these are resist responses, which is what I alluded to by saying formal tumor responses. It is a patient each in colorectal cancer and appendiceal cancer. These -- many of the patients dosed have yet to have repeat scans done. So, we expect in the coming few months to have a large amount of additional data at the target dose.

Recall that we just opened the expansion cohort not long ago and have had a flood of patients enrolling on that. We are -- continue to see very good tolerability. I've been involved in Phase I drug development for a long time now and I can say, I'm only very impressed with the emerging safety profile that we are seeing with AMG 510.

A - Unidentified Speaker

Dose levels?

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

And dose levels going forward it's all at 960 milligrams.

Operator

And our next question is from the line of Mohit Bansal from Citigroup. Mohit?

Q - Mohit Bansal {BIO 18070890 <GO>}

Great. Thanks for taking my question and thanks Arvind for the shout out. A quick one on your Lp(a) candidate. Could you please compare and contrast your siRNA approach versus the oligonucleotide approach mechanistically and should we expect comparable results when we see the data later this year or early next year? Thank you.

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

Yeah, I'll be happy to address that question. So, the question is around Lp(a). We've seen, I would say, very encouraging data in the healthy volunteer portion of the first in human study. We are now dosing patients with elevated Lp(a) levels and expect to move into the next phase of that development program based on the promising clinical data that we've seen to-date in the early part of next year.

We like the siRNA approach. I can't comment specifically on other molecules in antisense oligonucleotides. In the long term, safety will be a critical component of any of these development programs. In addition, I would point out that something like siRNA will

probably be required to tackle Lp(a) because of the nature of the molecule and the types of modalities that will be necessary to actually lower levels.

Operator

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

Q - Terence Flynn {BIO 15030404 <GO>}

Hi, thanks for taking the question. Maybe, Bob, a big picture one, we've obviously seen a lot of M&A in the space recently. Just as you think about your capital allocation strategy, how does the Enbrel litigation I guess fit into that? And again, as you think big picture about what's going on in the industry, how are you thinking about where Amgen can maybe play a role or part? Thanks.

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

I think Terence as I said in my remarks, we have strong cash flow, strong balance sheet. We think the company is performing well and we think we can grow the business organically and we're also looking at ways to grow through business development. So, we're -- I would expect that we will continue to be disciplined, looking at opportunities in our stated areas of therapeutic interest and the geographic regions where we have stated our desire to expand. But again, we have a world-class business development effort and we continue to look at opportunities, large and small.

Operator

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

Q - Kennen MacKay {BIO 18821382 <GO>}

Hi, thanks for taking the question. Maybe one for Murdo on Neulasta. I guess -- I just were thinking about your guidance on the majority of the erosion coming from the prefilled syringe. Should we think that this is basically gone now, given the Onpro still commands sort of mid-60% of this market and sales are down sort of 30% since biosimilar competition? Or, have we basically seen the impact of the biosimilars, or is there still more erosion to come? Thank you.

A - Murdo Gordon {BIO 18450783 <GO>}

Yeah, thanks, Kennen. The trends that we are seeing are a function of obviously having now two competition -- two competitors in the market. And since the advent of the second competitor, we've clearly seen more volume erosion and more price erosion. We are assuming that we could still see an additional competitor this year. And I would say that the current trends on the prefilled syringe will continue and we may see some price pressure on Onpro. What we are seeing with Onpro is stable unit evolution quarter-on-quarter and that makes us feel good about the differentiation that Onpro provides both physicians and patients and the convenience and persistency that it offers. I think looking

forward, we continue to think that this is going to be a competitive biosimilar place in that space.

Operator

And our next question is from line of Jay Olson from Oppenheimer. Jay?

Q - Jay Olson {BIO 18027199 <GO>}

Hey guys, congrats on the quarter and thank you for taking the question. There was a recent German court ruling in favor of Amgen confirming that Praluent infringes on your PCSK9 patents. And I was wondering if you could please share any thoughts you had on how market dynamics may evolve in Germany or other markets, if there are any, where Praluent may no longer be available?

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

Yeah, thanks for the question, Jay. First, the European Patent Office upheld our intellectual property for Repatha, and upheld the innovative contribution that we've made to the field with that product. The German courts found that they infringed obviously that IP and instructed them to be removed from the market. Sanofi filed an appeal and that matter is under review. And our focus, of course, will be on making sure that whichever patients need a therapy are able to receive it and we think we are in position to be able to satisfy the needs of that market.

But I think you're right that Germany is another market now where our IP has been upheld. As I said, the European Patent Office upheld our IP more broadly in that region, that follows Japan, which is also found in our favor. And of course, as you know, we've had two trials in courts in the U.S. on the matter, both of which were jury trials that found in our favor. So, the IP process continues to move forward in Europe, Asia and the United States.

Operator

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

Q - Michael Yee {BIO 15077976 <GO>}

Hey, great. Thanks for the question. David Reese, on KRAS, you talked about responses in colorectal et cetera. Maybe just going back to lung, can you comment on confidence around longer-term durability in monotherapy? And then to the comments around enrollment with the combination of P1, talk about what you would expect to see there, and when we could get first data, as obviously, I would assume that's an exciting opportunity. Thanks.

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

Yeah. Thanks, Mike. Yeah, in terms of durability, as I mentioned, we will be presenting a clinical update at the World Lung Conference in September, but I would say that to-date,

we've been favorably impressed with potential durability. We have to all recall that it's early days and many of these patients have been recently enrolled on trial. So, we'll gain further insight into durability as time goes on. But at least today, we are not seeing, for example, the rapid emergence of resistance.

In the PD-1 combinations, we have what I think are very strong preclinical data, suggesting potential synergistic interactions between KRAS inhibition and checkpoint inhibition, probably due to enhanced immune infiltration and up regulation of Class 1 MHC on tumor cells and our goal with that kind of combination would of course be very long-lasting, durable remissions.

Operator

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

Q - Alethia Young {BIO 17451976 <GO>}

Hey guys, thanks for taking my question. One question, maybe one clarification. Just can you talk a little bit about -- in the Repatha situation with the co-pays like kind of what are the moving pieces there to kind of get the ball rolling, is it just mostly negotiations, and maybe why is it occurring? And then on KRAS, are you planning on dosing beyond 960 in colorectal? Thanks.

A - Murdo Gordon {BIO 18450783 <GO>}

Okay. So Alethia, maybe I can start with the Repatha question, and then I'll turn it over to Dave. As you know, the PCSK9 market is a competitive one and given that competition last year there were payer negotiations in contracts that occurred. And since then some commercial access improvements have been realized. I would say that our reduction of the -- our introduction of the low-list price Repatha in October of last year was to try to improve the Medicare Part D reimbursement.

And we recognized that the time that we were off cycle or mid-cycle in the normal process by which PBMs and other payers produce their Part D benefit designs. And so while we had hoped that some payers and PBMs would move quickly to add low list price Repatha to Medicare Part D formularies at a fixed co-pay that has not transpired. So, we are optimistic that we will be able to make a significant improvement in Medicare Part D fixed co-pay listings for Repatha, as we enter the 2020 Medicare Part D formulary benefit year and we will know that in the fourth quarter.

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

Great. In terms of dosing in colorectal cancer beyond 960 milligrams, as I mentioned, we've enrolled now a fair number of patients at that target dose. I think we'll look for insights from that cohort. It remains early in this development program and with these drugs, of course, there is often tweaking of dosing and scheduling as you go along. But I would say that at this point 960 is our target dose. We will assess emerging data to see if we want to explore some other doses and schedules going forward.

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

Okay. Why don't we take two last questions, Ian and then we'll wrap up.

Operator

Very well. Our next question from line of Do Kim from BMO Capital Markets. Do?

Q - Do Kim {BIO 18706913 <GO>}

Great. Thanks for squeezing me in. Just on the acquisition of Nuevolution, I was hoping you could provide some context on the decision to acquire and bring the platform in-house, versus just licensing additional programs or buying another company with assets in clinical stage? And what is the plan for their existing collaborations and then the potential for new ones?

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

Yes, sure. I will be happy to address that. So, the new Nuevolution acquisition actually grew out of a partnership that we had with them on programs that was quite successful and when we looked at the breadth of expansion of that potential partnership. We thought that simply bringing them onboard made sense.

I terms of their existing obligation, obviously, those are things that we will fulfill as we move forward. I would point out that we plan on and have established them as Amgen's Research Copenhagen. And they will remain a standalone Amgen research site going forward and we're incredibly enthusiastic about what we think is world-leading technology.

A - Arvind Sood {BIO 4246286 <GO>}

Ian let's take one last question if there is, one after which Bob will make a few closing comments and then I'll close the call.

Operator

Very well. Our final question is from the line of Salim Syed from Mizuho Securities. Salim?

Q - Salim Syed {BIO 16887281 <GO>}

Hey guys, thanks for taking the question. Hey Bob, I appreciate the commentary on M&A. I just had a follow-up on it and I totally understand you're looking at how to grow the top-line both internally and externally. But I guess what would you say to what are the gating factors have been? Why haven't you done more M&A this year that the science that you're not seeing something that you want or the evaluation with FTC , or do you truly believe that the highest ROI, you can get right now is just buying back your own stock? Thank you.

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

I think Salim, we look at a range of opportunities. I think valuations have been stretched. It's been hard for us and some of the things that we like to find transactions at prices that we think can earn a return for our shareholders. It's easy to earn a return for the target shareholders, but we're keen in focused on trying to earn the return for our shareholders.

So, that's clearly been a consideration for us more than anything else, I think. But again, we continue to look for opportunities and fully expect that by being disciplined, we will find ones that enable us to win for our shareholders and to invest in programs that can help us grow the company. So, we're optimistic, we're pleased that we have the resources to be able to move forward and the money is not burning a hole in our pocket.

A - Arvind Sood {BIO 4246286 <GO>}

Okay. So with that, Bob, do you want to make some closing comments.

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

Sure. Let me just end where I started, which is to say that we're pleased with our performance through the first half of the year and excited about our long-term prospects, which we think are driven in large part by what we think will be unit volume gains across a number of our important products and excited as well about our innovative pipeline in the prospect of branded biosimilars adding to our top-line.

And let me just finally, thank our Amgen's staff around the world, who continue to help us deliver on our mission to serve patients, while remaining focused on driving value for our shareholders.

A - Arvind Sood {BIO 4246286 <GO>}

Excellent, thanks Bob. And thanks to all of you for your participation. If you have any follow-on comments, questions, if you would like to continue the discussion, feel free to call us the IR team will be standing by for several hours. Thanks again.

Operator

Ladies and gentlemen, this does conclude today's conference. We thank you greatly for your participation. You may now disconnect.
