AbbVie (ABBV) Earnings Report: Q3 2015 Conference Call Transcript

The following AbbVie conference call took place on October 30, 2015, 09:00 AM ET. This is a transcript of that earnings call:

Company Participants

- Larry Peepo; AbbVie; Investor Relations
- Rick Gonzalez; AbbVie; Chairman & CEO
- Bill Chase; AbbVie; CFO
- Laura Schumacher; AbbVie; General Counsel
- Michael Severino; AbbVie; Chief Scientific Officer

Other Participants

- Jami Rubin; Goldman Sachs; Analyst
- Jeffrey Holford; Jefferies LLC; Analyst
- Marc Goodman; UBS; Analyst
- Chris Schott; JPMorgan; Analyst
- Mark Schoenebaum; Evercore ISI; Analyst
- Vamil Divan; Credit Suisse; Analyst
- Alex Arfaei; BMO Capital Markets; Analyst
- Colin Bristow; Bank of America Merrill Lynch; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Welcome to the AbbVie third-quarter 2015 earnings conference call.

(Operator Instructions)

This call is being recorded. If you have any objections, you may disconnect at this point.

I'd now like to introduce Mr. Larry Peepo, Vice President of Investor Relations.

Larry Peepo (Investor Relations):

Good morning. Thanks for joining us today.

Also on the call with me is Rick Gonzalez, Chairman of the Board and Chief Executive Officer; Laura Schumacher, Executive Vice President, Business Development, External Affairs, and General Counsel; Michael Severino, Executive Vice President of Research and Development, and Chief Scientific Officer; and Bill Chase, Executive Vice President of Finance and Chief Financial Officer.

Before we get started, I'll remind you that some statements we make today may be considered forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Additional information about the factors that may affect AbbVie's operations is included in our 2014 annual report on Form 10-K and

our other SEC filings. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

On today's conference call, as in the past, non-GAAP financial measures will be used to help investors understand AbbVie's ongoing business performance. These non-GAAP financial measures are reconciled with comparable GAAP financial measures in our earnings release and regulatory filings from today, which can be found on our Web site. We want to remind you that we issued two separate news releases this morning in advance of today's call and have also posted slides on AbbVieinvestor.com that supplement some of the content we'll be covering this morning.

Following our prepared remarks, we'll take your questions. So with that, I'll now turn the call over to Rick.

Rick Gonzalez (Chairman & CEO):

Thank you, Larry. Good morning, everyone, and thank you for joining us. As Larry mentioned we'll be covering two topics on the call this morning.

I'll briefly discuss our third-quarter 2015 performance highlights, and Bill will walk you through the quarter in a bit more detail. I'll then discuss the Company's long-term strategic and financial objectives that we outlined this morning, including our expectations for growth and other financial metrics over our long-range plan. And as always, we'll provide ample time to answer your questions.

We delivered another quarter of strong performance, with third-quarter results well ahead of our expectations. Adjusted earnings per share were $1.13, representing growth of nearly 27% versus the third quarter of 2014.

This is the third consecutive quarter of delivering roughly 30% EPS growth. Our results in the quarter included operational sales growth of more than 26%.

Before I provide an overview of our highlights in the quarter, I'll briefly provide our perspective on the recent update to our US Viekira label. As you are likely aware, last week we updated the prescribing information to reflect a change in the use of Viekira in certain patients with advanced cirrhosis, specifically, Child-Pugh B patients. Viekira went from not recommended to contraindicated. Viekira was and remains contraindicated in Child-Pugh C patients. In addition, the updated label recommends a clinical and laboratory assessment for patients with cirrhosis to ensure that those with decompensated disease are identified.

Turning now to the other quarterly events, in the quarter, we advanced several important strategic priorities, continued to enhance operational efficiency, and achieved a number of clinical and regulatory objectives. Our third-quarter performance was driven by growth from several products in our portfolio, including strong growth from Humira and Imbruvica, continued global uptake of Viekira, and continued growth from Creon and Duodopa.

We also continued to improve efficiency across our operations, delivering roughly 640 basis points in operating margin expansion this quarter versus the prior year, achieving an operating margin of 44.9%. I'll discuss our commitment to further drive this metric in the context of our long-term financial objectives in just a few moments.

We continue to be very pleased with the advancement and derisking of our mid- and late-stage pipeline. During the quarter, we reported positive data, advanced programs into the regulatory approval cycle, and received approval for several assets.

Last month we reported positive top-line results from two Phase 2b studies of our selective JAK1 inhibitor. We believe ABT-494 has a very compelling profile, with the potential for best-in-class efficacy even in the

most difficult-to-treat TNF-inadequate responder patients and with once-daily dosing. We'll present the full results from the two mid-stage trials at an upcoming medical meeting and are on track to initiate the Phase 3 studies by year-end.

We also reported positive top-line findings from a Phase 2b trial of elagolix in patients with uterine fibroids. Preliminary results from the six-month study demonstrated that all of the treatment arms achieved the study's primary endpoint. Based on these findings, we plan to advance elagolix into Phase 3 development for fibroids, with initiation expected in the first quarter of 2016.

We recently submitted the US regulatory application for Imbruvica as a therapy in treatment-naive patients with CLL. In June, we announced the top-line results from the Phase 3 RESONATE-2 trial comparing Imbruvica monotherapy to chlorambucil in patients aged 65 or older. The results illustrate that treatment with Imbruvica significantly improved progression-free survival and multiple secondary endpoints, including overall survival in first-line therapy.

As we have said, a significant portion of our valuation for Pharmacyclics was attributed to advancing into first-line treatment. And while we assumed a very high probability of success, the RESONATE-2 data provides strong evidence of Imbruvica's efficacy in a frontline setting, further derisking this component of our model.

The trial results will be published in a peer-reviewed medical journal and presented at an upcoming medical meeting, and we anticipate a regulatory decision to use in treatment-naive first-line patients in the first half of 2016. Given the robust results we have a high degree of confidence that Imbruvica will be very successful as frontline therapy.

We also recently completed our US regulatory submission for venetoclax, or ABT-199, in relapsed-refractory CLL patients with 17p deletion. We also recently received regulatory approval for our two-pill, once-daily HCV therapy in Japan. We expect to receive reimbursement and launch in Japan in the next month or so.

Late last month we submitted our regulatory application for a once-daily formulation of Viekira Pak in the US. Finally, during the quarter, we received US regulatory approval for Humira as a treatment for HS, and we submitted our US and European regulatory applications for Humira as a treatment for uveitis.

In summary, we delivered another quarter of strong results, exceeding our guidance range for the quarter, and we raised our full-year 2015 outlook to the upper end of our previous guidance range, reflecting growth of roughly 28%. Our results year-to-date demonstrate the significant progress we've made towards our objective of delivering industry-leading growth.

I'll discuss our strong outlook for 2016 as well as our longer-term financial commitments after Bill covers our third-quarter results in more detail. With that, I'll turn the call over to Bill. Bill?

Bill Chase (CFO):

Thank you, Rick. This morning I'll review our third-quarter performance and provide an update on our outlook for 2015. As Rick mentioned, in addition to delivering strong top-line growth in the third quarter, we again exceeded our earnings per share guidance range with growth of nearly 27% versus the third quarter of 2014.

Operational growth on the top line was very strong at 26.2%, excluding a 7.8% negative impact from foreign exchange. Reported sales were up 18.4%.

Humira delivered global sales of more than $3.6 billion, up 19.6% on an operational basis. We continue to see strong momentum for Humira as the market leader around the world. On a reported basis, currency

had a negative 7.5% impact on global Humira sales and reduced international Humira sales by 16%.

US Humira sales increased 30.4%. We've seen acceleration and market growth this year in the US, with Humira driving strong growth across the gastro, rheum, and derm segments. Wholesale inventory levels remained constant at roughly half a month.

Internationally, Humira sales increased 7.1% on an operational basis in the third quarter, roughly double the rate of growth we reported in the second quarter. Humira's momentum has not been adversely impacted by the Remicade biosimilar. We continue to see only modest overall share gains for the biosimilar in the major markets, in line with our planning assumptions.

Humira's list of indications continues to grow, with recent EMA and FDA approvals for HS. Humira is also currently under regulatory review for uveitis, with approval expected by the end of 2016. Global peak year sales for HS are expected to be approximately $1 billion per year, while uveitis sales are expected to reach several hundred million dollars per year.

For the full-year 2015, we now expect global Humira sales growth in the high teens on an operational basis, an increase from previous guidance of midteens operational growth. This reflects a forecast for US growth approaching 30% and high-single-digit international operational growth.

This was the first full quarter of Imbruvica sales since the closing of the Pharmacyclics acquisition, and global sales were strong at $304 million. US sales were $267 million, and our international profit-sharing was $37 million. For 2015, we continue to expect Pharmacyclics to add more than $750 million to our top line for revenue occurring after the May 26 closing date.

Global Viekira sales in the third quarter were $469 million. The international launch has continued to exceed our planning expectations and has resulted in a higher mix of international sales this year.

As Rick mentioned, we recently received regulatory approval in Japan for our two-drug, once-daily ribavirin-free combination for the treatment of genotype 1b. We anticipate launching in Japan next month following the traditional 60-day reimbursement review cycle.

We also saw a strong performance across a number of our other products including Duodopa, Creon, and Lupron.

Turning to the P&L profile, we are pleased with our progress in the quarter, as we showed continued improvement in gross margin as a percentage of sales. The adjusted gross margin ratio was 83.3%, driven by exchange, operational efficiencies, as well as product mix.

Adjusted R&D was 15.4% of sales, reflecting funding actions in support of our pipeline assets. Adjusted SG&A was 23% of sales in the third quarter, down from the prior year, contributing to continued improvement in our operating margin profile.

We delivered an adjusted operating margin of 44.9% of sales, up 640 basis points versus the prior-year quarter. After adjusting for a modest negative impact from Pharmacyclics, more than 500 basis points of this improvement was driven by efficiencies and P&L leverage.

Net interest expense was $197 million, reflecting the impact of debt issued in connection with the Pharmacyclics acquisition. The adjusted tax rate was 21.9% in the quarter.

Third-quarter adjusted earnings per share, excluding noncash intangible amortization expense and specified items, were $1.13, up nearly 27% year-over-year and exceeding our previous guidance range. On a GAAP basis, earnings per share were $0.74.

Moving on to our outlook for the remainder of the year, we are raising our 2015 adjusted EPS guidance to a range of $4.26 to $4.28. This reflects EPS growth of approximately 28% at the midpoint. This guidance excludes $1.10 per share of intangible amortization expense, deal costs, integration, and other specified items.

We expect fourth-quarter revenue growth on an operational basis in the low 20% range, excluding approximately 5% negative impact from exchange in the quarter. For the full-year 2015, we are forecasting an operating margin of 42% to 42.5% of sales.

And as Rick noted, today we provided a 2016 adjusted earnings per share guidance range of $4.90 to $5.10. We'll provide more detail regarding this guidance as we normally do on the fourth-quarter call in January.

So, in conclusion, we are pleased with the drivers of our strong performance, further demonstrating the quality of our results in the quarter and thus far in 2015. We have driven strong top- and bottom-line growth and delivered operating margin expansion while also advancing our strategic priorities. This puts us in a strong position to deliver top-tier industry growth this year and in the coming years.

With that, I'll turn it back to Rick to walk you through our long-term strategic objectives.

Rick Gonzalez (Chairman & CEO):

Thanks, Bill. As a reminder, we have posted slides to our Web site which you can use to follow along. My remarks regarding our long-term strategy generally coincide with the presentation.

Today, we'll share with you some of the key assumptions from our long-range plan, which we review annually with our Board of Directors. Over the past couple of quarters there has been an increasing level of interest from investors for more detail on our views regarding a variety of topics, including AbbVie's long-term growth prospects over the next several years, our ability to expand margins, our expectations around biosimilars, and our pipeline prospects.

Additionally, as we evaluated our long-range plan's expected performance versus Wall Street's consensus, there is a clear gap in revenue and EPS growth. Based on these dynamics, we decided it was appropriate to provide investors with a clear view of our expected performance and the significant drivers of that performance.

Turning to slide 3, our mission when we launched as an independent company was to create an innovation-driven patient-focused specialty biopharmaceutical company capable of achieving sustainable top-tier performance through outstanding execution and a consistent stream of innovative new medicines. Our actions since our inception have clearly supported that mission.

We've built an innovation-driven culture, attracting top talent focus on developing new products to address some of the most serious health conditions. We've delivered outstanding performance from our promoted portfolio. This includes Humira, where we have accelerated growth and developed a comprehensive strategy for the future.

Our heightened level of R&D investment has generated above-industry success rate with positive clinical data and regulatory outcomes from a number of development programs. Our pipeline now has a number of late-stage derisked assets with multibillion-dollar potential.

We acquired Pharmacyclics, providing a major new growth platform in a key strategic area and significantly strengthening our long-term growth prospects.

We have placed a significant focus on driving operating efficiencies, with impressive results to date.

We've built shareholder value and confidence with investors based on consistent, strong performance. And we have delivered strong return of capital to investors, including a rapidly growing dividend.

Our actions have placed AbbVie in a position to achieve top-tier performance, and you clearly see that in our results. As I mentioned earlier, our current guidance projects EPS growth of more than 28% in 2015. Our fundamental strategy is strong, and we've built an excellent foundation.

As you can see on slide 4, since 2013 we have consistently delivered strong financial results, including acceleration across key financial parameters. We've generated significant top- and bottom-line growth and robust operating cash flows.

Turning to slide 5, despite our enhanced level of R&D spend as you can see on this slide, which has grown substantially since we were a division within Abbott, we've driven significant improvement in both gross and operating margin profiles. We remain focused on further margin expansion, and I'll outline our commitments to enhancing these metrics in just a moment.

Moving to slide 6, we've also established a strong track record of delivering on our financial commitments, consistently meeting or exceeding our earnings estimates. We're proud of this outperformance, and we remain disciplined in achieving our stated objectives.

As noted on slide 7, AbbVie's total shareholder return since separation is nearly 76%, a result that places AbbVie in the top third of our peer group. These strong returns have created more than $35 billion of value for our shareholders and a market cap of nearly $90 billion.

Turning to slide 8, while we've demonstrated a very strong track record of historical performance, we are also committed to delivering top-tier results in the years to come. As we evaluate our prospects over our long-range plan, we believe we're well positioned for success.

We're strategically positioned in attractive, high-growth market segments. And based on continued strong performance from our existing portfolio of on-market products, including our flagship brands Humira and Imbruvica, as well as growth from our pipeline products, we expect to deliver top-tier revenue growth through 2020.

Today, as you can see on slide 8, we're providing guidance for total Company sales of approximately $37 billion in 2020. This reflects 10% top-line sales growth on average over the five-year period.

This guidance includes estimated global Humira sales of more than $18 billion in 2020, which we believe appropriately captures the expected biosimilar dynamics globally. I'll share more detail on our comprehensive strategy to continue our leadership position in immunology later in these remarks.

Additionally, we expect AbbVie's Imbruvica revenues to reach approximately $5 billion in 2020, driven by continued growth within the hematological oncology market. And our pipeline has the potential to achieve nominal peak revenues of nearly $30 billion by 2024. This estimate excludes new Humira and Imbruvica indications and sales from our next-generation HCV combination, which are considered on-market products for the purpose of this calculation.

We have the potential to launch more than 20 new products or indications through 2020, including seven approvals that will contribute in 2016 and beyond. I'll discuss some of these promising programs today, but we will be covering our full pipeline in more detail at an R&D Pipeline Review to be held in Chicago during the 2016 ASCO meeting.

As I mentioned, our significant focus on operating efficiencies has resulted in strong improvement of our gross and operating margin profiles. The Company is committed to driving continued expansion of operating margin and is targeting an adjusted operating margin of greater than 50% by 2020, with an

average of 100 to 200 basis points of improvement per year.

AbbVie also remains committed to returning cash to shareholders through a strong and growing dividend. To that end, today we announced that our Board declared an increase in our quarterly cash dividend from $0.51 per share to $0.57 per share, an increase of approximately 12% beginning with the dividend payable in February 2016.

Our commitment to top-line growth and continued operating margin expansion will drive double-digit earnings per share growth on average through 2020. And today, we're issuing strong full-year 2016 adjusted EPS guidance of $4.90 to $5.10. This outlook represents 17% growth versus 2015 at the midpoint and positions AbbVie to be among the industry leaders for EPS growth again next year.

Turning now to slide 9. To accomplish these goals we have narrowed our focus and positioned AbbVie for leadership in extremely attractive market segments. Our core areas of therapeutic focus include immunology, where we have a strong leadership position across rheumatology, GI, and dermatology. We're leveraging our scientific leadership and expertise to develop next-generation biologics and small molecules that elevate standard of care. We have multiple pipeline assets in mid- to late-stage development with best in class potential.

The oncology market represents an $85 billion segment projected to grow at a compounded annual growth rate of 12% through 2020. Within this market, we have a developing leadership position in the hematological segment with Imbruvica, and we have several other mechanisms in development including our Bcl-2, PI3-kinase, and our anti-CS1 antibody drug conjugate.

We also have an emerging pipeline of assets for the treatment of solid tumors including our PARP inhibitor, veliparib, and ABT-414 for glioblastoma multiforma.

Virology also represents a large and durable segment for us. We've established a foothold in the marketplace with our current offering, Viekira. Our emphasis is on continuing to evolve HCV treatment, and our next-generation combination is poised to deliver meaningful improvements relative to currently available therapies.

Earlier this year we disclosed preliminary results from a Phase 2b study of our next-generation protease inhibitor, ABT-493, and our next-generation NS5A inhibitor, ABT-530. The interim data showed non-cirrhotic genotype 1a and 1b treatment-naive and experienced patients receiving the ribavirin-free therapy for 12 weeks achieved SVR12 rates of 99%. The dose we intend to pursue in Phase 3 drove SVR12 rates of 100%.

Preliminary results from the eight-week treatment cohort were disclosed last week. These data showed that 34 of 34, or 100%, of genotype 1 patients achieved SVR4. We'll share additional results from our next-generation combination at the AASLD meeting next month.

Neurology represents a large market with significant unmet need. We're focused on developing disease-modifying therapies for Alzheimer's and other neurodegenerative conditions. Our existing portfolio includes Duopa for the treatment of advanced Parkinson disease and Zinbryta, which is currently under regulatory review in the US and Europe for multiple sclerosis.

We're also placing focused investment in our late-stage programs in women's health with elagolix, and renal disease with atrasentan, as well as early-stage programs in cystic fibrosis. Endometriosis and uterine fibroids are both highly prevalent conditions, and elagolix has demonstrated promising results in the treatment of both of these conditions.

Now turning to slide 10. Based on our long-range plan for our marketed product portfolio and our risk-

adjusted pipeline, we are targeting total revenue of approximately $37 billion in 2020, reflecting a top-line compounded annual growth rate of 10%. As you can see, our estimates are roughly $5 billion above the current Wall Street consensus.

Our 2020 target revenue is based on a number of performance drivers. We expect Humira to continue to be a strong growth driver, adding close to $4 billion in sales by 2020. AbbVie's Imbruvica revenues will reach approximately $5 billion by 2020.

Our HCV franchise will remain a significant contributor through our long-range plan. Our pipeline will add more than $4 billion in risk-adjusted sales, and Duopa will reach blockbuster status globally.

Turning now to slide 11, we expect several key products within our current marketed product portfolio to add significant growth in the years to come. Including Humira, Imbruvica, HCV, and Duopa collectively will add $10 billion in incremental sales by 2020.

Growth of Humira will be driven by continued biologic penetration across disease categories and new indications. I'll talk more about our planning assumptions around Humira growth and the impact of biosimilars in just a moment.

Imbruvica's growth in this time frame will be predominantly driven by increasing penetration within our currently approved set of indications and movement into frontline use for those indications. The RESONATE-2 data further reinforces our view that Imbruvica will be a highly successful agent in frontline therapy for CLL. Growth will also come from label expansion into new hematological cancers such as diffuse large B-cell lymphoma, follicular lymphoma, and multiple myeloma.

Growth in our HCV franchise will be driven by continued uptake of Viekira Pak across geographies including Japan, the second-largest HCV market globally. We expect to commercialize our next-generation HCV offering in 2017, which will be a pan-genotypic once-daily retonovir- and ribavirin-free combination. Given the significant global prevalence of this disease, we expect the HCV market to be very durable well into 2020.

As I said, we forecast Duopa will achieve sales greater than $1 billion globally by 2020. And finally, other products in our on-market portfolio including Creon, Synagis, Lupron, and Synthroid represent steady and durable sales contributors over our long-range plan.

Turning to slide 12, our growth outlook for Humira is based on a thorough analysis of the global market dynamics and the strategy that we put in place. We've taken what we believe is a realistic view of the market and the competitive environment over the next five years and expect global Humira sales in 2020 to exceed $18 billion.

Turning to slide 13, we have a comprehensive strategy in place which we believe will allow us to protect and grow our leadership position in immunology. Our multifaceted strategy is comprised of Humira intellectual property, enhancements to Humira, innovation including a robust immunology pipeline, and strong commercial execution.

Turning now to slide 14, we are planning conservatively with respect to the timing for European biosimilars and for planning purposes expect direct Humira biosimilar competition upon expiration of our compound patent in Europe in October 2018. However, we are pursuing additional IP in Europe and expect the situation to evolve over time. Again, though, the guidance we've outlined today excludes any potential benefit from our IP in Europe.

Turning to our US patent estate, as you can see on slide 14 we have built a robust portfolio of intellectual property. Beyond our composition-of-matter patent, we had more than 70 additional later-expiring US

patents related to Humira. The vast majority of these patents, which reflect significant innovation and investment, were granted by the US Patent and Trademark Office within the past two years. These patents expire between 2022 and 2034.

The size of AbbVie's patent estate is a direct consequence of the groundbreaking work of AbbVie's scientists in the new field of biologics. Small-molecule drugs have been around for many decades, but therapeutic antibodies are much newer, larger, and more complex. Because they must be made in living organisms, biologics are more difficult to manufacture. In addition, because they are foreign proteins that are introduced into the human body, biologics present unique challenges in terms of formulation and treatment.

Not only is the field new, but Humira itself was a new type of biologic. It was the first fully-human therapeutic antibody ever approved by the FDA. The development of Humira was unchartered territory.

Those efforts resulted in the United States Patent Office granting AbbVie dozens of patents covering Humira. The coverage of our later-expiring patents includes methods of use for the drug in all Humira indications, methods to formulate the drug, and methods to make the drug, as well as other aspects of the Humira product such as the delivery device. Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate which AbbVie intends to enforce vigorously.

With respect to formulating the drug, we have patents on formulating the Humira antibody that also expire no earlier than 2022. Biologic drugs must be administered intravenously or as injections and can be difficult to formulate properly. Given our extensive experience with Humira, these patents cover not only our commercial formulation but also other related formulations that biosimilar companies might employ. 14 patents have been issued covering different formulations of Humira.

With respect to making the drug, we have important patents on the methods of manufacturing Humira that expire no earlier than 2027. The living cells that produce biologic drugs such as Humira can be sensitive to small changes in the manufacturing process. Minor differences in manufacturing process can affect the nature of the biologic drug and even its clinical effect. 24 patents have been issued covering methods of manufacturing Humira and Humira compositions resulting from those methods.

Today I'll focus on those patents which cover using the drug, otherwise known as method of treatment patents. While AbbVie's formulation and manufacturing patents for Humira also have broad coverage, without further information on the biosimilar we cannot know with certainty the extent to which these patents will be infringed.

Now turning to slide 15. Since the biosimilar statute requires the biosimilar to obtain approval for one or more indications previously approved for the innovator drug and have the same route of administration, dosage form, and strength, we know biosimilars will infringe these method-of-use patents. We have method of treatment patents covering all the indications for which Humira has been approved.

These patents do not expire until 2022 or later. These patents reflect the development work of more than 100 clinical trials spanning 18 years.

As discovered through this work and reflected in the Humira label, different diseases require different treatment regimens, which AbbVie discovered following significant investment in clinical development. These patented uses have been key to the success of Humira. They have opened up new and better treatment options for an increased patient population and improved the quality of life for those patients.

Our method of treatment patents cover the approved dosing regimens for each indication and are not mere refinements of previous dosing regimens, which is often the case with method of treatment patents in the small-molecule arena.

Furthermore, biologics like Humira are more complex and unpredictable by their nature than small molecules. As such, biologics present unique challenges in terms of treatment.

One challenge was the fact that Humira targets TNF-alpha, a protein that plays an important role in the human immune system. It is critical to find the right balance in terms of blocking the harmful effects caused by excessive TNF-alpha without interfering with the normal functioning of the immune system.

This made the development of safe and effective methods of administering Humira all the more difficult. And because Humira was the first human therapeutic antibody ever approved by the FDA of any type, the work by AbbVie's scientist was unprecedented.

In total, putting aside the composition-of-matter patents on Humira, there are 22 issued patents directed to the treatment of TNF-mediated diseases that expire in 2022 or later. Additional applications are pending and still being examined in the Patent Office. Again, a biosimilar company will have to contend with our method of treatment patents for every indication for which it seeks approval, as well as our formulation and manufacturing patents, which are not limited to any particular indication.

Turning to slide 16. As you evaluate the time frame for a potential US biosimilar market entry, it is important that you consider the legal process and the likely timeline for resolution. While it's always difficult to estimate the precise duration of the litigation process, the average time to trial for a patent action is nearly three and a half years. Appeals to the federal circuit court usually take one year, so based on similar cases, the total litigation timing may be as long as four or five years.

At-risk launches, when a Company launches a generic product before patent expiration and before a final determination that a patent is invalid or not infringed, are relatively rare due to the potential exposure. Because of Humira's success, such damages could be extremely large.

Of course, we can't know how other companies will evaluate that risk. However, in the event a biosimilar attempts to launch at-risk, AbbVie will seek injunctive relief. For the reasons we've already discussed, biosimilars will necessarily infringe our patents.

Given the unique properties of Humira and the lack of any prior experience with fully human monoclonal antibodies, these patents are strong. Courts considering requests for preliminary injunctions have considered these factors important and have granted injunctions where they are present.

Turning now to slide 17. Another important aspect of our immunology strategy is our pipeline. This includes both enhancements to Humira as well as our promising pipeline of new products in development, which are designed to restate standard of care in each of our areas of leadership.

We have two new indications for Humira that will contribute significantly to the product's continued growth. We also recently received approval in Europe for a new formulation of Humira which provides meaningful patient benefit, including lower levels of pain versus the current formulation.

We are submitting regulatory applications for an improved Humira pen device, which we expect to introduce in 2016. Finally, we are continuing to work on developing proprietary delivery technologies and devices to further enhance the product.

Behind Humira, we have a pipeline of mid- and late-stage immunology assets in clinical development. AbbVie is the clear leader in immunology. It is a category we understand extremely well, and our performance is reflective of our deep expertise.

As we embarked upon developing a set of next-generation assets, we did so with our knowledge of the type of breakthrough profile a new drug would require in order to achieve a significant market share position. Each of the assets that we have in our immunology pipeline has the potential to deliver that

type of market-changing product profile that we are targeting.

We were very pleased with the mid-stage results from our selective JAK1 inhibitor, ABT-494, which showed the potential to be best-in-class in RA, with high efficacy, once-daily dosing, and a favorable benefit/risk profile. We are particularly excited about the results of ABT-494 demonstrated in the most challenging patient population, the anti-TNF inadequate responders. Given that anti-TNF therapies have been available now for nearly two decades, this patient population has grown over time; in fact, this population currently represents roughly 35% of the US patient population.

We are rapidly moving ABT-494 into Phase 3 studies, and it is our goal to launch this asset into the US market well in advance of any biosimilar entry. Our large and experienced commercial organization, which currently represents Humira, will promote ABT-494 and our other immunology pipeline assets upon their US commercialization. We have tremendous confidence in the organization's ability to successfully represent these assets.

We also believe our DVD antibody platform holds tremendous promise in the treatment of certain immune-mediated conditions. ABT-122 is our combination anti-TNF, anti-IL-17, two proven mechanisms, which is currently in Phase 2 trials for RA and psoriatic arthritis. Our earlier development work with the platform has established that our DVDs have favorable drug-like properties, similar to monoclonal antibodies, and can be manufactured reliably.

We'll see data from the mid-stage trial in RA in early 2016 and results from our study in psoriatic arthritis later in the year. If the results are positive, we will quickly advance ABT-122 into Phase 3 development.

We are also working to advance several other early and mid-stage immunology programs including our partnered anti-IL-6 nanobody, and we continue to explore the L&A landscape for assets that fit our target product profile.

Moving on to slide 18, Humira's unique product profile and AbbVie's strong commercial execution has made Humira the number-one prescribed biologic, with the highest commercial prescription market share, including the highest percentage of new patient starts. Humira holds a preferred or co-preferred position on managed care of more than 90% of US covered lives.

Patients, physicians, and payers recognize the meaningful clinical and economic value of Humira as a treatment option for the broadest set of immune-mediated diseases. We've demonstrated that treatment with Humira is more cost-effective and saves payers on downstream costs associated with diseases like RA, Crohn's, and psoriasis.

Moving on now to slide 19. As I said, we have taken what we believe is a realistic view of our prospects over our long-range plan, given the competitive landscape, potential for biosimilars, and other factors. Our plan is built around a key set of assumptions that vary by geography.

Let me start with international. Internationally, we are planning for mid-single-digit market growth over the long-range plan. Our plan assumes some limited erosion upon Enbrel biosimilar launches starting in 2016. As outlined, embedded within our guidance is an expectation for a Humira ex-US biosimilar launch in the fourth quarter of 2018, with the expected pricing and market share performance for such products. We anticipate moderate erosion from direct Humira biosimilar competition beginning in 2019.

In the US, our long-range plan assumes that US markets deliver mid- to high-single-digit market growth driven by roughly a 4 point increase in biologic penetration. Despite competitive entries, we expect that Humira will only experience minor erosion of market share over our LRP. And as we've outlined, we believe the litigation process and our intellectual property estate will protect Humira from biosimilar entry until 2022.

Our LRP also assumes successful penetration of new Humira indications, and our immunology pipeline will begin to contribute new revenues with commercialization of ABT-494 in 2019 and other assets to follow. It is our expectation that AbbVie's immunology pipeline will contribute nearly $8 billion in nominal sales in 2024, with ABT-494 -- a significantly derisked asset -- representing roughly half that expected contribution.

Now moving to slide 20 and moving on to our oncology portfolio. As we've said, we acquired Pharmacyclics, and Imbruvica represents a pipeline in a molecule with significant growth potential through its existing and expanding list of indications and lines of therapy. This transformative therapy has already secured approval for the treatment of four indications, and there are more than 25 Company-sponsored clinical studies to evaluate Imbruvica as a treatment for a wide range of additional cancers.

In its first year on the market, Pharmacyclics and our partner have driven market-leading performance and therapeutic uptake of Imbruvica, clearly demonstrating the strength of the medicine's attributes and its clinical profile. We expect Imbruvica to achieve blockbuster status in 2015, with AbbVie's projected Imbruvica revenues growing to approximately $5 billion in 2020.

Imbruvica has vast potential for label expansion and future indications. It is currently being evaluated in mid- and late-stage trials in follicular lymphoma, marginal zone lymphoma, diffuse large B-cell lymphoma, and multiple myeloma.

We are also encouraged about Imbruvica's potential in graft-versus-host disease based on data from an earlier-stage study. If Imbruvica demonstrates clinical value in solid tumors, there would certainly be significant upside to our expectations. We recently initiated a Phase 3 trial evaluating Imbruvica in pancreatic cancer, and we are currently studying Imbruvica in other solid tumor types in combination with immuno-oncology agents, including early-stage studies in breast and lung cancer.

Turning now to slide 21. Our acquisition of Pharmacyclics significantly accelerated AbbVie's clinical and commercial presence in oncology. With Imbruvica, we've established a leadership position in the hematological oncology market, which is poised to nearly double to $50 billion by 2020.

We are well positioned to build upon our leadership in this category with other promising assets in development. Beyond Imbruvica, we have several other products in development that have the potential to offer differentiated efficacy in a wide range of blood cancers.

Our BCL-2 inhibitor, venetoclax, is in late-stage development for CLL and mid-stage trials for several other cancer types including NHL, AML, and multiple myeloma. Duvelisib is in mid- and late-stage trials for CLL and NHL. And we have an innovative antibody drug conjugate in early development for multiple myeloma.

Given our broad portfolio, we believe we have the potential to continue to evolve the treatment landscape within innovative combinations of these and other mechanisms. Our goal is to markedly improve efficacy by achieving deep, durable disease control or remissions while reducing or eliminating the use of toxic chemotherapy.

We recently completed the design for our first clinical trial evaluating venetoclax in combination with Imbruvica and Gazyva in first-line CLL, and we expect to initiate the study in the first half of 2016.

We also have an active discovery program with the objective to drive the next wave of immuno-oncology development beyond checkpoint inhibitors. We're particularly focused on the use of our bispecific biologic platform to support conditional activation of the immune system in the vicinity of tumor cells, and we are leveraging the emerging science of soluble T-cell receptor technology as well. We anticipate multiple immuno-oncology assets moving into human trials in 2016.

Moving to slide 22. The assets in our pipeline span attractive specialty categories. All told, we have more than 50 products or indications currently being evaluated in human trials, with more than 20 currently in registrational trials or under active regulatory review.

Turning now to slide 23. We've built a robust pipeline comprised of potentially transformational medicines in large markets with profound unmet medical need. Our pipeline has the potential to deliver nearly $30 billion in nominal new revenue by 2024. Several products currently in late-stage development have the potential to be multibillion dollar assets that will offer growth and top-line diversification. We also have numerous programs in early-stage development underway that have the potential to come to fruition in the later years of our long-range plan.

Now, turning to slide 24. Over the past year, we've seen data from numerous key assets that have further increased our level of confidence in our likelihood of clinical, regulatory, and commercial success. Based on our progress, we have significantly derisked a large number of major development programs that now have a very high probability of success.

For example, our first registrational study for venetoclax in relapsed-refractory CLL patients with 17p deletion met its primary endpoint and is currently under regulatory review. As mentioned earlier, the frontline data for Imbruvica in CLL were robust, and our regulatory applications are under active review.

Regulatory submissions for Zinbryta in MS are well underway, supported by a large registration program that showed the novel biologic was superior versus an active comparator. We've seen positive data from several elagolix studies in endometriosis and uterine fibroids.

Our partnered asset, elotuzumab, is currently under regulatory review for relapsed-refractory multiple myeloma following receipt of Breakthrough Designation. We disclosed top-line data from our selective JAK1 inhibitor, ABT-494, illustrating its potential for best-in-class efficacy in RA, even in the most difficult to treat TNF-inadequate responder patients.

We have successfully completed the Humira uveitis pivotal trial, with filings currently under regulatory review. And we announced top-line data from our next-generation HCV program, illustrating its potential to offer a highly competitive profile.

Turning now to slide 25. We've made significant progress with our pipeline, and we anticipate continued advancements between now and the end of 2016. As you can see noted on this slide, we have numerous product approvals, data readouts, registration submissions, and phase transitions anticipated over the next year or so.

Now, turning to slide 26. The continued growth from our existing portfolio combined with the risk-adjusted sales contribution from our pipeline will drive top-tier revenue performance over our long-range plan. This level of revenue growth puts AbbVie near the very top of our expanded peer group based on current consensus estimates.

Turning now to slide 27. In addition to the strong top-line growth, we also expect to deliver significant margin expansion in the years to come. Our focus on driving operating efficiencies to date has resulted in strong improvement in both gross and operating margin profiles. On this slide you can see the significant level of margin improvement that we've delivered since our first quarter as an independent Company.

Turning to slide 28. Our continued focus on operating margin will drive further expansion, with a projected operating margin of greater than 50% by 2020 and an average of 100 to 200 basis points of improvement per year. Expansion will be driven primarily by ongoing efficiency programs to optimize manufacturing, commercial infrastructure, administrative costs, and general corporate expenses; productivity initiatives in supply chain; and the reduction of Humira royalty expense in 2017 and 2018.

Additionally, we'll see continued sales leverage from our rapidly growing top line.

Our guidance for 2020 operating margin incorporates approximately 200 basis points of dilutive impact from partnered assets including Imbruvica, venetoclax, Zinbryta, and Synagis. As you can see on slide 29, this powerful combination of revenue growth and margin expansion positions AbbVie as one of the top EPS growth companies among our expanded peer group.

Turning now to slide 30. AbbVie generate significant cash flow which we expect will grow in 2016 and beyond. So far in 2015, we have repurchased $6.25 billion of shares, including the ASR associated with the Pharmacyclics acquisition; and we have $3.45 billion remaining on our current buyback program.

As I mentioned earlier, today we announced that our Board has authorized a 12% increase in our quarterly dividend. Since 2013, we have increased our dividend by more than 42%, and we intend to maintain a strong commitment to a growing dividend going forward.

We'll also use our strong cash flow to continue to augment our pipeline through strategic licensing, acquisitions, and partnering activity. Over the past several years, we've added numerous promising assets to our portfolio, and we continue to focus on identifying compelling programs that fit our strategic criteria.

Turning to slide 31. Since we became an independent Company in 2013 we've consistently delivered on our commitments, and we are positioned to deliver more than 28% bottom-line growth in 2015, a level of performance that puts us at the top of our peer group. As we look at 2016, we're once again poised to deliver top-tier financial performance with EPS growth of 17%, the midpoint of our strong guidance range.

Based on our 2016 midpoint, AbbVie will have grown its EPS by roughly 60% in just three years. Across our long-range plan, we're projecting our EPS growth to average nearly 15%, again putting AbbVie in the very top of our peer group.

In summary, we are well positioned to deliver strong top- and bottom-line performance through 2020 and beyond. We have established growth platforms in some of the largest and most attractive market segments, including immunology, oncology, virology, and neurology. And we've built a compelling pipeline in these areas which will contribute significantly to our performance in the years to come.

Our commitment to top-line growth and expanding our operating margin to greater than 50% will generate double-digit EPS growth on average through 2020. We've built a strong foundation and we are committed to delivering top-tier financial performance.

With that, I'll turn the call back over to Larry. Larry?

Larry Peepo (Investor Relations):

Thanks, Rick. We'll now open the call for questions. Operator, we will take our first question, please.

QUESTIONS & ANSWERS

Operator:

(Operator Instructions) Jami Rubin, Goldman Sachs.

Jami Rubin (Analyst - Goldman Sachs):

Thank you, and wow, that was a lot of detail, Rick. It's going to take time, I think, to digest it all, but I know that we certainly really appreciate it.

First question is this, was wondering if management's comp is tied to the long-term targets. Secondly, it seems that the biggest delta between the Street and your guidance on Humira is timing of a biosimilar launch. Wondering if you can comment on that, and also if you could comment on Amgen's CEO's comments on his earnings call, where he said that Humira has IP and Amgen has to respect that.

Is it the case that the Street's just coming around to your view on the strength of your IP and the timeline of the 351(k) pathway regulations? Or has something really changed in terms of your confidence with IP?

And thirdly, and I'm sorry for this, but with your operating margin guidance growing to over 50% by the end of the decade, it looks like that's really coming or driven by strong revenue growth, not by operating cost cuts. Can you confirm that?

And obviously in a bear case scenario, how much flexibility do you have to reduce your SG&A? We all know you're spending a lot on Humira; it's having a really good return on investment. But if that changes, how much flexibility you have. Thanks very much.

Rick Gonzalez (Chairman & CEO):

Thank you, Jami, for all those questions.

Jami Rubin (Analyst - Goldman Sachs):

I'm sorry.

Rick Gonzalez (Chairman & CEO):

No, we're writing them down, so we'll cover each and every one of them. Let me start with the management comp. I think similar to probably the other companies in our industry, the vast majority of the executive team's comp is in long-term incentive. It's associated with the appreciation of the stock; so I'd say we're directly linked to that.

In addition to that, for the top people within our Company, we have two levels of incentive plans. One is basically focused on the short-term plan year. And then we have one which is a longer-term plan that basically is designed to hit a three-year-out target, where you would set things like this operating margin target.

So the bottom line is, yes, there's perfect alignment between all of these metrics and how people will be rewarded against those.

To your second question, which was is the gap primarily the timing of biosimilars? I'd say that's accurate, for the most part. There's probably more penetration and more growth in the indications in general that are built in versus the Street. But the most significant part is the assumption that we're making around the timing of US biosimilar entry.

As far as the Amgen CEO, I read the comment and I find the comment encouraging, but I'm not going to comment specifically on what they said.

I think, to your point about is the Street just now coming around to our point of view, in fairness, much of this IP has only really come out in the last two years. I think both competitively, that is now something that people who were interested in coming up with a biosimilar are having to evaluate. So it's not like they had a lot of time, and the Street certainly didn't have a lot of time, to be able to evaluate that as well.

I'd say secondarily, look, there was no advantage to us going out early and touting that either. We wanted to make sure that our strategy was in a position that was solid and where we wanted to be, and we've worked hard over the last three or four years to get our strategy in place.

We're at a point now where we're confident to be able to talk about it. And you heard my words, so you probably can't be much clearer about what our intent is. So at the end of the day, I think in fairness to the Street you now have all the information and you can determine your point of view around that.

I'd say on the confidence in the IP, we have a high level of confidence in the IP. So I think we feel very good about our position.

If anything, our tendency when we do our long-range plan is to be a little bit on the conservative side. I'd say the Europe assumptions that we're making, as an example, I think are clearly conservative; there's far more opportunity for upside than there is downside, and that's normally how we try to build our forecast because we want an opportunity to be able to make sure that we achieve those.

On the operating margin, I think what your question was is it almost all driven by sales leverage? No.

I think the way to think about it is this. In Bill's comments we guided to the end of this year being 42.5%, because remember the fourth quarter will have high Synagis sales and we'll also have a full quarter of Imbruvica, so we have more partnered revenues in the fourth quarter, and so that tends to be dilutive, as I described. So we'll exit this year somewhere around 42.5%.

But then I think the way to think about the target that we've set here is you have to back out the dilutive impact over the five-year LRP, which is about 200 basis points. So you're back down to about 40% as your starting point.

So you're going to go to 40% to something north of 50%, so about a 10-point improvement. If you look at that 10-point improvement, and I have Bill here with me, roughly 25% of it comes from the royalty reduction on Humira that will occur between 2017 and 2018; about 30% of it comes from cost reductions, cost management kinds of programs; and the remainder comes from the leverage that we see of a fast-growing top line with expenses being managed at a significantly lower growth rate. That's how you ought to think about it.

Jami Rubin (Analyst - Goldman Sachs):

Okay. Super helpful. Thank you very much.

Operator:

Jeffrey Holford, Jefferies.

Jeffrey Holford (Analyst - Jefferies LLC):

Thanks very much and thanks to the team for the very comprehensive midterm outlook today, which I think really sets out your positioning on Humira and the rest of the business very clearly.

Now obviously the debate on Humira will continue, and it seems that the linchpin for you near term is the achievement of an injunction against any would-be at-risk launches. We've recently heard from Amgen regarding at-risk launch, and we certainly heard that also from other large biosimilar players.

But could you be more specific on the trigger for starting either the patent infringement process and the injunction processes, so we can think better about the timing of those? Are they more likely to be tied to filings, or FDA approvals? So that's the first piece there.

Then second, on 2016 guidance it would just seem to us that you're potentially implying you do not expect to increase the $3 billion exit rate for the hep C franchise in 2016. If you could speak to that too.

Then just last, you've talked about being ready for larger deals again by 2017. To be clear, the current

guidance does not include anything for additional M&A, just be clear on that?

Then can you tell us a bit more about substantial share repurchase is that might be part of your midterm plan, too, at least as a backstop if you can't find substantial M&A targets? Thank you.

Rick Gonzalez (Chairman & CEO):

Okay. I'm actually going to have Laura address your first question, Jeff, and then I'll cover the rest.

Laura Schumacher (General Counsel):

With respect to the trigger for the filing of litigation, there is a process that's laid out specifically in the statute, which there has been litigation over whether or not that process is mandatory or not. From our standpoint, we are anticipating that in the event that there is a biosimilar applicant they will or won't choose to follow that process; it's been found to be not mandatory. Should they choose not to follow that process, upon notice of the filing of the application of course we would initiate the litigation.

With respect specifically to an injunction against an at-risk launch, that injunction against an at-risk launch would be triggered upon the approval of a biosimilar. And of course we would then request that the court enforce our IP.

As Rick laid out earlier, we intend to vigorously enforce the IP, and we believe we have a very strong case for an injunction, given first of all that we believe any biosimilar applicant will infringe at least certain of our patents. Because in order to follow -- to be classified as a biosimilar, they will need to have the same dosing regimen as the innovator product.

As to validity, we think we have a very strong case on validity given the uniqueness of Humira and the fact that Humira was the first fully human antibody approved by the FDA. And there was nothing known about its effectiveness or its optimal dosing regimen at the time that we did extensive clinical work, trial, investment, etc. So we believe in the event that there was an attempt at an at-risk launch, we would have a very strong case for a preliminary injunction.

Also, as you know, in the event a biosimilar would choose to launch at-risk, the damages for such a launch, should it be found to be violative of our patents, would be very significant.

Jeffrey Holford (Analyst - Jefferies LLC):

Thank you.

Rick Gonzalez (Chairman & CEO):

Okay. Thanks, Laura. So let me take the M&A question. Yes, the guidance that's laid out today doesn't cover any significant acquisition activity or licensing and acquisition activity. Obviously, as that played out we would look at -- based on the significance of it, we would make a decision how we would deal with that, either something we could manage or something that we could not; and then we would obviously pass that into our guidance and communicate it appropriately.

As we talked about before, I'd say that our focus for the next couple of years is more trying to fill out our portfolio of assets within the therapeutic areas that we're in. We don't anticipate a large transaction in that time frame; and nothing has changed around that front.

That kind of gets to the whole share repurchase, although I'll have Bill talk about that just for a moment as well. But ultimately how we look at share repurchase versus M&A is we're trying to manage between those two to make sure that we have the appropriate capacity to be able to do the things that we need to do for the business longer term. And share repurchase is more of an opportunistic kind of an

approach. Bill I don't know is there anything you want to add to it?

Bill Chase (CFO):

No, I mean obviously if you look at this long-range plan, there's going to be pretty robust cash generation. As we get out a couple years, that can clearly fund larger M&A if we deem that's necessary.

To the extent that an opportunity isn't readily apparent, well, then we would certainly have to look at other things to do with that cash. And share repurchases could very well be part of that.

Rick Gonzalez (Chairman & CEO):

Yes. On the 2016 guidance, I mean obviously we've just gone through our planning process for 2016. The way we do planning is we build everything up from the bottom up, product by product. We make determinations as to what we're going to assume for each product based on a set of assumptions that we think are absolutely realistic.

So we have an HCV number that's in our 2016; we tend to be a little bit on the conservative side when we build these up so that we have the flexibility to make sure that for any unforeseen events we have the ability to be able to manage our way through those. And I'd say this plan is no different than previous ones that we've built.

But specifically for HCV, I'd say HCV will have some growth built into it year-over-year, because just of the gating of how the countries have rolled out over time internationally, you're going to get year-over-year. We're just launching in Japan now -- well, we're not launching, we will be launching shortly in Japan now.

And Japan's a significant opportunity for us so it will create a year-over-year growth driver for us as well. So, I'd say there is growth built into the HCV franchise.

But let me specifically talk maybe about this $3 billion running rate, because I know I made that prediction in the early part of the year. If you look at where we are right now, what I would tell you is we're going to be close, but we're slightly below that right now in the fourth quarter, at least as what we have built into our current guidance for the year. It's a function primarily of the fact that in the beginning of the year the number of patients being treated was significantly higher. We've seen that trend down; we've seen some changes in VA in the United States.

So I'd say we're going to be close. We could make it, but we might miss it. And as I said, we tend to build conservatively. What we have in the fourth quarter right now is slightly below that.

Jeffrey Holford (Analyst - Jefferies LLC):

That's great. Thanks very much.

Operator:

Mr. Marc Goodman, UBS.

Marc Goodman (Analyst - UBS):

Yes, morning. 494, $4 billion in 2024 is a pretty big number. Can you help frame how you're thinking about that?

Then secondly, just AndroGel continues to be a little stronger than we think. Why is that? What's going on behind the scenes? Thanks.

Rick Gonzalez (Chairman & CEO):

Well, I'd say 494, based on the profile that we've set up, I would say $4 billion of risk-adjusted revenue for an asset that has that profile in that time frame isn't a stretch number from our perspective at all. When you look at the level of response that you have in the TMF-inadequate responder patient population -- which as I said in my remarks, represents about 35% of the US patients. We'd assume it's something similar to that in Europe; it's a little more difficult to get to the data in Europe. It's a sizable population and it's a population that has relatively limited number of options available to it.

In addition to that, when you think about how biosimilars will ultimately roll out, I think it's a good assumption to assume that biosimilars are going to capture some portion, maybe a significant portion, but at least some portion of the new patients. So they're going to be generating more TNF-inadequate responders.

Now they might rotate through another TNF after that. But a proprietary product will have an opportunity in a biosimilar world to go after those nonresponders. So that's a very significant opportunity.

In addition to that, obviously to my comments about our organization representing this product, there will be a goal to be able to take the appropriate patients and try to move them to the appropriate kinds of therapies. So patients that aren't responding as well on Humira, obviously we would want to move them to 494 as an alternative.

So when you look at all of that, I'd actually say that a $4 billion number is not a number that we're uncomfortable with.

Bill Chase (CFO):

Marc, on AndroGel, clearly it has performed better than the Street was thinking; and frankly, it's performed a little bit better than we were thinking. The market still is in decline. However, what you're really saying is less uptake or less impact on the brand from the generic 1% formulation. It's something we're just going to have to keep our eye on, but so far so good.

Operator:

Chris Schott, JPMorgan.

Chris Schott (Analyst - JPMorgan):

Great. Thanks very much and thanks for all the details today. I just had three quick ones here.

First, following up on Jami's question, if for whatever reason the Humira IP falls and sales end up closer to let's say consensus than your $18 billion target, is a 50% margin realistic in that scenario? I'm just trying to get a sense of like where margins could go in that downside case. I know that's not the scenario you laid out, but just trying to understand that.

Second, just thoughts on what happened earlier this year with Amgen and Sandoz with Neupogen, are there any learnings, similarities, or differences that we should apply when we think about the Humira situation?

Then finally, on the longer-term international Humira targets, could you just give us a little bit more color on the type of erosion you're assuming given biosimilars for Enbrel and potentially Humira over that window? Just how much price and volume impact are you reflecting here? Thanks very much.

Rick Gonzalez (Chairman & CEO):

Okay. I don't know that the 50% margin target would be realistic in a more catastrophic kind of situation. What I would tell you is we've obviously laid out contingency plans by country. Because this will be rolled out by country, obviously -- right? -- as biosimilars enter those countries. And we have an erosion curve that we've built by country.

If the country starts to fall below that erosion curve, then we'll do what we always do. That is, we will manage the expense base accordingly. so we have the ability to be able to manage and offset the profitability like we would do with any type of LOE.

So at the end of the day I think whether or not it had a 50% margin target or not, we would put a contingency plan in place that would allow us to try to maximize profitability or preserve profitability under that scenario.

Having said that, what I will tell you is we have a high level of confidence in what we've built here. We don't build LRPs that we don't believe we can achieve.

Again, we're not showing you anything different than what our internal LRP says that we present to our Board every year. So at the end of the day I can tell you we have a high level of confidence that we can deliver against what we've put here.

The learnings from Amgen, I'm assuming you're talking about the whole IP and litigation process for Amgen, so I'm going to have that Laura address that for you.

Laura Schumacher (General Counsel):

Yes, with respect to the Amgen Neupogen litigation, a lot of the debate in that litigation surrounded whether or not the prelitigation exchange process whereby patents and information were exchanged between the innovator and biosimilar, whether that was a mandatory process or a voluntary process. And ultimately, as I said previously, we're not anticipating from a timing standpoint that there will be a litigation exchange. It will be something that the biosimilar applicant will choose to participate in or not.

With respect to the underlying patent infringement litigation with Amgen and Neupogen, our litigation -- our patent estate is very different than that. In that case, there's very few claims and patents in ours.

As we've said before we have over 70 patents, many of which, certain of which will be infringed and some which may be infringed. So we'll have to see when we know more specifically about what formulation and/or process a particular biosimilar applicant uses.

Rick Gonzalez (Chairman & CEO):

Okay. Thanks, Laura. Then on the European erosion curve, obviously as part of this planning process, we have built a very specific erosion curve for both Europe as well as the United States when we get beyond 2022. But what I would say to you is -- and I'll walk through the European one -- or I'll walk through the international one, I guess, more generally.

But what I'd say is it's fairly complex because there are lots of different variables if you think about it, right? You're going to have countries rolling out at different times as they enter those countries and they get pricing approval within those countries. Not every country is exactly the same how you get pricing approval. So there is this gated period where you go across country by country as biosimilars would enter it.

The second thing is you have to layer in what our strategy will be. We build a strategy by country.

There will be countries where we choose to take price erosion to maintain all of the patients -- new

patient and well-maintained patients. There may be countries where we choose to only keep well-maintained patients and do something different from a pricing standpoint. So there are some complexities around that.

Then the third point that I'd say to you that's very important as you think about this -- because I'm going to walk you through what the erosion looks like here in just a moment -- is when a biosimilar enters the international markets, these markets are still growing. As I said, there growing like mid-single digits. So as I described to you what the erosion looks like, the number I'm going to give you is lower than what they could actually capture or the price erosion might ultimately translate to, because they will take a certain portion of that market growth within those markets.

So having said all of that, I think the simplest way to think about the erosion curve is this. If you think about international Humira sales, they will peak in the forecast we've laid out for you here, all the financials we've laid out, they peak in 2018; and from 2018 then they start to decline. If you move out two years to 2020, which is the year we're characterizing for you, the erosion of the international Humira business is about 15% to 18%.

Now, having said that, the impact -- or the opportunity lost probably is the best way to think about it -- would be greater than that. Because without biosimilar competition, Humira would have continued to grow in those international markets beyond that period of time.

So it probably sounds a little lower than you would expected, but it's because you have to think about it in those two components. Part of the component is it will take some price out of the market, which will reduce market growth. The other component is they may take some new patients, so they are taking some of the market growth out that way.

But you just say what is the impact on AbbVie , it is the brand peaks at that point and it declines about 15% over that period of time.

Chris Schott (Analyst - JPMorgan):

Very helpful. Thank you.

Operator:

Mark Schoenebaum, Evercore ISI.

Mark Schoenebaum (Analyst - Evercore ISI):

Hey, guys; thanks for all the detail. I'm in agreement with the other analysts on that. A couple questions.

Number one, what was operational Humira growth rates quarter-on-quarter as well as year-on-year in international markets?

The second question is, you didn't comment on your tax rate over the long term. I don't think I saw that in your slides. I would assume that as the Company diversifies away from Humira you're going to diversify into more tax-optimized drugs, tax-optimized assets. So I would personally be comfortable modeling a decline in your tax rate, and I wanted to hear your thoughts on that.

When I do that, and when I use an operating margin of only 51% -- even though your guidance says greater than 50%, and it could be 55% or 60%, who knows? -- I'm getting to an EPS number in 2020 of around $10 a share. I'm just -- I know you're not giving an EPS number, but am I thinking about this all wrong? Because most people say I'm not very good with math.

Rick Gonzalez (Chairman & CEO):

Why don't you cover the tax rate first and I'll cover --?

Bill Chase (CFO):

Yes. If you look at this business since we've separated from Abbott, the tax rate has been pretty consistently in the 21% to 22% range. That's largely driven by our need for US cash for certain items.

So as we do our LRP, again, what we do is we build it on a fairly conservative basis. What I would tell you is our assumptions are that that tax rate in the 21% to 22% is the right assumption for this business over the next 10 years.

Mark Schoenebaum (Analyst - Evercore ISI):

That's because of your repatriation needs? Because I would imagine the tax rate on single assets that are large, like your new JAK and Imbruvica, on a P&L basis, single-product P&L basis, would be much lower.

Bill Chase (CFO):

Yes, but you've got Imbruvica, which is largely a US product for us from a tax rate. So that actually lifts the tax rate the other way.

Mark Schoenebaum (Analyst - Evercore ISI):

Okay.

Bill Chase (CFO):

So you've got a lot of different things in the mix, Mark.

Mark Schoenebaum (Analyst - Evercore ISI):

Okay, thanks.

Rick Gonzalez (Chairman & CEO):

Look, on the EPS target, I would just tell you that at the end of the day we build it up from the bottom up, and we don't come up with your number. At the end of the day you can assume 50%, 60%, 70% operating margin profile and get pretty big numbers; but if you're going to drive this level of growth you have to invest in the business in a way that allows you to be able to do that.

So I think the numbers we have forecasted certainly represent the top tier in this industry, and they're the numbers that we're willing to stand behind.

On operational growth internationally for Humira quarter versus quarter, what I'd tell you is this. We sell Humira in almost 100 countries around the world, right? And many of those countries have tenders, and tenders don't always fall consistently in the same quarter. So, quarter-over-quarter doesn't necessarily give you a very accurate picture of how the brand is growing, although I will address it here in a moment to answer specifically your question.

I think the best way to think about Humira internationally -- and let's just use this year as the example -- is to look at what the growth rate is for the first three quarters' worth of growth and compare it to what the prior year was. I think that's the most reflective way to look at it.

That would say that revenues are up about 8.3% year-to-date, year-over-year. Volume is up about 10%, okay? So it's slightly down in price, which is consistent with what we've seen in previous years; nothing

unusual there.

And market share is stable at just under 34% versus the prior year. I would tell you that's well within the range of what we expected when we did our plan, and it's tracking consistently with what we expected as it relates to our plan. So international Humira is performing the way we would have hoped and expected it to be able to perform.

Now if you look at quarter versus quarter -- and I'm assuming you're specifically talking about third quarter versus second quarter. If you look at third quarter versus second quarter, it's down about 1.3% or 1.4% -- 1.4%. What you have to recognize, and I'm sure you're aware of this, the month of August in Europe is the holiday month, right? So most physician offices don't have the same number of office days; in fact they have very limited number of office days.

So you get a significantly lower level of new patient starts in the month of August versus other months in the year. Therefore every year the third quarter is lower. In fact, if you look at last year, I think last year it was down about 4% -- 4.4%, and so that's a common trend that we see.

I'd also tell you, as I mentioned at the very beginning, if you look at it quarter to quarter and you don't make all of the adjustments for any kind of an anomaly of tenders between those periods of time, it's not very meaningful information for you. So I think the best way to look at it is year-to-date how were we performing? And I'd say when you look at this level of performance, we're pretty comfortable with it.

Mark Schoenebaum (Analyst - Evercore ISI):

Rick. I got a bunch of emails in from clients to the answer to my previous question about the $10 number, where you said you didn't come up with it. Were you trying to suggest that you came up with numbers higher than that or numbers lower than that? Thanks.

Rick Gonzalez (Chairman & CEO):

No, I was trying to suggest the number that we communicated is the number that we came up with.

Mark Schoenebaum (Analyst - Evercore ISI):

Okay, okay. Thanks a lot.

Operator:

Vamil Divan, Credit Suisse.

Vamil Divan (Analyst - Credit Suisse):

Great. Thanks for taking the questions; and again thanks for all the details you provided. So one more if I could on Humira and then one on a different topic.

But just to Humira, I think obviously a lot of focus on the biosimilars, and you addressed that pretty well I thought. Just what about the other innovative products that are coming in to target some of the indications of Humira that I'm thinking about the IL-17s, competing oral JAKs, oral products for Crohn's.

I know you guys highlighted what you have in your pipeline, but can you give some sense of how you think the market share erosion might be for Humira as some of these new innovative products come into these other indications?

And a second just on neurology. This is an area I've always struggled a little bit for you guys. So if you can just touch on that a little bit more.

You mentioned Duopa could be a big product, but maybe a little bit more around the number patients you think would be willing to use the product like that. Zinbryta, where does that fit in? Most neurologists we've spoken to kind of struggle to see where that fits into a very crowded MS space.

Even Alzheimer's, you highlight that in the total market opportunity, but your products are pretty early. So just maybe a little more color on how you see your neurology franchise growing would be very helpful. Thanks.

Rick Gonzalez (Chairman & CEO):

Let me start with Humira competition. I think as you know, this is -- particularly take RA, as an example, it's a pretty field already and there some pretty good mechanisms in there. And yet still the TNFs still control the vast majority of this market. It's a tough market to break into, even with fairly good profiles of drugs.

Now, having said that, I'd say there are some good profiles that are starting to emerge. The IL-17s are a good example; I think IL-17s have a pretty strong profile.

But what typically happens in this area is those mechanisms for quite a period of time are relegated to the failure patient population, because physicians are comfortable. There are many other factors that are built into it, and they tend to take up that failure population for at least a number of years, and that tends to be the areas that they grow in.

Now, over a longer period time they might have a more material impact. But as I mentioned, our assumption is -- and I think this is a valid assumption based on our experience in the past -- is that Humira will have some erosion in the United States, but relatively modest erosion over this five-year period of time.

And that, because we're assuming biosimilars don't come into the marketplace, that is driven by these other innovative products that enter the market. So that is our assumption around that.

As it relates to neuro, maybe I'll have Mike talk a little bit about some of the earlier stuff. But I'd say our work in Alzheimer's as an example, there really isn't anything that's built into this planning period. But --

Michael Severino (Chief Scientific Officer):

Certainly. Perhaps to address your question on Zinbryta first, what we see with MS, unfortunately, is that it afflicts patients often relatively early in their lifespan and they deal with many, many years of ongoing relapses and ultimately in many patients a downward clinical trajectory. So what that does is it creates a need for different mechanisms, mechanisms that attack the problem from different directions mechanistically, and mechanisms with considerable efficacy.

So we feel that there is a real place for Zinbryta in the treatment armamentarium, particularly when folks are looking for agents that have substantial efficacy as has been demonstrated in that program.

When you look at the rest of our neuroscience efforts apart from Duopa, obviously, and Zinbryta, they are very early and they are not contributing, as Rick said, to the financial numbers yet in a large way. But we do feel that we have a number of very promising approaches to go after in the longer term. The neurodegenerative aspects of MS, for example, which is still a large unmet medical need, and diseases such as Alzheimer's, so that's a focus in our labs on the early end.

Rick Gonzalez (Chairman & CEO):

Yes, and I would just add a couple of points on Zinbryta. We're obviously doing a lot of the work to prepare as we anticipate approval of this product. So we've been doing market research and a fair

amount of work in preparation.

I'd say the profile of Zinbryta is a pretty compelling profile. As Mike mentioned, the unfortunate thing about this disease is that patients relapse, and they relapse on average probably about every two to three years on the current agents. This is certainly a high-efficacy agent from an annualized relapse rate reduction; and when you look at it versus the active comparator it has good performance.

I think the other thing that is appealing to physicians is the compliance aspect of it, that from a dosing standpoint they know they'll have drug onboard for an extended period of time. So I think Zinbryta will have a very important role in the treatment of MS.

One of the things that physicians are able to go to a more, I'd say a higher efficacy kind of agent -- we don't view it coming in as the first line but certainly as patients rotate through that, we think it will compete quite effectively in that second line.

Operator:

Alex Arfaei, BMO Capital Markets.

Alex Arfaei (Analyst - BMO Capital Markets):

Good morning. Thank you for taking the questions and I'll also say thanks for all the details; it certainly helps. I have a few questions on Humira, if I may.

In 3Q, how much of your 30% growth in the US was volume and price? Because our audit suggests it was 11% to 14% volume. So could you comment on the price component? And what are your long-term pricing assumptions in the US for Humira?

And a follow-up for Rick. I just wanted to make sure I understood your comments earlier. Are you assuming no biosimilar products that compete with Humira in the US? I just want to make sure that -- what your timeline for biosimilar competition for other products is in the US.

And finally if you could provide your thoughts about the baricitinib head-to-head versus Humira, thank you very much.

Rick Gonzalez (Chairman & CEO):

Why don't you go with the price?

Bill Chase (CFO):

Sure. Our numbers for Q3, our volume was higher than what you're seeing in the script. I think the way you've got to think about price in the US on the quarter, it was around a third of the overall growth was related to price.

In terms of over the LRP, look, again we've said multiple times that as we build out our LRP we try to put in conservative and realistic assumptions. Along those lines, we don't take what is currently happening in price and extrapolate that out across the LRP.

In the US, it is an environment where we do think we'll be able to maintain some degree of positive price. But what I would tell you is we're modeling a little lower than mid-single digits on that as you go out over the long-range plan period. Ex-US, it's actually a negative pricing environment.

So when you actually look at the additive of the two across the LRP, we've got very, very, very low levels of price built into our forecast.

Rick Gonzalez (Chairman & CEO):

Okay. Then as it relates to biosimilars, I just wanted to clarify. You're talking about a Humira biosimilar, or you're talking about a biosimilar to something else?

Alex Arfaei (Analyst - BMO Capital Markets):

No, biosimilar of competing products such as Remicade, Enbrel, etc., in the US?

Rick Gonzalez (Chairman & CEO):

Oh, okay; I'm sorry. Obviously we're not assuming any -- because of the IP and the litigation strategy we talked about, we're not assuming any Humira biosimilar. I think as you click through the rest of them, as we look at the Enbrel IP we think they have pretty good IP, so we're not assuming that we'll see Enbrel biosimilars in the United States.

Then as it relates to any kind of Remicade, I think it would be a similar scenario to what we see outside the US. Because it's an infusion product it doesn't necessarily compete directly against us.

Then on bari, Mike, why don't you cover the head-to-head on bari?

Michael Severino (Chief Scientific Officer):

Sure. When we look at the baricitinib head-to-head data, clearly both agents are very active. When we focus on higher levels of response, which we think are the most clinically significant -- for example, DAS load, disease activity, or DAS remission -- we really see very similar response rates at week 24.

Of course, also consider the very long track record with Humira, the well-understood safety and efficacy profile. So we feel good about the overall performance of Humira over the course of its lifespan and think it will continue to play a very important role in the treatment armamentarium, as Rick has already outlined.

Alex Arfaei (Analyst - BMO Capital Markets):

Thank you, folks.

Larry Peepo (Investor Relations):

All right. Thanks, Alex. Operator, we have time for one more question, please.

Operator:

Colin Bristow, Bank of America Merrill Lynch.

Colin Bristow (Analyst - Bank of America Merrill Lynch):

Morning. Thanks for squeezing me in; and as others have said, great presentation today. Most of this has been covered, but on hep C what proportion of your contracts are exposed to competition in 2016 versus being multiyear? And just how have your expectations changed for your performance in 2016, if at all, based on the recent label update?

Then, two, just from a high-level, not to get -- given the focus on drug pricing exclusivity periods recently, could you give us your thoughts on these ongoing debates and whether you anticipate any impact to your business? Thanks.

Rick Gonzalez (Chairman & CEO):

Okay. I'm not sure I could give you the exact percentage of the contracts. I would say the vast majority of them are protected through -- the vast majority of the volume is protected, I'd say, through 2016. But let us get back to you with something that's maybe a little bit more specific.

As it relates to the label, as I outlined in my comments, this was obviously moving from not recommended to contraindicated. If you look at the patient population in Bs and Cs it's a relatively small patient population; it's probably something in the 3% or 4% range of US patients. So if you look at it purely from the perspective of that, it wouldn't be a big impact.

Frankly, the fact that we weren't recommended and contraindicated in Cs, you wouldn't assume that there was a lot of volume of testing -- or I'm sorry, of treating those patients anyway.

Having said that, I will tell you we've gone out and contacted probably now around 80% of the physicians that prescribe the drug to make sure that they understand the changes in the label. I think that's gone well. The feedback I'm getting directly back from the commercial organization said that has gone well.

We've gone back to all of our contracted -- our managed care contracts and other contracts, and that has gone well. They understand it and I think agree that in the previous label it was outlined in a way that probably there wasn't a tremendous amount of use there anyway.

Having said that, I think we have to wait to see how this plays out for the next maybe 30 days or so to be absolutely sure. But right now we are assuming, based on everything that we know, that it won't have a material impact on the brand. Oh, drug pricing?

Larry Peepo (Investor Relations):

Right.

Rick Gonzalez (Chairman & CEO):

Well, certainly I think if you look at the debate around drug pricing, it's not likely to go away. In fact I think with the political debate that's going on, we'll probably continue to hear more about it.

I think there -- everything isn't consistent across our industry. Certainly a lot of the debate came around taking old drugs and raising the prices a very significant amount. That's not a model that we have or we participate in.

I think the important thing for our industry, the innovative industry, is that we continue to bring out drugs that have a significant impact and we price those drugs in a way that gets the right value proposition, the right return for the value that those drugs have -- both the clinical value but also the economic value. And we demonstrate that economic value.

I will tell you in the international markets like Europe, where Humira has competed for a long time, those are markets that look very carefully at the economic value that their healthcare system pays. And obviously Humira has done extremely well in those markets, and it's because it is a good value proposition.

I think a lot of the areas that we're in, in specialty pharmaceuticals, it allows you to be able to do that. It allows you to be able to create a medicine that has a truly outstanding impact for patients and also has great economic value proposition and then pricing them accordingly.

So I don't fundamentally believe we'll see a significant change. But I think the debate will continue on, and I think our industry needs to respond in a way that's appropriate to that.

Larry Peepo (Investor Relations):

Thanks, Colin.

Colin Bristow (Analyst - Bank of America Merrill Lynch):

Thanks.

Larry Peepo (Investor Relations):

That concludes today's conference call. If you'd like to listen to the replay of the call, please visit our Web site at AbbVieinvestor.com. Thanks again for joining us today.

Operator:

That concludes today's conference. Thank your for participating. You may now disconnect.