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EDITED TRANSCRIPT

AZN.L - Q3 2017 AstraZeneca PLC Earnings Call

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OVERVIEW:

Co. reported 3Q17 results. Expects low-to-mid single-digit percentage decline in total revenue in FY17.



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CORPORATE PARTICIPANTS

David Fredrickson *AstraZeneca PLC - Executive VP & Global Head Oncology Business Unit*

Marc Dunoyer *AstraZeneca PLC - CFO & Executive Director*

Mark Mallon *AstraZeneca PLC - EVP-Global Product & Portfolio Strategy, Medical Affairs, Corporate Affairs & International West*

Pascal Soriot *AstraZeneca PLC - CEO & Executive Director*

Sean Bohan *AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development*

CONFERENCE CALL PARTICIPANTS

Alex Arfaei *BMO Capital Markets Equity Research - Pharmaceuticals Analyst*

Andrew Simon Baum *Citigroup Inc, Research Division - Global Head of Healthcare Research and MD*

James Daniel Gordon *JP Morgan Chase & Co, Research Division - Senior Analyst*

Jo Walton *Crédit Suisse AG, Research Division - MD*

Keyur Parekh *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Mark Douglas Purcell *Redburn (Europe) Limited, Research Division - Research Analyst*

Richard J. Parkes *Deutsche Bank AG, Research Division - Director*

Sachin Jain *BofA Merrill Lynch, Research Division - MD*

Simon P. Baker *Exane BNP Paribas, Research Division - Analyst*

Timothy Minton Anderson *Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst*

Vincent Meunier *Morgan Stanley, Research Division - Research Analyst*

PRESENTATION

Operator

Good afternoon, Europe, and good morning to the U.S. Welcome, ladies and gentlemen, to the AstraZeneca's year-to-date and Quarter 3 2017 results.

Before I hand over to AstraZeneca, I'd like to read the safe harbor statement. The company intends to utilise the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Participants on this call may make forward-looking statements with respect to the operations and financial performance of AstraZeneca. Although we believe our expectations are based on reasonable assumptions, by their very nature, forward-looking statements involve risks and uncertainties, and may be influenced by factors that could cause actual results to differ materially from those expressed or implied by these forward-looking statements. Any forward-looking statements made on this call reflect the knowledge and information available at this time on this call. The company undertakes no obligation to update forward-looking statements. Please also carefully review the forward-looking statements disclaimer that accompanies this presentation and webcast.

I will now hand you over to Pascal Soriot.

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Hello, everyone, it's Pascal Soriot here, CEO of AstraZeneca. Welcome to the year-to-date and Q3 2017 results conference call and our webcast for investors and analysts. We are here in Cambridge U.K., our global headquarters. We have people on the phone and the webcast. The presentation, as always, is available on astrazeneca.com for you to download.



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Please turn to Slide 2. This is our usual safe harbor statement, so please turn to Slide 3. We plan to spend about 30 minutes to the -- on the presentation and then leave the same time for Q&A. (Operator Instructions) There's also an option to ask questions online if you want as part of the webcast. And we would like to provide everyone with an opportunity to ask questions. (Operator Instructions) Thank you for your help.

Today, I'm joined by Marc Dunoyer, our CFO; Mark Mallon, Executive Vice President of Global Portfolio and Product Strategy, Global Medical Affairs and Corporate Affairs; we also have Sean Bohan, our EVP of Global Development and Chief Medical Officer; and then we also welcome Dave Fredrickson, our new Executive VP and Head of the Oncology business unit. Dave was previously the head of our Japanese business, launching Tagrisso there with great success, and before that, Dave was head of the U.S. Oncology business of AstraZeneca, and he launched Lynparza and Tagrisso in the U.S. market. Dave replaces Jamie Freedman, who's now the President of our Canadian organisation. Jamie has moved back to his native Toronto.

Please turn to Slide 4. Here is today's agenda, which I think you will be familiar with, so let's turn to Slide 5. On our conference call today, we will be making comments on our financial performance, using Core reporting metrics and at constant exchange rates, which are both non-GAAP measures. All numbers will refer to million U.S. dollars and gross rates at constant exchange rates, or CER, unless we otherwise state. With the formalities behind me, I will now kick off.

In summary, the business performance in the first 9 months continued in line with our expectations. Total revenue decreased as anticipated and reflected the clear impact of Crestor and Seroquel XR, U.S. loss of exclusivity. The decline in product sales decelerated from 8% year-to-date to only 2% in the third quarter. Sales from our growth platforms increased overall and actually improved during the third quarter, and particularly -- in particular, in the Emerging Markets and specifically in China, where we are doing extremely well.

Emerging Markets sales were up by 7%. Within this region, China continued to excel with a 10% growth rate. Underlying growth is actually closer to 15% and accelerating. There was a diminishing negative impact from the overall economic and geopolitical situation in some countries in the international region.

Our Respiratory business improved in the third quarter versus year-to-date, but also continued to be impacted by sales of Symbicort in the U.S., while this medicine remained a global leader in its class.

In what we call New CVMD, Brilinta continued with a high growth, and in diabetes, Farxiga continued to be the #1 -- the world #1 in its class and also got back to growth in the important U.S. market. Japan was up by 5%.

And finally, now Oncology is now 20% of the total business, continued up with new oncology medicine, Lynparza. Back to U.S. growth we had a very nice trend for Lynparza, and Tagrisso is also continuing its global launch.

Earnings per share were as expected and are now supported and updated. 2017 guidance -- where 2017 Core EPS anticipated to be closer to the low teen's percentage decline. As you all know, we updated our guidance.

Finally, we made progress in our sustainability agenda with 2 listings by the Dow Jones Sustainability Index as well as a very favorable A listing by CDP for climate and water.

Please turn to Slide 6. Our pipeline news flow continued since the last results announcement. This list may even be the most extensive list we've ever presented. Therefore, we'll only cover a few highlights. Lynparza, first of all, got U.S. approval in the second-line setting of ovarian cancer with a broad label, but importantly, we also had tablets approved at the same time. This was important for patients and for our company and our partner, Merck, with the upcoming last cycle programme for the medicine. So as I said before, we've seen a very nice uptick of our Lynparza prescriptions in the last few weeks.

We presented the exciting Phase III data from Tagrisso's FLAURA trial at ESMO, and we got a Breakthrough Therapy Designation for first-line use in the U.S. We also presented the Phase III data from Imfinzi's PACIFIC trial at ESMO, and we've achieved 7 regulatory submissions, including the



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U.S., EU, Japan and a few others. Together with Tagrisso, Imfinzi will make up a strong future presence in lung cancer, building on the legacy of Iressa, and a quite unique opportunity in our industry today.

Last but not least, Calquence became our fourth new oncology medicine and the first for AstraZeneca in blood cancer. This was a major milestone for the majority investment in Acerta that we announced in December 2015, a very exciting product with a nice label, and the team is ready to go. As usual, Sean will cover more pipeline milestones later.

So please turn to Slide 7. When we look at product sales, we continue to see underlying growth, now 5%. This growth comes from our 3 main therapy areas of oncology, CVMD and Respiratory and from the Emerging Markets, and we expect this growth to become more visible as we fully annualise the key patent expiries. And as we see our new launches gain momentum, we expect to see an acceleration of our growth rate for the growth platforms.

During 2017, we've seen an improving quarterly performance for product sales, and we look forward to keeping you updated on this journey.

Turning to Slide 8, as we deliver an improved sales performance and we return to growth, our focus on commercial execution will become more important. There are good examples today, for instance, the Emerging Markets, Brilinta, Farxiga, oncology. We've launched an unprecedented number of new medicines with benralizumab expected this quarter. This will be our first biologic medicine in Respiratory to treat severe uncontrolled asthma.

As with most years, there are positive and negatives, like the recent setback for tralokinumab. However, overall, on an aggregate basis, it has been a defining year for our company and a year with unprecedented news flow. We are committed to returning this company to growth in product sales, which will be the first time in many years, and will be a successful conclusion of the pipeline-driven transformation since 2012.

This really would not have been possible without the support and the dedicated work of all AstraZeneca colleagues around the world. Together, we look forward to keeping you, shareholders updated on the continued journey ahead.

With this, I will stop here, and hand over to Mark Mallon for our review of product sales and growth platforms.

Mark Mallon - AstraZeneca PLC - EVP-Global Product & Portfolio Strategy, Medical Affairs, Corporate Affairs & International West

Thank you, Pascal. I'm pleased to be here today to update you on the performance of our growth platforms. So let's get started with the next slide, please.

Today, I will cover our non-oncology growth platforms and hand over to Dave to cover New Oncology. The growth platforms, demonstrated overall growth in the quarter with a small acceleration during Q3, but with continued headwinds in Respiratory. Combined revenue of our growth platforms represented over 3/4 of the product sales year-to-date, and good momentum was seen in Emerging Markets, New CVMD and in New Oncology.

Next slide, please. Firstly, starting with Emerging Markets. We continue to be aligned with our long-term performance guidance of the mid- to high single-digit growth in product sales. Underlying growth without the impact from partnerships and investments, as Pascal mentioned, was approximately 5% higher. China exhibited a strong quarter with growth up to now 10% in the year-to-date, mainly driven by Respiratory, CV metabolic and Tagrisso.

Outside of China, we saw good growth across the region with Russia and Brazil outgrowing the local market.

Next slide, please. Respiratory sales continued to see challenges in the year with pricing pressure in the U.S. easing slightly. Sales declines in the U.S. and Europe have been largely offset by Emerging Markets and Established Rest of the World performance. With Symbicort, we're seeing a slight easing with product sales now down by 4% in the quarter. This reflects some moderation of pricing headwinds in the U.S. and competitive dynamics in Europe. We believe the easing is partially driven by our ability to differentiate with Symbicort, which continues to lead volume share in the ICS/LABA class globally.



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In the U.S. and in Europe; Symbicort product sales declined by 15% and 11%, respectively. Symbicort in Emerging Markets delivered growth of 8%, with China sales up by 18% in the year.

Pulmicort continued to demonstrate strong growth up to 7% until year-to-date, mainly driven again by China, the biggest market for the product.

Bevespi launch continues with new to brand share, stabilising.

Next slide, please. In New CVMD, sales were up by 5% despite intense competition with Emerging Markets continuing to offset a slower U.S. performance. Brilinta delivered product sales of \$780 million in the year-to-date, with 31% growth. A notable pickup was seen in the quarter with 67% growth in the U.S. and continued strength in Emerging Markets, including China.

Overall, the Diabetes franchise exhibited a softer year-to-date with sales down 3%. U.S. sales declined by 10% as a result of intense pricing pressure and competition from market share.

Farxiga maintained a 40% volume share globally, with product sales of \$742 million in the year-to-date and 24% growth. In the U.S., Farxiga product sales returned to growth, up 4% in the quarter, in part due to optimised affordability programmes. Farxiga continued to deliver strong growth in Europe and in Emerging Markets, with sales up 27% and 72%, respectively. We maintained leadership and share of voice across many markets.

Next slide, please. And staying on Diabetes, we're really pleased to announce an improved device for Bydureon, Bydureon BCise, previously known as the autoinjector. Bydureon BCise was approved by the U.S. FDA in October and has been accepted for review in Europe. The improved device plays at par with other devices in the weekly GLP-1 market, delivering a weekly Bydureon dose and a new formulation that requires no reconstitution.

Next slide, please. And in Japan, we continue to grow with product sales up by 5% in the year, driven by Tagrisso and Farxiga. Diabetes continued to impress, up 14% in Japan, driven by Farxiga growth of 60%. Farxiga is now the leading -- leading in the SGLT2 class in value and volume terms with class exhibiting strong growth.

Crestor, our largest product, saw its first generic entered during the quarter, and we do expect more soon, which will be an important factor as we move into 2018. We continue to have great success with Tagrisso, with although, with a slight sequential dip due to the Ryotanki lift, seen in Q2.

Just as a reminder, prescriptions for new medicines in Japan are limited to 2 weeks for their first year in the market. As a lift to this restriction occurred in Q2, there was a volume bonus at that point.

So with this, I will now hand over to Dave, the Head of Oncology business unit. Dave?

David Fredrickson - AstraZeneca PLC - Executive VP & Global Head Oncology Business Unit

Okay, thanks, Mark. I want to say how much I appreciate the opportunity to speak to you all on the phone today, and look forward to meeting many of you soon.

Just as oncology supported steady growth in Japan, you can see from the chart on Slide 16 that strong oncology sales in Q3 '17 made an important contribution to our global performance for the quarter. We exceeded \$1 billion in quarterly sales, up 19% versus the same quarter last year, and as Pascal mentioned, oncology sales now comprise over 20% of total product sales. Also, with the approval of Calquence on October 31, we've now delivered 4 new medicines within our New Oncology portfolio, and we are on track to deliver against our commitment of 6 new medicines by 2020.

Later in my section, I'll speak in more detail about Calquence as well as commercial performance of Lynparza, Tagrisso and our regulatory efforts for Imfinzi in lung cancer. But before I do that, a brief update on Imfinzi and bladder cancer. The U.S. approval and launch in the setting has been strategically important for us, allowing us to raise awareness, open accounts, obtain formulary access and set important groundwork for the future



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potential launches in lung cancer. Imfinzi was the fourth of now 5 PD/PD-L1s to launch in the second-line bladder space, and in this competitive space, we have seen steady progress month-over-month with market share now in the mid-single digits in our first full quarter post-approval.

Slide 17, please. The turning now to Lynparza, we saw strong performance in the quarter with sales of \$81 million, as steady growth continued in Europe. And again, as Pascal mentioned, very noteworthy, we drove a resurgence in U.S performance following the SOLO-2 approval, which expanded our label to second-line maintenance in ovarian cancer, and importantly, marked the launch of tablets. Eliminating the pill burden for patients that we had with capsules. Looking forward, we anticipate several important catalysts over the coming year for Lynparza, with potential launches of the tablet formulation in Europe, breast cancer in the United States and launches within Japan.

The Merck collaboration is progressing well, and we've had various joint working teams already established and good collaboration well underway. I am working closely with Frank Clyburn, my counterpart at Merck, and together, we're rapidly advancing the collaboration between our 2 companies. We look forward to the Merck sales force coming on board in 2018 and both companies eventually developing equal sized field force efforts on Lynparza. With this combined effort, we expect Lynparza to remain the leading PARP inhibitor.

Please turn to Slide 18. Now turning to lung cancer and Tagrisso and the soon to be expected Imfinzi. Tagrisso demonstrated continued growth on the quarter with global sales of \$248 million. We are on pace to eclipse \$1 billion in annualised sales. You already heard about the strong performance in Japan. In the U.S., performance was underpinned by continued efforts to drive testing, where now 2 out of 3 patients are tested for their T790M status. One such initiative is a voucher programme for plasma testing, which provides streamlined process for plasma draw, testing and delivery of results. Also, very importantly, we saw strength in Emerging Markets with sales of \$45 million in the quarter, China being the key driver.

As we look to Imfinzi, following on the exciting PACIFIC data and locally advanced unresectable non-small cell lung cancer, which we shared at ESMO, and the simultaneous New England Journal of Medicine publication, we are very pleased to announce that we've achieved 7 regulatory submissions to date in the key markets, including U.S., EU and Japan. We've also initiated an early access programme globally to allow patients to have access to this new therapy.

Please now turn to Slide 19. Lastly, we are very excited to have announced the U.S. approval of Calquence, also known as acalabrutinib, our BTK inhibitor in development for blood cancers. We received approval on a smaller indication for previously treated mantle cell lymphoma. We estimate that about 3,000 patients are diagnosed with mantle cell lymphoma each year in the U.S. Based on its efficacy, a 40% complete response rate and an 80% objective response rate, combined with its safety profile, we believe Calquence is a compelling best-in-class option for previously treated MCL patients. The launch of Calquence was our fifth launch of a new product or line extension in oncology in the U.S. in 2017. Our launch experience and execution continues to build, and with Calquence, our field force was in front of customers within hours of approval and we shipped product into the channel within 24 hours.

While still very early, initial feedback in the marketplace has been positive, and we look forward to a more thorough update on the launch in the year-end results.

With this, I'll now hand it over to Marc for the financials.

Marc Dunoyer - AstraZeneca PLC - CFO & Executive Director

Thank you, Dave, and hello, everyone. I'm going to spend the next few minutes taking you through our financial performance in the year-to-date. Please turn to Slide 21.

As usual, I will begin by showing you the Reported P&L numbers before turning to the Core performance. Total revenue declined by 3% in the first 9 months of the year, with product sales impacted by the receding effects of the Crestor and Seroquel XR losses of exclusivity in the United States. As you heard earlier from Pascal, product sales have seen a gradual quarterly improvement during the year.

Externalisation revenue grew by 50% in the year-to-date, with income from Merck of 1 billion making up around half of the total.



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Please turn to Slide 22. If we now turn to the Core performance, we can look further down the P&L and see that our gross margin ratio in the year-to-date was down at 81.8% from 82.9% in the same period of 2016. The third quarter, however, our gross margin ratio declined by 4 percentage points to 79.6%, impacted by unusually high level last year and manufacturing variances this year as well as the initiative profit share agreement on Lynparza. As part of the agreement, we will book all products sale of Lynparza and reflect the profit share, again through our cost of sales. This is in line with the comments I made back in July, that we didn't anticipate such a high Core gross margin ratio, that we saw in the first half, over the whole of 2017.

It's important to note that the Core gross margin was also impacted by losses of exclusivity and supply agreements on externalised or divested medicines.

Turning to operating expenses, Core R&D cost declined by 2% in the year-to-date, and Core SG&A cost declined by 5%. This reductions reflected our unrelenting focus on cost discipline. We did see an uplift in Core SG&A cost of 4% in the quarter, reflecting some specific factors. I will talk more about SG&A cost in a moment.

Core other operating income nearly doubled in the first 9 months, reflecting the level of disposal activity. The Core tax rate in the year-to-date was 18%. You may remember that last year, a one-off tax benefit impacted our quarter 3 performance at that time.

Please turn to Slide 23. I know that some of you find it challenging to model our future externalisation revenues. Here, I'd like to provide you for more clarity as well as reiterate that the externalisation remains the key part of our strategy. We have talked to you for some time about sustainable and ongoing externalisation revenue. In the first 9 months of the year, even when you take account of the Merck collaboration, this was 26% of total externalisation revenue versus 22% in the whole of 2016. Over time, this is in proportion rising further. The Merck collaboration is expected to provide further and increasing income in the years to come. We recognised around \$1 billion in externalisation revenue in the third quarter from Merck, with \$600 million deferred to the balance sheet. This will be released via the profit and loss account over time.

As you may remember, the agreement also includes spending by Merck of \$750 million for certain license options for the 2017 to 2019, and up to \$6.15 billion contingent upon successful achievement of future approval and sales milestone for monotherapy and combination. We anticipate the first milestone in 2018.

Please turn to Slide 24. This familiar slide illustrates the important progress in reducing our operating cost base. As I just mentioned, our OpEx base continued to reduce with Core R&D costs and Core SG&A costs declining so far this year. I did say in July, that from time to time, you may see the occasional rise in Core SG&A costs, and that is what you saw in the third quarter, as we had the low comparison as evidenced by the chart, made early investments in incoming launches and also invested in Emerging Markets, in particular in China.

I want to make it clear, however, that I remain committed to our principle of cost discipline as we look to reduce SG&A costs further over time and become a more efficient company.

Please turn to Slide 25. This new slide illustrates our cash flow performance in the year-to-date. Cash generation is a commitment and a key focus for me, Pascal and the rest of the management team, as we look to maximise our cash flows during our return to growth. On this chart, I want to highlight the \$622 million improvement in Reported operating profit, as well as a slow increase in working capital. The progress that we have made, especially in payables, has been outweighed by increases in inventory levels, including inventory of new biologic medicines, and I'm determined to address this.

As we look at net cash flow from operating activities on this slide, you can see that we strip out the gain on disposal, which are then added back further down in the cash flow statement.

With the good news on the approval of Calquence, it is worth reconfirming that we will soon pay \$1.5 billion to the selling shareholders of Acerta Pharma.

However, overall, the near \$400 million improvement in cash generation in the first 9 months was very encouraging, especially as we enter 2018.



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Please turn to Slide 26. I'd like to conclude with this more familiar slide, and I want to reiterate and refine the 2017 guidance, which is at constant exchange rate. I expect the low to mid-single digit percentage decline in total revenue. The guidance for Core EPS, has, however, been updated today. Core EPS is now anticipated to decline towards the more favorable end of the low to mid-teens percentage range. This refinement partly reflects the final agreement on the accounting for the Merck collaboration on Lynparza.

Outside of guidance, the total returns revenue and other operating income is still expected to be ahead of that of 2016. As I mentioned, sustainable and ongoing income is expected to increase as a proportion of externalisation revenue over time.

We anticipate that Core R&D cost will be broadly in line with 2016, and as I just mentioned now, we will reduce Core SG&A cost for this year. We remain very disciplined on costs as we return to growth.

And finally, I want to reiterate our capital allocation priority. We will continue to strike a balance between the interest of the business of financial creditors and our shareholders after providing for investment in the business, supporting the progressive dividend policy and maintaining a strong investment-grade credit rating, we will then keep under review any potential investment in value enhancing and immediately earnings accretive opportunities, that is last on the list.

With that, I will hand over to Sean.

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Thank you, Marc. I will now run through the late-stage pipeline events since the last results announcement and highlights of recent data presentation. I will then wrap up with a look at our upcoming news flow.

Please turn now to Slide 28. For the quarter, most pipeline news supports progress in each of our main therapy areas. In Oncology, we received several U.S. Breakthrough Therapy Designations. Imfinzi received U.S. BTM for patients with stage 3 unresectable non-small cell lung cancer. Submission to the U.S., EU, Japan and regulatory authorities in other countries were also made in the quarter.

Tagrisso received U.S. BTM after meeting its primary endpoint of progression-free survival in the first-line FLAURA trial. Calquence also received U.S. breakthrough designation, which subsequently led to approval by the FDA in October.

In Type 2 diabetes, Bydureon BCise, the autoinjector, received U.S. approval and EU regulatory submission acceptance. Furthermore, we received U.S. and EU approval for the combination of Farxiga and Bydureon in Type 2 diabetes.

In Respiratory, Symbicort received U.S. approval for COPD exacerbations. For Duaklir, another Phase III trial met its primary endpoint for COPD. Further, on data readouts, tralokinumab did not meet its primary endpoint in severe uncontrolled asthma in 2 trials.

Please turn to Slide 29. At ESMO, results from the Phase III FLAURA trial showed a statistically significant and clinically meaningful PFS benefit with Tagrisso over the current standard of care, erlotinib or gefitinib, as first-line treatments in previously untreated patients with locally advanced or metastatic epidermal growth factor receptor mutation, positive non-small cell lung cancer.

Median PFS was nearly doubled at 18.9 months for Tagrisso, compared with 10.2 months for the current first-line EGFR tyrosine kinase inhibitors. Improvements were seen in all pre-specified subgroups, including patients with and without brain metastases.

For FLAURA, we anticipate regulatory submission acceptances during the fourth quarter of 2017. Furthermore at ESMO, results from the pivotal Phase III PACIFIC trial also showed a statistically significant and clinically meaningful PFS benefit with Imfinzi, in patients with locally advanced stage 3, unresectable, non-small cell lung cancer following standard chemo radiation therapy, the clinical setting where there are currently no approved treatments.



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The PACIFIC regulatory submissions and/or acceptances in the U.S. with Priority Review, EU, Japan, Switzerland, Canada, Australia and Brazil, have been achieved. We anticipate first regulatory decisions in the first half of 2018.

Please turn now to Slide 30. For Brilinta, we've presented at ESC the sub-analysis of data from the Phase III PEGASUS-TIMI 54 trial, demonstrating a 29% risk reduction in CV death from treatment with Brilinta 60 milligrams given twice daily versus placebo in patients taking low-dose aspirin, but still at high risk for an atherothrombotic event, a major cause of acute coronary syndrome in CV death. At EASD, we presented the Farxiga DEPICT-1 results, which highlighted the safety and efficacy of Farxiga in patients with Type 1 diabetes uncontrolled on insulin. The trial demonstrated significant and clinically relevant reductions from baseline in hemoglobin A1C, weight reductions and also lowered daily insulin dose at 24 weeks versus placebo.

The Bydureon EXSCEL trial results were also presented at EASD. As a reminder, the trial met its primary safety objective but did not meet its primary efficacy objective.

Please turn to Slide 31. We believe our biologics portfolio for severe asthma is emerging as the strongest in the industry. Today, the science points to a precision approach. Benralizumab is an anti-eosinophil monoclonal antibody that targets the IL-5 receptor, thereby inducing direct and near complete depletion of eosinophils via antibody dependent cell-mediated cytotoxicity. We believe benralizumab is the precision biologic with the best clinical profile for severe asthma patients with an eosinophilic phenotype.

Tezepelumab is a first in class investigational monoclonal antibody that blocks thymic stromal lymphopoietin or TSLP. Recent Phase IIb clinical data from a study known as PATHWAY evaluated Tezepelumab in a broad population of severe asthma patients. The results were published in the New England Journal of Medicine and presented as a late-breaking abstract at ERS. TSLP is produced in response to pro-inflammatory stimuli such as allergen viruses and other pathogens in the lung, and acts as an upstream master switch driving multiple downstream inflammatory pathways, including Th2 cytokines such as IL-4, IL-5 and IL-13. However, TSLP also activates many types of cells involved in non-Th2 driven inflammation, and may play a role in non-Th2 driven disease.

Please turn to Slide 32. As you know, 2017 was a busy year. Activity will continue into 2018. Before the end of 2017, we expect to receive a U.S. regulatory decision on benralizumab for severe uncontrolled asthma. We expect regulatory submission acceptance for Tagrisso in first-line non-small cell lung cancer. In 2018, we expect Lynparza in first-line ovarian cancer -- data from Lynparza in first-line ovarian cancer from SOLO-1; the final MYSTIC OS data, plus a number of other news items, including first data readouts for IO trials KESTREL and EAGLE in head and neck cancer. We will also see data on PT010 in COPD.

Starting this time next year, we'll begin to see readouts for lupus from anifrolumab and have the potential for quite a few regulatory submissions before the end of next year.

Importantly, we also expect a number of regulatory decisions, including for lung cancer. We hope to soon have Tagrisso benefit patients in the first-line setting, as well as have Imfinzi benefiting patients with unresectable Stage III non-small cell lung cancer.

Thank you all for your continued support and thanks to all the hard-working people who come to work every day to make this happen. I will now hand back to Pascal for closing comments.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thank you, Sean. Please turn to Slide 34.

So before we end and move to the Q&A, let me summarise. Our performance to date was in line with expectations. AstraZeneca grew underlying product sales by 5%. Our financials were on track. We updated our guidance for revenue and Core EPS. We updated this Core EPS guidance to low mid-teen decline. During the period, we also had an unprecedented amount of pipeline news flow.



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We delivered good execution with Lynparza back to U.S. growth. Tagrisso continued its global rollout and we completed the important regulatory submission for Imfinzi's PACIFIC trial. We also saw our first medicine for blood cancer, Calquence.

Everyone in the company is proud of the significant difference our new medicines make to patients' lives.

Outside of oncology, Emerging Markets continue to impress, and Brilinta and Farxiga continued solidly, too.

We're looking forward to sharing more news flow from our pipeline that we think will further support our return to growth.

We will now go to the Q&A. (Operator Instructions) Thanks in advance, and perhaps we can take the first question from the conference call.

QUESTIONS AND ANSWERS

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

There's one question here from Richard Parkes of Deutsche Bank.

Richard J. Parkes - Deutsche Bank AG, Research Division - Director

Struggling to pick which one to choose, so I'll go with the obvious one, which is around 2018. Obviously not asking you to give guidance now, but maybe you could talk about the pushes and pulls to performance in 2018. I mean, you talked about returning the company to product sales growth, but I'm wondering about how we should think about profitability, and obviously, the extent to which you continue to generate additional externalisation, revenue will impact that. So I wondered if you could talk about how you expect that to evolve in 2018.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Richard. Good question. Let me quickly comment on the sales and then I'll ask Marc to comment on the P&L in more detail. As far as sales, you've got to see 2 major moving parts, really. One is the last part of our patent expiries. We're losing Crestor next year in Europe. You know that, but I think it's important to keep in mind. But that's the last one and sort of by the end of next year, we'll be without any major patent expiries for quite some years after that. But certainly next year, that's happening. On the positive side, we have a raft of launches. We're launching -- we're in the process of launching 7 new products. So that's a very substantial number of launches that will boost our growth. We also have obtained reimbursement, full reimbursement in China, 5 products that are on the national drug reimbursement list. That will further accelerate our growth rate in China. So those are kind of mostly the 2 big growth -- the big events on the top line. And of course, as we continue moving forward, these new launches will drive our growth more and more rapidly. So you have to see us become a company with a rapid growth rate as we emerge out of this final patent expiry next year. Marc, do you want to add any color on the externalisation and the cost?

Marc Dunoyer - AstraZeneca PLC - CFO & Executive Director

Yes, maybe a few factors to talk about 2018 without giving a detailed guidance. But first of all, there are 2 structural issues: the first one is, as we transition from primary care to a mix of primary and specialty care over time, and therefore, the proportion of specialty care and the greater oncology products will help operating leverage; the second structural issue is, we continue with our cost discipline and productivity initiative. We have seen that in the last 3 years, '15, '16 and '17, that we have derived continuous improvement in our productivity, and also these are shown as cost savings. So these are the 2 positive. You asked also a question about the externalisation and other income, and I can confirm that they will continue, and it is part of our business model. But we can also see that 2017 will probably be a peak in our externalisation and disposals. And lastly, as Pascal was just referring to, we have several launches which have taken place in the immediate past or near future, and therefore, we'll also have to do justice to these products so that we put them on the best possible trajectory. So I think these 4 factors have to be combined to arrive at a good projection for 2018, and I'd be happy to provide a more detailed guidance when we meet for the fourth quarter early next year.



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Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Marc. As you would expect, Richard, we're still going through our planning and budgeting process. It would be premature to comment more specifically.

Tim Anderson of Bernstein. Tim, do you want to go ahead?

Timothy Minton Anderson - Sanford C. Bernstein & Co., LLC., Research Division - Senior Analyst

Yes. More of a, kind of a science question. On tumour mutation burden, can you describe how you guys are incorporating this into any of your trials? For example, is there a way you might incorporate this into MYSTIC, like Bristol is contemplating with 227 even if only for exploratory purposes? And then just a quick question on the dividend. With Glaxo, there is fears of dividend risk. With Astra, do we have anything to fear? Are there any particular items that could create uncertainty with your dividend as you look forward over the next couple of years?

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Tim. So let me start with the dividend, and then I'll ask Sean to cover the scientific question, and then I'll ask Marc to cover the dividend again. So what I want to say about the dividend is, there has, and we have said this from the beginning, it has been part of our value proposition that, we actually realise that it'd take time to rebuild our pipeline, rebuild the company, and in the meantime, we were very committed to the dividend because our shareholders have to be rewarded for their patience. So I'll say that, what I've said before, we're committed to the dividend today, tomorrow, the day after. Our commitment to the dividend is full. Sean?

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Yes, sure. Thanks, Tim, for the question. To answer your question, so in the trials that are already ongoing and enrolling, obviously, we -- it's hard incorporate a new exploratory market prospectively. Retrospectively, we did collect tissue from the patients in the MYSTIC trial, and it does give the opportunity to look at things like TMB or even other markers like interferon signature as exploratory endpoints with a retrospective analysis. The -- we have not finalised plans for that, however, or analyzing it as an option. One thing I would add is, tumour mutational burden is not one simple test. It's not quite like PD-L1 expression techniques that you use, what -- where you look for the mutations, how you measure the load, remain quite variable. So that's a complexity that we see, but we're definitely examining it closely.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Sean. I think, the dividend, you'll want to hear it from the CFO again. So you'll hear it twice.

Marc Dunoyer - AstraZeneca PLC - CFO & Executive Director

So first of all, we remain committed to our progressive dividend policy. I've just mentioned it a few minutes ago in my presentation on the capital allocation priorities. So again, we affirm, once again, that we are all committed to a progressive dividend policy for the company.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Marc. Sachin of the Bank of America.



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Sachin Jain - *BofA Merrill Lynch, Research Division - MD*

All right. Sachin Jain, Bank of America. On the recent study start with IDO in the PACIFIC setting, really just outline why you chose out IDO versus CTLA-4. And then Sean, I've asked the questions frequently, but how do you think about IDO versus CTLA from broader development beyond a single study? And then just a clarification on MYSTIC, if I could. My interpretation is the messaging has changed from the 2Q call from don't over-interpret PFS and I guess, still has a chance to one of limited confidence in the combo and the real focus being mono. So I wanted to check whether that shift is correct. If so, what's behind it? And if the delay to Merck's KEYNOTE-189 change your thought process at all?

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Thanks. So I'll let Sean cover this. But let me just say, overall, I don't think there is any shift, at least in our view. There's no new news, let's say, that would shift our confidence. But Sean, do you want to add?

Sean Bohan - *AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development*

Sure. So the first question was about IDO versus CTLA-4 in stage 3 unresectable and maintenance setting like PACIFIC. It's important to recognise that when you go into a maintenance setting, tolerability is a very important aspect of the regimen that you choose, and was indeed one of the real unknowns for Imfinzi as a single agent prior to doing PACIFIC. It turned out that the tolerability is quite favorable, particularly in light of the PFS benefit that was demonstrated. We know that adding tremelimumab to Imfinzi adds autoimmune toxicity. And so it's really a question of whether that tolerability would support a maintenance indication. That led to looking at an IDO combination where tolerability looks quite similar to, again, single agent Imfinzi. And that consideration will also be carried as we look forward into other combinations, and whether we might go into this maintenance setting after chemoradiotherapy. I think, with regard to broader combos, hopefully I just answered the question with the last part. We consider not only evidence of efficacy but also tolerability. Messaging around MYSTIC. Yes, I agree with Pascal. We haven't really changed our messaging or our confidence. Our messaging, almost 2 years ago now, was that we thought overall survival was the endpoint that better captured the benefit of IO therapies. I think over the course of that period, since we changed MYSTIC, we feel even more strongly, based on data -- from both our own data and in the field as a whole, that that's true. The difference, I guess, I would say, and you're right, overall survival remains to be analyzed. So we expect the results first half of next year and it still -- it is quite possible that, that will be a positive result, even though PFS was not a positive result. But the last part I would say, with regard to combo versus mono, perhaps the only thing that's changed over time is that there's more mono data showing that, that's a validated treatment paradigm and PD-1, PD-L1s as a mechanism of action for non-small cell lung cancer. So in one case, we have a test hypothesis, which is durva + treme, in another case, we have a fair amount of data that monotherapy can benefit at least subsets of patients in this setting. So that might be the only thing that's changed.

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Yes, I think we were very clear on Q2, Sean, that we saw a lot of probability for the combination. And so, I mean, not achieving PFS was not a good sign either. So I don't -- I think we were relatively clear sometimes. The use of word, I guess, can be read one way or another.

Andrew at Citi, if you want to go ahead.

Andrew Simon Baum - *Citigroup Inc, Research Division - Global Head of Healthcare Research and MD*

Yes. A couple of questions. Number one, just to confirm that neither within the PFS OS or OS of MYSTIC is a prospective analysis in TMB high patients as part of the primary analysis. I think that's what Sean was saying, but I just wanted to confirm. And then the question is, why didn't you? Was it a question of lacking power? Was it data capture, that you just didn't have enough sample set? Or some other issue? And then a couple of other quick ones. Timing for the expansion of the Lynparza programme with Merck. We were obviously expecting many more trials to be announced. When should we expect them to hit clinical trials? And finally, if Pascal wants to say something about Jamie Freedman's departure to Canada, and David's ascension?



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Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Sean, do you want to cover the first 2 questions?

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Yes, sure. So TMB and MYSTIC. Again, no, there is not a prospective analysis. It would be a retrospective exploratory analysis for TMB high versus low -- why is that? Well, a couple of reasons for that: one, when MYSTIC was designed and enrolled, the TMB hypothesis didn't really exist as a hypothesis. PD-L1 expression hypothesis was the stronger hypothesis. I would add, at this point in time, I think in non-small cell lung cancer, that really remains the validated hypothesis, that PD-L1 high is a better predictor of benefit from IO therapy. And so as I said, we do have the opportunity to potentially look at TMB in a retrospective exploratory sense. The last part I would say is, I do not think as a diagnostic modality that TMB has been operationalised in a way that really lends itself to a companion diagnostic yet. So that's a consideration we also use. There was another question about...

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Lynparza programme with expansion with Merck.

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Yes. Expansion of Lynparza programme with Merck. Obviously, these discussions are ongoing. I will say that from -- Dave talked a little bit about the success that they're having in the collaboration in the commercial setting. The development collaboration is also progressing very, very nicely, and we're formulating plans and beginning to implement them. So as those turn into trials, we will announce them collectively, and you'll also see them appearing on clinicaltrials.gov. So that should be coming next year.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

So the last question on -- as far as Jamie, we are as a company very committed to talent development. And essentially, what I've learned in my career as far as learning and developing is 2 things: one is, you have to experience different roles, both in the field and globally. So we want people to alternate global and local roles. The second is, what I've also learned is, there is the perfect development plan that you can put together, and then there is the opportunities that arise, and you seize those opportunities when they arise. So what happened here is that, it's a great opportunity for Jamie to gain field experience. He's never led a country. So that's a great experience to learn a country, to lead the country. And secondly, his parents are aging. He's from Toronto. So it's a great opportunity to match personal development and also the personal family dimension. So that's basically what happened here. And I really think that it's a fantastic opportunity to develop 2 leaders, in fact, Jamie in the field-based leadership role -- commercial role; and look forward to working with Dave, who comes historically from Genentech -- actually, Roche Genentech, and joined us in the U.S. organisation a few years back, and has been in Japan for the recent past. So that's really -- there's nothing more than this behind this move. It's really a talent development move, Andrew.

So let's move to Vincent at Morgan Stanley.

Vincent Meunier - Morgan Stanley, Research Division - Research Analyst

I mean, on product sales. On Imfinzi, I mean, there is no sales contribution this quarter. \$1 million for the first 9 months. Should we expect sales contribution inlaying as from fourth quarter on the back of the updated NCCN guidelines? Or later in the beginning of next year when it is approved? And it's more or less the same question for Calquence. I mean, should we expect Calquence to remain a kind of niche product, waiting for the next label extensions as from 2020? Or do you think it can generate more than the MCL indication?



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Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Vincent. So Dave, speaking of you. It's a good opportunity for you to cover those 2 questions.

David Fredrickson - AstraZeneca PLC - Executive VP & Global Head Oncology Business Unit

Absolutely. So thank you for both questions. So on Imfinzi. Certainly, we today promote only in the second-line bladder setting, which is where we have our approval, and we were encouraged certainly by the NCCN's category 2A finding for the data coming out of PACIFIC. Though that NCCN compendia listing occurred on the 29th of September, so the last week in the third quarter, so obviously, it had no impact on any third quarter treatment decisions. Certainly, we know that NCCN guidelines do factor into physician treatment decisions and formulary decisions within institutions. We won't be promoting, at all, in this setting, as we don't have a label until we do get approval next year. And we do feel that this is a tremendous opportunity once we have the opportunity to launch into the Stage 3 setting. Imfinzi is the first medicine to come into a setting and to show results like the ones that Sean talked through, and so we really see this as a great opportunity for future growth. In terms of Calquence, again, the opportunity that we have in front of us and where we launched into is in the mantle cell lymphoma space, and we have ongoing studies in CLL, and we'll look forward to seeing those results come back. We believe that in mantle cell, we've got a best-in-class therapeutic, and we have every expectation of pursuing the mantle cell marketplace with that as the objective of making it as such.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thank you, David. Alex, BMO. Go ahead.

Alex Arfaei - BMO Capital Markets Equity Research - Pharmaceuticals Analyst

Congratulations on Calquence and all the progress in oncology. Just following up on the earlier PACIFIC question. How should we think about upstage in this setting? Are these patients readily diagnosed? Or is the rate-limiting factor going to be the inflow of patients? Just want to get a better sense of how we should think about the trajectory. And also, could you please provide your outlook on Diabetes, obviously, getting more and more competitive. I know there SGLT2 and GLP-1 expected in 2018. So how should we think about your growth prospects there?

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thank you, Alex. Two great question. One question -- sorry -- 1 PACIFIC uptake for you, Dave, and then the other one, the Diabetes market, Mark Mallon will take this one. I'm sure Mark would be happy to talk about Diabetes, because we still have great expectations for Diabetes. Should we start with PACIFIC, Dave?

David Fredrickson - AstraZeneca PLC - Executive VP & Global Head Oncology Business Unit

Sure, absolutely. So Alex, as I guess maybe to start on this, and there was this second question within yours around, is this regularly diagnosed. I think it's worth a reminder that so in Stage 3, the design of the study was such that Imfinzi was added in maintenance following chemoradiotherapy. And so what this means is that actually physicians know very well who their patients are today in Stage 3 on chemoradiotherapy. And they have the opportunity to be thinking about those patients in anticipation of when that set of cycles of chemoradiotherapy will end, and begin thinking about adding Imfinzi on to that. So there really is a group of patients that today are already in Stage 3 that are being treated with CRT. The majority of those patients do achieve disease control, and would be, therefore, eligible for treatment with Imfinzi. Today, the primary therapy or the primary approach that physicians take is watch and wait, and they watch and wait basically for a progression to take place. And with Imfinzi now, they have an opportunity to provide, if approved, active therapy within that setting. So that's how I would think about the uptake within that setting on that regard. Mark?



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Mark Mallon - AstraZeneca PLC - EVP-Global Product & Portfolio Strategy, Medical Affairs, Corporate Affairs & International West

Thanks, Alex, for your question. Thomas, I don't know if this is allowed, but can I give like a bottle of champagne for the first person that asks a question about CV metabolic or respiratory? So very happy to answer the question. So the short answer, we continue to be very positive and excited about the possibilities and growth in the Diabetes area, both for Farxiga in the SGLT2 class and also for Bydureon in the GLP-1 class. I think the thing to keep in mind with Farxiga is to understand how much more potential there is for the SGLT2 class. This is a class that's now been shown in clinical studies and also with our CVD-REAL to have a very material impact on heart failure, CV mortality, on likely renal disease. And the penetration of the class is still relatively low. So the headroom to grow and make a huge difference for patients is enormous. We are the leader globally, as I mentioned in my remarks. We think Farxiga's got a great profile. We're excited about the possibilities with DECLARE study coming next year, which is the only study that's looking at primary prevention as well as the secondary prevention. So really see lots of possibilities for us in the SGLT2 class and very confident in Farxiga's position. We're also very excited with the possibilities of launching Bydureon BCise. We've got a product -- a new device that is very competitive with the weekly devices, and a lot of people still need further glucose and weight control, and so we're looking forward to launching that and ready to go.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Mark. Just one other is that, we have a better access profile for mix on the U.S. for Farxiga. So it's a good place also.

So to make sure we call out as many questions as we can, because we have a few questions waiting, we will extend the call for 15 minutes to 1:15 U.K. time.

So we'll maybe move to one question online, and I will read it out, and I think it's for you, Sean. How should we view the decision to initiate new pivotal trials with the treme + durva combo this quarter, for instance in liver and the HIMALAYA trial, when the benefit from the combo remains unclear? Why not wait until more proof of the benefit from the combo is available, not least to manage your return on investment?

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Yes, great question. So thank you for the question. There are a couple of things about durva + treme combo that I think are important to capture. The first is that, as you know, with anti-CTLA-4, even as a single agent, different tumour types have different levels of sensitivity to the mechanism of action. And we believe, similarly, that different tumour types will likely have different levels of sensitivity to the Imfinzi/treme combo. And what that means is that a PFS readout from MYSTIC not only may not read through to an OS readout from MYSTIC, but lung cancer may not read through to other tumour types. We believe that we have an opportunity for the combination in hepatocellular carcinoma liver cancer, and that's why we initiated the HIMALAYA trial. The HIMALAYA trial has as a comparator the standard of care sorafenib. It has Imfinzi monotherapy, and then it also has the durva + treme combos. The reason we don't wait is because we feel like it's an independent opportunity and, of course, time-sensitive.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Certainly. And learning will not inform us that much in the energy setting.

So Jo Walton from Credit Suisse.

Jo Walton - Cr dit Suisse AG, Research Division - MD

Respecting your one question limit, I'd like you to go back and talk a little bit more about costs, if possible. The consensus expectation for marketing costs on your Core numbers is for a small decline in 2018. Given that you have so many drugs to launch, and you clearly want to maximise their opportunity, do you think that, that is still a realistic expectation? And in terms of costs, could you also address what may be happening at the gross margin level, and how quickly it will turn back to being above 80%?



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Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thank you, Jo. Marc?

Marc Dunoyer - AstraZeneca PLC - CFO & Executive Director

So I will start with the second question, Jo. First of all, the gross margin. So you have seen that the impact on the third quarter -- we had a gross margin ratio of 79.6%. We have signaled that this was unusual, and therefore, I would not recommend that it be used as a measure of underlying performance. However, we have also said that, earlier in the year, that the first half would not reproduce in the second half. So I believe for margin ratio, the -- if you look at the year-to-date and the quarter 3, 2017, this could provide a good indication for where 2017 is going to finish. And I do not expect enormous variations for 2018. I will provide more detailed guidance next year in February. But as of today, what I can say that there shouldn't be large variation in the gross margin ratio over 2018.

And then your next question, I can only go back to the earlier explanation, which is you have structural trends, which is a move towards more specialty in oncology care. We continue our cost discipline. We have a productivity initiative, but as you point out, there are also quite a few launches to support presently and in the near future. So all of this will be taken into consideration as we finalise our budget for next year. And I will be happy to comment further, or with further detail, in February 2018.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thank you, Marc.

Mark Purcell of Redburn. Mark, go ahead.

Mark Douglas Purcell - Redburn (Europe) Limited, Research Division - Research Analyst

I was just going to ask for a little bit more color, if I may, on Lynparza. Recently, some positive data in glioblastoma. They're very exciting in combination with radiotherapy. And obviously, internally, you have some early-stage data for Lynparza in combination with Imfinzi. So I know you're not going to say specifically which trials you're starting next year, but can you help us understand sort of how broad this opportunity is in terms of sort of tumour types and lines of therapy based on the data you've seen so far? And if, as you're focusing on the stage 3 unresectable patients, whether there's an opportunity in combination with chemoradiation. And just related to that, in terms of the Merck \$750 million of option payments. Given how competitive the IO and PARP inhibitor space is, under what circumstances would the full \$750 million not be realised over the next 12 months as these trials, I expect, are going to start in 2018? In the slides, there's a suggestion that, that \$750 million will also shift into 2019 as well.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Maybe we should start with the second question which relates to milestones. (inaudible). Marc?

Marc Dunoyer - AstraZeneca PLC - CFO & Executive Director

(inaudible) this option's for 3 years. It is an option for 3 years: '17, '18 and '19. So we expect this option to continue over the year. But of course, as they are options, they are at the decision of collaborator. So we expect them to be paid, but obviously, we can't be certain.



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Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

So the other question related to Lynparza, Sean, in combination with PD-1, but also this GBM. I assume, the reference was to this GBM study done in Scotland that was communicated recently. I assume, Mark, that's what you're referring to or whether you're...

Mark Douglas Purcell - Redburn (Europe) Limited, Research Division - Research Analyst

No, exactly. There seems to be a very broad -- potential broad mechanism of action here using Lynparza in combination with other agents. So just some thoughts there based on the data you have in-house in that recent study you mentioned, Pascal.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Okay, so it's a broad question about combination with IO and other agent.

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

So let me go -- let me start with the -- I'll start with the IO PARP combination. Now, obviously, we're not going to share data that we haven't published but that we have and we know about it. So -- I hate to disappoint, but that's the way that it's going to end up. Obviously, the study we have that's ongoing is MEDIOLA. MEDIOLA has really demonstrated the tolerability of the combination, which is our first step in development, and that then gives us the opportunity to opportunistically expand into a variety of other indications, and we've shared some of those -- the Lynparza indication, BRCA-mutated ovarian cancer and platinum-sensitive HER2 negative breast cancer, small cell lung cancer, a place that we've looked at IO, gastric cancers. So those are things we've shared with everyone. We then will also look opportunistically at what we would like to initiate as Phase III programmes, and we'll announce them in due course once we've started them. And we'll look at outside data as well and decide what opportunities we want to initiate and complete. With regard to combinations more broadly, I think, again, there are a lot that we can explore, and some of it will be using preclinical data to prioritise. Some of it will really be empirical as we generate safety data and the combinations, and then, again, use the trials to expand, if they're tolerable, opportunistically. And I think there was a question also about PACIFIC, the idea of using a Lynparza IO combination...

Mark Douglas Purcell - Redburn (Europe) Limited, Research Division - Research Analyst

Through chemoradiation, yes.

Sean Bohan - AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development

Yes. Okay, good. Again, as I mentioned there, I think 2 things are going on: one is, we want some evidence that the combination is -- has showed some level of activity before proceeding; and then, the other thing I mentioned in that maintenance setting that is important is tolerability. So expanding the Lynparza, Imfinzi and Imfinzi/treme combination gives us the opportunity to assess that tolerability and generate data to decide which regimen, or both, seem appropriate for going into an Imfinzi maintenance setting, a bit like PACIFIC.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

Thanks, Sean. Mark, as it relates to your specific GBM question, it's small Phase I study. You got to remember, Lynparza doesn't cross the blood-brain barrier area, but in circumstances, like with GBM, when the barrier is disrupted, the study showed that it penetrates it. So we would have to see what we do with this study. But we also have other DDR agents that do potentially penetrate the blood-brain barrier and may be a better option than Lynparza. But certainly a very interesting thing to look at.

James Gordon at JPMorgan. James, do you want to go ahead?



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James Daniel Gordon - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Sure. A question on HIMALAYA which was, how does the HIMALAYA CTLA-4 dosing differ to MYSTIC? Is it higher, and is it an ongoing CTLA-4 dose? And if so, if there are differences in the dosing, what made you choose this different dosing approach? And similarly, I could see a reference to the STRONG trial. Is that a different approach in how CTLA-4 is administered? Also, just one clarification. I think there was a comment about final OS in H1 '18, implying that if there were interim OS analyses that have already taken place, they would presumably have informed any newer approaches you're using in terms of how you were going to dose CTLA-4.

Sean Bohan - *AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development*

So I'll take the 2 separately. The first, HIMALAYA. So we have -- what was disclosed about HIMALAYA. So HIMALAYA, again, is the unresectable hepatocellular carcinoma study. It has 4 arms. One's the standard of care, sorafenib. But then, we also have single agent, Imfinzi. And then we have -- and that Imfinzi is given monthly at a flat dose of 1,500 milligrams. I think what we have disclosed is that we have 2 different doses and regimens of tremelimumab in the combination arms, but we haven't disclosed what those are exactly. And so we're not going to do that now, we'll do that in due course. The other question was one, was that informed by MYSTIC. The answer is, no. It wasn't informed by MYSTIC. It was informed by other data we have. And then, the other question was, commenting on an interim. I'll do a couple of things with the interim question -- overall survival interim question. We don't comment on if or when they will occur. I will tell you that if the IDMC doesn't tell us that there's something to look at, we don't even see the data. So that it wouldn't inform anything because it wouldn't get to the company. We do that in order to preserve the integrity of the endpoint for the final analysis, which is in the first half, as we've mentioned many times, of 2018. So it really isn't MYSTIC that's informing this. It's other information that we have.

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Thank you, Sean.

Keyur of Goldman Sachs. Keyur, go ahead.

Keyur Parekh - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Just on 2018. Consensus has moved significantly over the last 3 months, and is now forecasting Core EPS to decline relative to 2017. Do you think that is directionally the right place for consensus to be at? And then, within that Marc, you've already confirmed the externalisation in 2018 would be lower than that in 2017. Would that also be true for the cumulative of externalisation plus other operating income?

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Marc?

Marc Dunoyer - *AstraZeneca PLC - CFO & Executive Director*

So let me comment first on your second question. So what I said just a few minutes ago, I said that the total of externalisation revenues and other income in 2017 would be sort of peaking, and therefore, one can conclude from there that the level of externalisation and other income in 2018 will be at a lower level than '17. However, I said that this is still part of our strategy, and therefore, this is part of our business model and will continue. So you can expect a reasonable amount of externalisation revenue than other income also in 2018.



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Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Thank you, Marc. So we'll take 2 last questions, one online, which is a quick one, and one from Simon of Exane.

So the online question is, why is there a regulatory timing change for ARCTIC from second half of '17, first half of '18? Sean, do you want to cover that?

Sean Bohan - *AstraZeneca PLC - Chief Medical Officer and EVP of Global Medicines Development*

Yes, sure. That is accurate observation. We've updated the timing to delay it from the end of '17 to the first half of '18. The regulatory timing change is a knock-on effect from the data availability timing change being pushed out. The way that ARCTIC is designed, it's third line or later non-small cell lung cancer, and it has both PFS and OS as primary endpoint. The thing is that, in third line non-small cell lung cancer, because the patients really don't have good therapeutic alternatives, progression and death occur fairly close to each other. So that the overall survival in that there's only one analysis that's triggered, and it's triggered by the maturation of overall survival, and it's just an event rate accumulation that it hasn't accumulated the overall survival events to initiate the database lock and analysis.

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

Thanks, Sean. Very clear.

Simon, Exane. Now, Simon, go ahead.

Simon P. Baker - *Exane BNP Paribas, Research Division - Analyst*

Let me return to the outlook. I know you're not going to give any guidance on 2018, so let me try my luck on 2019, '20 and beyond. In terms of the -- how we should think about the margin evolution. At the moment, you have R&D in the high 20s as a percentage of sales, which is one of the highest in the industry as you're developing the pipeline. It's reasonable to assume at some point in the future that, that will decline to a more normalised level. So I was wondering if you could give some thoughts on how we should think about how that evolves in the qualitative terms over the coming years. And similarly, with SG&A, as you achieve this move from primary to specialty care, high 30s SG&A as a percentage of sales would be somewhat unusual for a specialty-focused company. One would expect it to come down. And again, how should we think about the longer-term trajectory of that spend?

Pascal Soriot - *AstraZeneca PLC - CEO & Executive Director*

So let me just make a general comment, and then Marc you can also add. In 2020, if you kind of project yourself out to that year, it's an important year for us, and I can tell you it's very firmly on our radar screen, because we are entering this is very critical period of execution where we have to turn the pipeline into a reality for patients of course, but also a commercial reality. It has to turn into top line and earnings for us. So you have to think of -- as I said earlier, you have to think of our company as we leave the last patent expiry, Crestor Europe, behind us next year, and we -- you have to see us as a fast-growing company. So by 2020, we certainly would expect those ratios to drop as the top line grows rapidly. We have the critical mass, and the ratios would drop. So we can't give specific numbers, but it is clear that the goal will be to improve operating margin, and the horizon is not that far. It's 2020. And it's really going to be driven by, of course, cost management as always, but very much a very good top line growth. Marc, any additional (inaudible)?

Marc Dunoyer - *AstraZeneca PLC - CFO & Executive Director*

Well, I can only go about the various factors. As I said earlier on, I think our discipline to contain cost will continue. We have a greater -- we'll have a greater productivity because we have several initiative across the company. We are moving, definitely, with the place that the oncology products

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are taking, we are moving towards a more specialty care company. So therefore, I think the phenomenon for normalisation of the R&D as well as SG&A is going to continue. And you're on the right track. But I also signaled earlier on that, we also need to take care, in the short term, of the launch of several new products. So all this has to be sort of aggregated for you to derive projections on '18, '19 or '20.

Pascal Soriot - AstraZeneca PLC - CEO & Executive Director

We've got a couple of people still on the line for Q&A. If you send the questions to the IR team, we'll make sure you get answers back as soon as possible.

So let me now close. And to summarise again, to say that our performance is very much in line with expectations. We can see the new AZ emerge, and we have underlying product sales growing by 5% for this new AstraZeneca. Our financials are on track, in fact, doing quite well, to the extent that we were able to upgrade our guidance a little bit for the year, and we certainly continue working up to do even better if we can. But we are on the right track. We are -- as I said, we are very much moving into an execution mode. We're launching Tagrisso. Dave talked about a \$1 billion running rate already, and we are going to get first-line indication, hopefully, very soon.

Lynparza is back to growth, and the last few weeks have been really, really pleasing for Lynparza in the U.S.

We are gearing up for the launch of Stage 3 Imfinzi. That said, Lynparza was really a nice way to get ourselves prepared. We've done quite well, actually, in a very tough market in the broader segment that really, essentially, was about getting electronic processing of claims in the systems to get formulary listing, and we're getting ready for PACIFIC.

Calquence is our new launch. So we're really proud as a company to make a difference to cancer. And beyond cancer, we're also making good progress. Brilinta is now a \$1 billion drug, and growing very, very fast. Farxiga is doing, also, well. The Emerging Markets, in particular, China, doing well.

So all of this, as I said earlier, will see us emerge as a fast-growing company in the not so distant future.

So thank you so much for your attention, and I also want to take this opportunity to thanks very much our colleagues from around the world for delivering such an outstanding result from a pipeline viewpoint, but also now from a commercial viewpoint. Thank you so much, everybody.

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