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PRESENTATION

Operator

Good afternoon. Welcome, ladies and gentlemen, to the AstraZeneca's Half Year 2017 Results Analyst Conference Call. Before I hand over the call to Pascal Soriot, AstraZeneca, I would like to read the safe harbor statements.

The company intends to utilize 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. By their very nature, forward-looking statements involve risk and uncertainty, and results may differ materially from those expressed or implied by these forward-looking statements.

The company undertakes no obligation to update forward-looking statements. (Operator Instructions) We will now hand you over to the Chief Executive Officer, Pascal Soriot, for the call is about to start.



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Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Good afternoon, everyone. Pascal Soriot here. Welcome to the first half results conference call and webcast for investors and analysts. We're in Cambridge in the U.K. in our global headquarters. And we have people on the phone and the webcast. As always, the presentation is available on AstraZeneca.com for you to download.

Please turn to Slide 2. This is our usual safe harbor statement. Please turn to Slide 3. Today, we plan to spend about half an hour on the presentation, and then leave almost 1 hour for Q&A. We have lots to talk about today, and it's very important for us to put all of today's news into context.

(Operator Instructions)

Today, I'm joined by Marc Dunoyer, our CFO; Mark Mallon, our EVP for Global Products and Portfolio Strategy, Global Medical Affairs and Corporate Affairs; Jamie Freedman, EVP for Oncology, the Oncology Business Unit; and Sean Bohan, our EVP for Global Medicines Development and our Chief Medical Officer.

Please turn to Slide 4. This is our agenda for today. And I would like to ask you to move to Slide 5. These are the highlights for the first half. On our conference call today, we will be making comments on our financial performance using core reporting metrics and at CER, at constant exchange rate, which are both non-GAAP measures. So with the formalities behind me, I'll now kick off.

In summary, the business performance for the first half of 2017 was in line with expectations. Total revenue declined as anticipated and reflected the tail impact of Crestor's and Seroquel XR's U.S. loss of exclusivity and some phasing of externalization revenue.

On the other hand, sales from growth platforms increased overall. They now account for 70% of total revenue. Emerging Markets, we are at 6%. Within this region, China continued to perform well. And we saw the launch in the first sales of Tagrisso. Outside China, there were impacts from the economic and geopolitical situation in some countries.

Our Respiratory business continued to be impacted by U.S. Symbicort, while the medicine remained a global leader in its class. And for new CVMD, Brilinta continued with its high growth. And in diabetes, Farxiga continued to be the world leader in its class, despite a subdued U.S. performance due to price and managed care access. But overall, Farxiga delivered very good results. Japan was up by 6% and actually accelerated in Q2. Tagrisso expanded on its impressive global launch and recorded the first sale in China, as I mentioned a minute ago. Finally, earnings per share, we are underpinned by continued cost management and other operating income.

So please turn to Slide 6. The pipeline news flow continued since the last results announcement. We were, of course, disappointed by today's MYSTIC progression-free survival readout, and we now have to wait for the overall survival data in the first half of 2018. But we were pleased by a number of successes including the PACIFIC trial. Let me cover a handful of news items. First of all, Imfinzi -- the Imfinzi news include the strategic and early U.S. launch in bladder cancer as well as the early positive PFS results obtained from the PACIFIC trial. Earlier today, we provided an update on progression-free survival from MYSTIC, where there is no PFS benefit and we need to wait until first half of 2018 when we expect to get the full picture of the clinical profile with the overall survival final analysis.

On the other hand, we met the single primary endpoint of progression-free survival in the FLAURA trial for Tagrisso, which we are very pleased by -- when you see the growth coming from Tagrisso in this first half. We think we now got clinical data to unlock more value for patients and AstraZeneca and to help our ambitions in lung cancer.

Next news is Faslodex. It obtained approval in first-line breast cancer in the EU and in Japan. And Lynparza was accepted for review in the EU and in Japan in second-line ovarian cancer based on the SOLO-2 trial. Unfortunately, Bydureon for Type 2 diabetes didn't show a statistically significant reduction in cardiovascular events in the EXSCEL outcomes trial, but the safety profile of this medicine was reconfirmed.

In Respiratory, Bevespi was accepted for review in the EU for the treatment of COPD. We need to wait for the STRATOS 2 trial for tralokinumab to fully characterize the clinical profile for severe uncontrolled asthma.



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Outside our main therapy areas, our externalization efforts were boosted by the approval of Kyntheum for psoriasis. Through partnerships with focused dermatology companies like Valeant in the U.S. and LEO Pharma in Europe, we have been able to bring this medicine to patients in need of better therapies.

Given our strategic focus on the 3 main therapy areas, AstraZeneca is not able to provide the same support to dermatology medicines as our partners are, underpinning the strategic rationale for the decision to externalize. There are more pipeline milestones that's shown we will speak it to later. We will also cover today's news in detail.

Please turn to Slide 7. When we look at new AstraZeneca, we continue to see growth. Product sales grew by 4% and more underlying. Mark Mallon will get back to this later. As we move forward, and very soon exit the patent cliff for Crestor in the U.S., we will start to see this growth become more visible, and we look forward to keeping you updated on this journey. I will now move to Slide 8.

As we begin returning to growth, our focus on commercial execution will increase. A good example is, today, for instance, Brilinta and also Tagrisso. We've now also launched Qtern in Europe and of course Imfinzi in the U.S. At the end of the year, we anticipate the launch of benralizumab, our first biologic medicine in respiratory disease to treat severe uncontrolled asthma.

On the news flow side, we were able to add one more tick mark for Imfinzi approval and the exciting data for -- from the PACIFIC trial in Stage III unresectable lung cancer. I believe this is an indication that is still underestimated. It has a lot of potential, and we will be by ourselves in that indication. We also recognize, however, that the MYSTIC PFS results are disappointing. And that we now wait -- we need to wait until first half of 2018 before we get the final OS data, and therefore, the full picture of the clinical profile of Imfinzi in lung cancer and the combination.

On the other hand, today's news from the FLAURA trial for Tagrisso is very encouraging, and it supports our focus on lung cancer and the benefit we can bring to patients. There's a lot more pipeline news flow expected over the remainder of the year. In summary and despite some disappointments and some successes, together with management team, we are very committed to delivering our return to growth and to deliver the value and the benefits of the pipeline to patients in need around the world. I have to say that I'm very impressed by the progress we've made. And we would like to thank every colleague in the global AstraZeneca network for their contribution. I'm very proud to be the CEO of this company. I look forward to continuing on our journey. And I would like to say that, I'm very, very committed to seeing this implementation of this strategy through.

Speaking of our journey, please turn to Slide 9. I'd like to touch on the collaboration that we have announced earlier today with our partner Merck. The primary purpose of the collaboration is to accelerate and to expand the potential for Lynparza, and essentially make Lynparza the PARP inhibitor of choice. This collaboration affirms Lynparza as the leading PARP inhibitor for I/O combination. And also with the leading PD-1 in terms of clinical trials ongoing. Jamie will elaborate on this further in his section, but essentially the collaboration will also enable further studies to be initiated faster than we could have done ourselves and in broader patient's population. In a nutshell, we actually partner products where we believe we can create more value with our partner. And here, there is a clear benefit in partnering with Merck, who is a very strong company. A company that shares our focus on science and has a strong I/O presence. And in combining Lynparza with KEYTRUDA on the one hand and nivolumab on the other hand, we believe we can make Lynparza a much bigger product. The total deal value is worth up to \$8.5 billion, which we consider very attractive for Lynparza. And just as a short reminder, \$8.5 billion for half of this asset, which 4 years ago was written-off in the books of the company, we believe is actually a reflection of the valuation that a very respectable company is actually able to see in Lynparza, and we believe together with our partner at Merck, we can make Lynparza a big product. With this, I will now hand over to Mark Mallon. Mark, over to you.

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

Thanks, Pascal. And I'm pleased to be here again to update you on the performance of our growth platforms. So let's jump right in. Next slide please. I'll cover our nongrowth -- our non-Oncology growth platforms, and then hand over to Jamie to cover New Oncology. The growth platforms, as Pascal mentioned, demonstrated overall growth in the quarter despite the continued headwinds in Respiratory. And the combined revenue of our growth platforms represented an impressive 70% of total revenue in the first half. Momentum was seen in Emerging Markets in Japan and in New Oncology.



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Next slide, please. Starting with Emerging Markets. We continue to deliver in line with our long-term performance target of mid- to high-single digit growth in product sales. In fact, when you take out the revenue from divestments, growth in the half was more than 10% across Emerging Markets. Growth in China of 8% in the half was mainly driven by new products, new launches of Farxiga and Tagrisso and on the strong performance of Brilinta. Importantly, for our long-term business, we have seen 5 of our medicines added newly to the Chinese National Reimbursement Drug Listings, one of the best performances of any company in China and including, most importantly, Brilinta. Outside of China, we continue to see headwinds in Saudi Arabia and Venezuela due to challenging economic environment in those countries, but other parts of the Emerging Markets performed well. And notably, Middle East and Africa with growth of 28% in the first half of the year.

Next slide, please. The Respiratory franchise sales continue to see challenges in the half, with downward pressure in the U.S. being slightly offset by Emerging Markets and established rest of world performance. As expected with Symbicort, we continue to see challenges with global product sales down 10% is reflecting price headwinds in the U.S. and competitive dynamics in Europe. We do not see a lessening of competitive pricing pressure going forward. However, Symbicort continues to lead volume share in the ICS/LABA class globally.

In the U.S. and Europe, Symbicort product sales declined by 19% and 10%, respectively. Symbicort Emerging Markets delivered growth of 4%, with Symbicort China sales up by 18% in the half.

We've launched an extensive Symbicort campaign to highlight its strong differentiation versus competitors. The campaign focuses on the 39% greater reduction in exacerbation versus Seretide and SABA, the 7x improvement in asthma-controlled days versus baseline standard of care. In fact, this was achieved with a 25% lower ICS dose than Seretide and SABA.

Next slide, please. Touching briefly on Bevespi. The U.S. launch is going well, with new-to-brand prescriptions almost at 15% after only 6 months. The performance is ahead of what you would expect to see of a fourth to market launch. And actually, right now, we are the only LAMA/LABA growing market share in the U.S. While the growth of the LAMA/LABA class continues to be below expectations, we still believe it has an important role to play with COPD patients. And we continue to believe that Bevespi offers a unique proposition with the Aerosphere technology, supported by a differentiated clinical profile.

As a reminder, Bevespi is the first of our portfolio of new products launching on our new pMDI platform utilizing the co-suspension technology that enables a consistent delivery of one or more medicines from a single pMDI.

Next slide, please. In new CVMD, sales were up 4% despite intense competition with a strong performance in Emerging Markets offsetting slower U.S. performance. Brilinta delivered product sales of almost \$0.5 billion in the half with 28% growth. Notable performance seen in the U.S. and Emerging Markets, including China. The overall diabetes franchise exhibited a softer half, with sales down 4%. U.S. sales declined by 9% as a result of intense pricing pressure and competition for market share.

Farxiga maintained a 40% volume market share globally, and it continues to be the leader in volume market share, with product sales of \$457 million in the half and 22% growth, as Pascal highlighted. Farxiga continued to deliver strong growth in Europe and Emerging Markets with sales up 24% and 83%, respectively. In the U.S., Farxiga product sales were down 1% due to managed care access and affordability programs and a competitive market. Moving forward, we're working to optimize our affordability programs in the U.S.

As we wait for CV outcomes data from the DECLARE trial, the CVD-REAL study has already demonstrated the CV benefits for the SGLT2 class and Farxiga in a real-world setting. These data have been well shared and accepted by the medical community. We continued our efforts highlighting the overall benefits of Farxiga, which include excellent glucose control, weight loss, blood pressure and a proven tolerability profile.

Next slide, please. Finally, touching on Japan. We continue to grow the product sales up 6% in the half, driven by Tagrisso and Farxiga. Farxiga is the leading SGLT -- leading in the SGLT2 class in terms of value sales, and the class itself is exhibiting strong growth in Japan. Our diabetes business in Japan was up 21% in the first half. And as I mentioned, we continue to have great success with Tagrisso in Japan. But I'll, at this point, turn it over to Jamie, and he will tell you more about that and the rest of our New Oncology portfolio.



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James Freedman - AstraZeneca PLC - Executive Vice-President of Oncology

Thank you, Mark. Hello, everyone. I'm going to cover the Oncology franchise. This quarter is the first quarter since 2010 that we've achieved \$1 billion in product sales. This is a 20% growth since the previous year. For the first half, we've achieved \$1.9 billion in sales, which is 19% improvement since the previous year. This is primarily driven by 4 products: Faslodex, which is an older product. It has seen renewed growth due to expansions in the first line. We just found out yesterday, actually, that we got approval in Europe for the FALCON trial, which is a first-line metastatic breast cancer. We hope to hear soon with the U.S. And we've also seen combination use in second line with CDK4/6 inhibitors. This is 16% growth and about \$250 million in sales for the quarter. For New Oncology products, we are halfway to achieving our goal of 6 new medicines by 2020. Three have already been delivered. Tagrisso has shown very strong growth globally, particularly in Asia. Imfinzi, we initiated our strategic launch in May 2017, and I'll cover that more in detail. And with Lynparza, there has been continued strong news flow. We announced SOLO-2 results, which is the second-line maintenance setting for ovarian cancer that was very impressive, and more recently, for metastatic breast cancer with BRCA mutation.

Next slide, please. So Tagrisso has shown strong growth quarter-on-quarter. This is primarily due to Emerging Markets and established rest of world. In Japan, we've had the highest testing rates of all, at about 96%. In China, we had the fastest launch in the history of AstraZeneca, in May, with sales starting to pick up. In Europe, we've seen more reimbursements, most recently in Italy, for a total of 14 markets in Europe with partial or full reimbursement. And in the U.S., we're starting to see testing rates for T790M mutations in the second line increase due to education around ctDNA plasma retesting. We previously reported the first-line results in Phase I that had an impressive progression-free survival of 19.3 months. We just announced today the results of FLAURA, which is the pivotal trial in first-line EGFR mutant non-small cell lung cancer that were positive, and you'll hear more about that from Sean.

Next slide, please. For Imfinzi, we received accelerated approval in second-line bladder cancer and launched in May. We've only been on the market for a couple of months, and we've already seen 35% share of voice, which is second to the other competitors. This is really a strategic launch to set us up for Stage III unresectable non-small cell lung cancer based on the positive PACIFIC trial where we met the primary -- the progression-free survival endpoint, which is the primary endpoint of the trial. We anticipate regulatory submission in second half of this year. This is a tremendous opportunity for us with about 100,000 Stage III lung cancer patients where there is no other PD-1 or PD-L1 inhibitor. This has the potential to be a blockbuster, and we're 2 to 3 years ahead of the competition.

Next slide, please. With Lynparza, we remain a global leader. We are the first on the market with ovarian cancer. Now there is competitors. And we are the first to announce positive results in a second indication for a PARP inhibitor, which is metastatic breast cancer. We've seen steady growth, particularly in Europe. In the U.S., we've seen some headwinds as a result of still having the fourth-line indication in ovarian cancer, and we have a very high pill burden. SOLO-2 results in the second-line maintenance setting were submitted for regulatory submission, and we hope to hear back in the third quarter. And as a result of that, when we can launch, we will be able to reduce the pill burden from 16 capsules a day to 4 tablets a day, and also be in the second-line maintenance setting, which would make us very competitive. We have a very favorable safety profile. Our development program with Lynparza is extremely robust. The goals are to move to earlier line settings with the SOLO-1 trial reading out at the beginning of 2018. It will position us in first-line maintenance ovarian cancer. Eventually, we're going to have the OlympiA results that will put us in the adjuvant breast cancer setting, and then we have additional indications with pancreatic cancer and prostate cancer. We have several combination trials underway with VEGF inhibitors, including bevacizumab and cediranib, that will expand the activity of Lynparza beyond BRCA mutation. And then beyond that, we have an extensive DDR portfolio to combine with Lynparza that will put us in different segments of different diseases as well as the immuno-oncology combination.

Next slide, please. Pascal mentioned earlier that we entered a strategic collaboration with Merck. And this is a critical partnership that we believe will maximize the value of Lynparza by combining 2 immuno-oncology agents: one, a PD-1 inhibitor, KEYTRUDA, which is one of the leading immuno-oncology agents; as well as Imfinzi. And the goal behind it is to enhance activity in the BRCA-mutant subpopulation but also to expand beyond BRCA mutations into the wild-type population. We are pursuing this not only with I/O but DDR and VEGF inhibitors, and this is something that Merck will participate in with us as well.

Next slide, please. The goal again around the partnership is, Merck has the most number of clinical trials in immuno-oncology, with about 39% in multiple indications, that's shown in the light-green segment, and the darker-green segment is Imfinzi, also very active in clinical trials. The 2 of us



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together would have, by far, the most clinical trials with immuno-oncology. And by partnering with each other and combining with Lynparza, we should maximize the value of Lynparza.

Next slide, please. So in summary, around the Merck collaboration, we combined the capabilities of 2 main oncology players. We established Lynparza as the preferred PARP inhibitor backbone of PD-L1 and PD-1 inhibitors; it accelerates Lynparza development with KEYTRUDA; we maximize the potential number of treatment options; and as Pascal mentioned, the total value of the deal is \$8.5 billion.

And with that, I will hand it over to Marc Dunoyer to cover finance.

Marc Dunoyer - AstraZeneca PLC - CFO and Executive Director

Thank you, Jamie, and hello, everyone. I'm going to spend the next few minutes taking you through our financial performance in the first half.

If you could please turn to Slide 25. As usual, I will begin by showing you the reported P&L numbers before turning to the core performance. Total revenue declined by 9% in the half with product sales impacted by the residual effect of Crestor and Seroquel XR's losses of exclusivity in the United States. Externalization revenue declined by 1%. As previously highlighted, we expect the sustainable and ongoing proportion of externalization revenue at a high of 34% in the first half to increase over time.

Please turn to Slide 26. If we now turn to the core performance, we can look further down the P&L and see that our gross margin in the half was stable at constant exchange rate at 83%. This reflected the mix of sales and the growing influence of specialty care medicine, together with the impact of the losses of exclusivity and the resilience of some legacy medicines in established markets. Important to note that we do not anticipate such a high gross margin over the full year given the phasing of supply cost and some nonrepetitive benefit that will not be seen in the second half.

Core R&D costs declined by 4% in the half, and core SG&A cost declined by 9%. These reductions reflected our focus on cost discipline, and supported our full year commitment of keeping core R&D cost broadly stable and reducing core SG&A cost.

Again, we do not anticipate such a reduction in core SG&A cost over the full year as we saw in the first half. Core other operating income and expense more than doubled in the half, partly reflecting the level of disposal activity as well as a milestone received from Pfizer.

The core tax rate in the half was 19%, in line with 16% to 20% range we continue to anticipate for the full year. As Pascal mentioned a moment ago, the increase in core EPS in the half was primarily driven by continued focus on cost as well as increase in other expense and income.

If you could please turn to Slide 27. This familiar slide illustrates the important progress in reducing our operating cost base. As I've just mentioned, core R&D cost declined by 4% in the half, whereas core SG&A decreased by 9%. One example of what we are doing is prioritization, making sure that we have the right people and resources focused on the best medicines and opportunities.

We also recently launched a Global Business Service Organization, which over time will increase the level of integration and allow us to focus on cost further. We remain committed to continue reducing our operating cost base this year.

Please turn to Slide 28. Turning to our operating profit margin. You may have noticed that we have achieved 30% plus margin for a number of consecutive quarters. This has even been before the overall pipeline delivered in the way we anticipate. We also know that our gross margin is being supported by the growing influence of specialty care medicine sale. Core R&D investment is not targeted as a ratio to product sales, and core SG&A cost has the capacity to reduce further. So we recognize the long-term operating leverage opportunity. However, depending upon the success of the pipeline, we would also want to retain some flexibility to invest in high-return pipeline and launch opportunities.

In short, as a big patent cliff cycle ends this year and as the pipeline delivers, new AstraZeneca has a potential to deliver a growing margin while keeping some flexibility on pipeline opportunities.



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Please turn to Slide 29. To conclude, I want to reiterate the 2017 guidance, which is at constant exchange rate. I expect a low- to mid-single digit percentage decline in total revenue. Core EPS is anticipated to decline by low to mid-teens percentage. Outside of guidance, the total of externalization revenue and other operating income is still expected to be ahead of that in 2016. As I mentioned, sustainable and ongoing income is expected to increase as a proportion of the externalized revenue in 2017 and beyond. We anticipate that core R&D will be broadly in line with 2016, and as I just mentioned now, we plan to reduce core SG&A cost this year.

As highlighted before, variations in performance between quarters can be expected to continue with year-on-year comparison beginning to ease in the second half, particularly as we begin to lap the impact from the loss of Crestor in the United States.

Finally, as you know, capital allocation priorities before and they remain unchanged. We will continue to strike a balance between the interest of the business, our 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 keep under review any potential investment in value-enhancing and immediately earnings accretive opportunities.

With this, I will now hand over to Sean.

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

Thank you, Marc. I will run through the late-stage pipeline events occurring since the last results announcement, today's important news and highlights of recent data presentations. Then I'll wrap up with a look at our upcoming news flow.

Please turn now to Slide 31. As in Q1, it was an equally busy 3 months, where we mostly saw progress in each therapy area. Imfinzi got U.S. approval in bladder cancer, our first biologic and our first immunotherapy. The PACIFIC trial met its progression-free survival primary endpoint during a planned interim analysis, and we are now very excited to be working with regulators to bring Imfinzi to patients with Stage III unresectable non-small cell lung cancer. As you saw, this did not show benefit on PFS, and we now will await the final overall survival in the first half of 2018. This is a disappointment for us. But as we have said on several occasions, we need overall survival to fully qualify the clinical profile of the I/O medicines, which is why we refined the MYSTIC trial design.

Further in lung cancer, Tagrisso met its primary endpoint in the first line FLAURA trial. Lynparza had regulatory submission acceptance in the EU and Japan for second-line ovarian cancer. In Type 2 diabetes, Bydureon met the primary safety objective in the cardiovascular outcomes trial, but did not reach statistical significance in showing superior CV benefit over placebo.

These data will be shared at EASD later this year. Further on data readouts, we had some mixed news with tralokinumab not meeting its primary endpoint in severe uncontrolled asthma, although the study did provide valuable information regarding potential in a subpopulation of patients expressing a specific biomarker. These learnings have been incorporated into the second Phase III study of tralokinumab, STRATOS 2. Staying on Respiratory, we had regulatory submission acceptances of Bevespi for COPD -- acceptance of Bevespi for COPD in the EU. Last week, we learned that our partner LEO Pharma received European approval for Kyntheum, formerly known as brodalumab and marketed as Siliq in the U.S.

Please turn to the next slide. In June, we took our science to ASCO and shared 100 abstracts, including updates on Lynparza, Tagrisso and Imfinzi. We shared the OlympiA data from Lynparza and BRCA-mutated metastatic breast cancer, which made the plenary session. We also shared health-related quality of life data in ovarian cancer from SOLO-2. For Tagrisso, we shared encouraging data from AURA3 for patients with EGFR, T790M mutation-positive non-small cell lung cancer and CNS metastases, strengthening the case for Tagrisso's move to first-line EGFR-mutated lung cancer and its ability to cross the blood-brain barrier.

And for Imfinzi, we highlighted the data included in our recent approval for bladder cancer and further non-small cell lung cancer data from study 1108.

Please turn to Slide 33. As you all know, a large unmet medical need remains in non-small cell lung cancer. This slide illustrates the depth and breadth of AstraZeneca's commercialized and late-stage potential medicines in this disease area. Expanding the EGFR-mutated tumors with small



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molecules like IRESSA and Tagrisso and addressing the non-EGFR and non-ALK-mutated tumors with Imfinzi and tremelimumab. AstraZeneca's ambition is to provide a treatment option for as many patients with non-small cell lung cancer as possible. Over the past 3 months, we have received 3 major data points: PFS for PACIFIC and MYSTIC, and we are waiting for the overall survival for both trials. Then we received the positive results from Tagrisso in the FLAURA trial with only one primary endpoint progression-free survival. We are working on regulatory submissions for PACIFIC and FLAURA at the moment, and we hope to bring these 2 opportunities to patients as soon as possible.

Please turn to Slide 34. This slide highlights the status of the 3 recent news items and the progress that we have made in non-small cell lung cancer to date. First with the positive progression-free survival readout from the PACIFIC trial with Imfinzi in Stage III unresectable non-small cell lung cancer. We will make regulatory submissions as soon as possible this half. We believe this is a very meaningful opportunity. Second, we have announced the MYSTIC PFS data. We are disappointed that the combo of Imfinzi and tremelimumab and Imfinzi alone in monotherapy did not show a benefit on progression-free survival. I will come back to this in a moment. Third, we had the good news from Tagrisso that met at single primary endpoint in the first-line FLAURA trial, not only was trial statistically significant but also clinically relevant. The 2 positive news items will increase our presence in lung cancer across stages and key segments of the market. This is good news for patients and for the company as well.

Please turn to Slide 35. As just discussed, MYSTIC did not meet its progression-free survival endpoint, both for the combo and monotherapy and both at the 25% PD-L1 expression cut point. We are continuing the trial to assess overall survival for both monotherapy and combination therapy, which are the remaining primary endpoints. We expect these readouts to come in the first half of 2018, and as we have previously mentioned, all trials of this nature have interim analyses built into the statistical analysis plan. However, we do not comment on the exact timing of those interims. We remain confident that overall survival is the best measure of efficacy in immuno-oncology and look forward to keeping you updated with our progress.

Turn now to Slide 36. As a reminder, there is more to come beyond progression-free survival for MYSTIC. We recently saw positive readout for PACIFIC, and we are currently studying either Imfinzi, Imfinzi plus treme in 6 other randomized-controlled trials. Studies include ADJUVANT with a disease-free survival endpoint to PEARL, the first-line trial in the Asian patient population as well as POSEIDON with chemo combination with I/O therapy. AstraZeneca's commitment to immuno-oncology remains strong, and non-small cell lung cancer is at the forefront of our overall strategy in oncology.

Please turn to Slide 37. Concluding on immuno-oncology, here is a familiar slide including our trials in head and neck and bladder cancers as well as non-small cell lung cancer. KESTREL has been moved into the first half of 2018 due to a slower-than-expected event rate, causing a slight timeline movement from the end of 2017. Next year, we will have final overall survival data from both MYSTIC and NEPTUNE as well as results from DANUBE in bladder cancer.

Next slide, please. Looking now beyond immuno-oncology, I wanted to highlight the additional news items in our overall oncology portfolio that we expect to share between now and the end of 2018. Acalabrutinib, where we are looking to update you on next steps, as a reminder, we generally communicate regulatory submission acceptance once we have heard back from the regulatory agency. Faslodex continues to make strides in first-line breast cancer, and regulatory approvals for Lynparza in second-line ovarian cancer and regulatory submission in first-line breast cancer are forthcoming.

Similarly, opportunities for moxetumomab in leukemia and selumetinib in thyroid cancer round out the broad range of news items that you can expect to see from AstraZeneca in the next few quarters.

Next slide, please. Moving away from oncology for a moment, I wanted to highlight some of the important science happening in our CVMD therapy area. At ADA, we recently shared additional CVD-REAL findings, supporting the benefit of SGLT2 inhibitors over other oral antidiabetic medicines in both all-cause mortality and hospitalizations due to heart failure. Also, data on DURATION-7 and DURATION-8 showing added benefit when combining Bydureon with either Farxiga or basal insulin. At ESC, in August, with our partners, the TIMI group, we will share new data from the PEGASUS trial in high-risk PMI patient. And at EASD, in September, AstraZeneca will participate in an EASD-sponsored discussion panel on SGLT2 inhibitors as a novel treatment for Type 1 diabetes as well as present the exciting 24-week data from the DEPICT-1 trial of Farxiga in Type 1 diabetes.



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Further, we announced today that the DECLARE trial timeline is being moved forward to the second half of 2018 from 2019 previously. With that, I would like to end with a snapshot of upcoming news flow from our late-stage pipeline.

Next slide, please. As you can see from this slide, 2017 will continue to be a busy year and activity will continue into 2018. We've now broken 2018 into first and second half. Before the end of 2017, we expect to receive U.S. regulatory decisions on Faslodex in the first-line setting, Lynparza in second-line ovarian cancer, the Bydureon autoinjector and benralizumab for severe uncontrolled asthma. We will also be submitting Lynparza in breast cancer; Tagrisso in first-line EGFR-mutated non-small cell lung cancer based on today's news; and of course, Imfinzi based on the PACIFIC trial in Stage III unresectable lung cancer.

There is certainly still the potential for a faster market opportunity with acalabrutinib. Please note my previous comments on when we generally announce potential regulatory submission acceptance. In 2018, we expect the final MYSTIC OS data plus a number of other news items, including Lynparza in first-line ovarian cancer based on SOLO-1. And first data readouts for the I/O trials, KESTREL and EAGLE in head and neck cancer. We'll also see data on PT010 in COPD. Starting this time next year, we will begin to see readouts for lupus and bladder cancer and have the potential for quite a few regulatory submissions before the end of 2018.

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

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Thank you, Sean. So let me summarize. First of all, the first half was in line with expectations. New AstraZeneca grew product sales by 4%. Our financials are on track, and we reconfirm our guidance. Second, the pipeline is advancing at pace, with 12 new potential medicines in Phase III under registration. The oncology pipeline in particular is progressing. Tagrisso and Lynparza are ahead of expectations. We recognize, of course, that the MYSTIC news is a disappointment, but we also recognize the positive surprise with the PACIFIC trial, which is a very large opportunity that will belong to us for a period of time.

We are looking forward to sharing further news flow that we think has the potential to mark a meaningful step-change for AstraZeneca, in particular the details of the PACIFIC and the FLAURA Phase III trials in lung cancer, which we hope to present very soon. We will now go to the Q&A.

(Operator Instructions)

And perhaps we can now take the first question from the conference call.

QUESTIONS AND ANSWERS

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

And I think the first question would go to Tim Anderson at Bernstein. Tim, go ahead.

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

Over the last many weeks, you had suggested that you'd provide a fair bit more in your top line release for MYSTIC than a normal top line release. But to me, it seems pretty scant on details, given the materiality of it. And I'm hoping you can say at least whether there was a trend on PFS and whether it might have just been a powering issue? And kind of related to this, is there a working hypothesis for why the monotherapy with durva didn't hit on PFS at 25% and above? Are you confident that, that's not an indictment of the PD-L1 approach versus the PD-1 approach?



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Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Okay, Tim, thank you so much. Sean, I think it's for you this one.

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

Yes, okay. Tim, thank you for the question. With regard to what's been disclosed here, we actually have disclosed more than we usually do. Usually we -- in high-level results, we disclose just the outcome positive or negative of the primary endpoint that's being evaluated at the time and we did that. That primary endpoint was the Imfinzi/treme combination for PFS in tumors expressing tumor cells greater than 25% PD-L1. We also then went on -- we didn't formally test the secondary endpoint because obviously once you fail with the primary, you aren't recycling that power. And we did, however, because we know it's relevant to everyone to get a sense of what happened with the monotherapy in that same patient population. We went on to say that we did not meet the criteria. Had we been able to go on to monotherapy, that would have made that positive. So that we think is quite a full and transparent disclosure. With regard to the design of the trial, we are very confident that the trial was adequately powered to show a clinically meaningful PFS benefit. With regard to confidence going forward, the PFS endpoint has not been a very reliable endpoint for predicting benefit in immuno-oncology. There are certainly cases where it has been positive and in line with overall survival. But there have been multiple cases, particularly in the second line non-small cell lung cancer, where progression-free survival has not shown a benefit. But when you continue to overall survival, the benefit is shown. That is, in fact, in part why we changed the clinical trial design of MYSTIC to elevate overall survival to a primary endpoint to allocate the majority of the power to overall survival and also increase the size of the trial to enable that.

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

And then on PD-L1 as a general approach?

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

Well, PD-L1 is, at this point in our minds, a validated therapeutic approach in non-small cell lung cancer. We talk about the specific data, unfortunately, without yet having a venue at which to actually share it with you. But we have conveyed our confidence that it's a clinically meaningful benefit. And it will mean Imfinzi is brought to patients with non-small cell lung cancer.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

I would only add actually, Tim, that you cannot really -- we cannot actually say PD-L1 and PD-1 are different. I mean, nivolumab in first line lung also didn't show a PFS benefit. So the -- I think there is variability from study-to-study. That's probably the best we can say. But I don't think we have evidence there is difference between PD-1 and PD-L1. Let's move to Richard Parkes at Deutsche Bank.

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

I've got a bunch on MYSTIC, but I'm going to just skip those and ask something about FLAURA. I just wondered if you could talk about the context in which you've gauged clinical meaningfulness of the FLAURA data. I wondered if you've taken into consideration obviously the option physicians have to seek when it's Tagrisso in the second line setting. And obviously, that sets a high bar as to what needs to be demonstrated to make this maybe clinical practice-changing data. So I suppose my question is, is this data likely to be practice-changing as well as clinically meaningful? And just -- could add as well, when would we expect survival data from FLAURA to mature?

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Thanks, Richard. So maybe, Sean, if you want to comment? And then also later on, Jamie, if you have anything you want to add from a sort of a payer and clinical practice viewpoint?



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

Yes. So obviously, what we're reporting with high-level results is again, a bit scant for us to give you details. We found a highly statistically significant and, we believe, a clinically quite meaningful difference in progression-free survival. It is an endpoint that in a first line setting is a robust regulatory endpoint. And we do have an interesting design to the trial in that patients who got the standard of care first generation, if they have a T790M mutation on their progression, they within the trial have the option of crossing over to Tagrisso. So as time goes on, we're going to be able to really characterize this better. But we are quite confident in the results we have now. With regards to timing of overall survival, overall survival is a key secondary endpoint. The primary endpoint was PFS, that has been met. We will continue to follow for a couple of key secondary endpoints. The second progression, PFS2, as well as overall survival. We can't give you a timing on that now because the trial, it's event-driven and it's quite immature. It takes a while for that endpoint to actually mature because there are not only the option of going to Tagrisso if you have a T790M mutation. But for all patients who progress on the trial, there's the option of chemotherapy in a second line setting. And I'll let Jamie comment as well.

James Freedman - AstraZeneca PLC - Executive Vice-President of Oncology

Yes, in terms of the sequencing and why we believe it will be used in first line as opposed to second line in patients who develop a T790M mutation, you'll recall that about half the patients do not develop the T790M mutation. And so they wouldn't be eligible for Tagrisso if they waited until second line. So that's one point. Second point is some patients actually don't make it to second line because they -- because of death. So we believe the clinically meaningful results will play into why it should be prescribed. And the third is that it crosses the blood-brain barrier and treats and, we believe, prevents brain metastases, which is another reason to use it upfront because a significant number of patients will present with brain metastases from the beginning. So we feel confident that it will be used in first line and it will be a great option for oncologists.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Next question is from Andrew Baum at Citi.

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

So could you confirm that there was an interim overall survival analysis at the time of the PFS and that did not meet the statistical hurdle and therefore the trial is ongoing until the next interim? Am I correct in my understanding of that? And second, perhaps you could comment, given the change in outlook potentially there in relation to MYSTIC and how it impacts your cash flows, how that impacts both dividend strategy as well as the anticipated run rate for R&D for the company.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Let me just quickly address the second one and you can address the first one, Sean. The second one, Andrew, is when we do our plan, as you know, we do our risk-adjusted plan. And then what has just happened in the last recent past is we have adjusted PACIFIC in our forecast to close to 100%. Of course, it's not approved yet. So until it's approved to 100%, it's close to it. And when you see the data, I'm sure you will agree with us that the chance of approval is fairly good and the impact of this dataset will be large. So we've gone from relatively low probability of success in our plan because PACIFIC was not guaranteed, of course, to close to 100%. So this is going to be a substantial opportunity then for FLAURA. On the other hand, of course, we'll have to adjust MYSTIC in our forecast, ups and downs. Of course, we would have preferred to have everything positive. But ups and downs overall, we believe, we can continue to secure the dividend. And if Marc later on wants to add anything, he will. But I think we -- at this stage, we see no reason to find -- to feel that the dividend is not secure. Sean, do you want to cover the first question?



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

Sure. I think, as you know, Andrew, we don't comment on interim analyses, when they would occur, whether and what the outcome is. So I can't really comment on it other than to say, yes, there are interim analyses and yes, there's an independent data monitoring committee that looks at interims and as well as the safety and conduct of the trial as it's ongoing.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Okay. We shall move to questions online, maybe. I think that's going to be for you, Sean. Can you please walk us through all the hypothetical reasons why an I/O drug that didn't show a PFS benefit could show an OS benefit, especially as you don't seem to believe in pseudoprogession with the checkpoint inhibitors? And the question is from Steve Scala at Cowen for you, Sean.

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

Yes, okay. So all of the hypothetical reasons, probably not. But I can probably get through some of the major ones. So pseudoprogession is one of them. It's not to say that we don't believe in it, but we do think it's uncommon. It could contribute information around the tumor that is marked as progression but actually represents an immune response to the tumor and may in fact be beneficial. I think perhaps the thing that we've wondered about most is the speed of onset of I/O therapies such that you may find that the tumor has some time to grow before the full effect has taken. And then you will get a progression score. But when that immune response comes, you get a benefit down the road that shows up in overall survival. I think it is important to recognize, these are post-hoc explanations for very real data that we have seen repeatedly in second line head and neck cancer at least and also in -- I'm sorry, second line non-small cell lung cancer and also in head and neck cancer, where trials have shown overall survival benefits that were not indicated earlier with progression-free survival. There were two other questions, I think, in Steve's email. One was what percent of patients -- one was about the interim look, I already answered that. The other one was what percent of patients in MYSTIC had greater than 25% tumor cell PD-L1 expression? So the MYSTIC percentage was consistent with what we had said before, which was about 40% to 45% of first line patients have that level of PD-L1 expression and that's what we saw.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

So one thing I would add maybe, Steve, to what Sean said in terms of why you can get an OS benefit when you can see a PFS benefit is it's not only theoretical reasons. There is evidence of the fact that it happens. There's about 7 studies, in fact, where an OS benefit was shown when there was no PFS benefit. And out of these studies, 5 are -- I'm sorry, 4 are in lung cancer. So there's quite a lot of evidence that not meeting a PFS endpoint doesn't necessarily -- I mean, not meeting it doesn't mean that you may not hit it with the OS endpoint. So we have to be patient and wait for this overall survival result. So we go to Sachin Jain of Bank of America.

Sachin Jain - BofA Merrill Lynch, Research Division - MD

I'll take a question on the Lynparza deal if I may. You've referenced access to KEYTRUDA on multiple times. Can you just talk about the need to access KEYTRUDA relative to any changed confidence in Imfinzi/durvalumab? And related to that, just frame sort of the various aspects of this deal. What was the main driving factors? Was it financial attractiveness of the \$8.5 billion and securing externalization over a short period of time versus an NPV increase in Lynparza? Just to frame that debate for us.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

So the question is -- the answer is very simple is that, as I said before, we partner assets when we believe that we can create more value with a partner, i.e., we increase the NPV of the asset. So of course, you can imagine, it's much more obvious to see that we can achieve this when it relates to an asset that is non-core. Because we have no capability, no presence, and therefore, the partner that has the expertise in the field will do better than we would. It is less obvious to see when it relates to core assets. But I believe we're going to show this with hematology with Celgene. Of



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course, we have to deliver positive clinical results. But that's sort of the obvious part. But if the combination works, I have absolutely no doubt. When I look at how fast we're progressing with this program and how well we're doing with our partners, Celgene, I have no doubt we'll create more value with them than we would ever have been able to do on our own. As it relates to Lynparza, same story. And then here, that brings me to your first question, here the value creation essentially comes from the increased effort that will be brought to combining Lynparza with PD-1 and PD-L1. We have total confidence in durvalumab. But we're also realistic. I mean, durvalumab will not get 100% share of the immuno-oncology market. Pembro is a great product, Merck is a great company. They're going to get a share of this market. And therefore, combining our efforts, the durva efforts, if you will, with the pembro efforts to combine with Lynparza, clearly will make Lynparza bigger than if we were trying to do that by ourselves simply with durva. So that's really the logic behind it, ultimately a bigger NPV. So move to Simon Baker at Exane.

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

And just continuing on from where Sachin was asking on the deal with Merck, there are two schools of thoughts in the market this morning, one suggesting that the size of the potential payments would indicate that the consensus assumptions for Lynparza have been significantly underestimated. And others believing that you are giving away long-term value for short-term cash. Now the difference between those two is the nature of the contingency on these payments. So I wonder if you could give us a little bit more color on how and when the \$6.2 billion or so dollars of contingent payments are triggered.

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

Yes, that's a great question. Thank you for attracting everybody's attention to the fact that I personally think half of the value that -- well, sorry, the value we received for half of the asset is actually -- even half the value is more than what is in the consensus for the totality of the asset. So essentially, we have created value beyond what is in the consensus today. But Simon, to answer your question more specifically, I'll hand over to Marc Dunoyer.

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

Simon, thank you very much. So you have seen the upfront of \$1.6 billion. You have seen the options, short-term options for \$0.75 billion, so that's \$2.35 billion. And then you have the \$6.15 billion of contingent. Approximately 1/3 is linked to regulatory milestone and 2/3 is linked to sales milestones. So of course, they come over time. We actually disclosed the more detailed schedule and also some guidance as to how we will be accounting for these various payments over time.

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

So we move to a question online. And I think, Mark Mallon, this time, this is more going be for you. It's an e-mail from Jo Walton at Credit Suisse. And it relates to U.S. primary care, particular diabetes, Farxiga and respiratory and the impact of price pressures. And so the question here is that this price pressure and the reduction, is it a result of a deliberate policy to sell promotional dollars? I assume Jo is implying that we are sacrificing the price to sell promotion? Or is it impacted by patent expiries and competition, patent expiries that are set to annualize out. And so when might the decline be? For you, Mark.

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

So our focus wherever we're trying to get medicines is to get them to as many patients as we can. So the first thing I would say is we're not trying to minimize or reduce promotional efforts in exchange for lower prices or vice versa. We're trying to get the right combination to get this to as many patients as we can. In terms of the dynamics in the marketplace, I think as we've seen in many places in the world, we've seen in this in Europe, I mean, I think realistically we're going to continue to see pricing pressure as countries, and the U.S. is no different, try to find ways to balance the cost that they're facing. I think certainly things like generics or analogs add pricing pressure. And so when those come in, you have an increase in pricing pressure and over time it will stabilize. I think it's hard for us to say, because there are so many different factors in each market, when that will happen. Right now, what we're focusing on is making sure we're getting the medicine to as many people as we can, being able to [leave] them.



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We have great medicines like Farxiga and Symbicort, which we are making the case for the value of the medicines and bringing most importantly new medicines that are going to make a difference and have a higher value. So we've launched Bevespi. We've got benralizumab launching soon in respiratory. We're waiting for the DECLARE study coming as well to demonstrate the value of Farxiga. We've got new products like ZS-9 and roxadustat coming. All of these will have, I think, a high value to payers and to patients because of the value they can provide.

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

We should go back to Jeff Holford at Jefferies.

Jeffrey Holford - *Jefferies LLC, Research Division - Equity Analyst*

So I wondered if you could comment for us on the relative level of crossover that you think you're going to see or are seeing in the MYSTIC study, and then just how that impacts your confidence and ability to hit on overall survival following not hitting on progression-free survival. And then if you can just make a very quick comment on why it does seem to be taking a bit longer than expected to get acceptance of the filing on acalabrutinib. I thought we would've had an update on that by now.

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

Thank you, Jeff. I mean, I'll ask Sean to cover both of those questions. We can't comment. We can't give you the details on the crossover. But we can be confident that it doesn't impact so much the OS. But go ahead actually.

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

Yes, we can't give -- what we're reporting today is high-level results. And there's a lot more detail for us to look at as we look at the detailed information in the trial. We remain confident that overall survival is a more meaningful endpoint and we're adequately powered in order to see a clinically meaningful benefit with monotherapy or with combination. But we can't comment on the rest of those details. Of course, crossover goes both ways in these trials. One is that if you get chemotherapy and you progress on it, you could crossover to a PD-1, PD-L1 agent. The other is that if you get one of the I/O arms and you progress, you can get treated with chemotherapy because you'll be chemotherapy-naive. So that will benefit the overall survival on those arms. Moving on to the acalabrutinib acceptance, we're on target for what we had hoped in terms of acknowledgment of acceptance and timing of submission. So I'm not quite sure what to say about the expectation. It may just be that your expectations are different than ours.

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

Yes. I mean, on this one, we're totally inside the normal range of 60 days between submission and acceptance of filing. And we, of course, do not confirm when we have filed. I can only tell you we are within the normal range that you would expect. So we'll move to Vincent Meunier at Morgan Stanley.

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

I mean, one question back to the Merck collaboration. I mean, how would you intend to allocate the \$1 billion or \$1.6 billion upfront payment. Do you want to return that to the shareholders, maybe doing a little bit of buyback? Or would you prefer to make bolt-on acquisitions or just invest that in the business? And related to that question, I mean, do you consider potentially acquiring more I/O candidates to derisk the I/O portfolio? Because one may say that if you just have one PD-L1 drug, which is the core of your I/O portfolio and if you have a problem like MYSTIC, the entire portfolio then is at risk and maybe better to have different assets. So would you consider buying more assets in I/O?



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Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Well, thanks for the question, Vincent. I mean, first of all, I think it's good to start with reminding everybody that durvalumab works and it works very well. I mean, we have MYSTIC. But importantly, we have the PACIFIC study. And it's unfortunate, it's just the timing, it's just the norm. We haven't shown you the results yet in detail. But when you see the results, you will agree with us that it certainly works well. So there's no issue with durvalumab per se. In terms of having more targets, of course, frankly we have lots of those. So I have to say, first of all, we have to wait for OS as far as lung cancer and the mono and the combo. Then we have additional studies in combination in other indications, bladder, head and neck. So that's for the I/O heavy combination. And then we have quite a number of new targets. So net-net is we're not planning to acquire any other targets. At least, that's not the intent at this point. I mean, if something came up that was attractive, we might do it. But we don't feel the need for that. In terms of what we're going to do with the cash, there's no intent to do any share buyback at this point. We will use that to reduce our debt and continue to sustain the dividend, and also of course, take some of this and invest it in our business. So we're basically continuing to do what we've been doing. Essentially, the financial aspect of this collaboration is discussed. It enables us to continue doing what we're doing, and then certainly should give everybody comfort that the dividend is not at risk at all. In terms of the pipeline of new targets, Sean, anything you wanted to add?

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

Yes, it's a very rich pipeline. I'm not exactly sure what we would acquire from the outside. I mean, obviously the deal that we did with Merck gives Merck access to one potential combination partner, Lynparza, in addition, a second partner, selumetinib, a MEK inhibition. We also in the pipeline have the GITR agonist, the OX40 monoclonal antibodies from MedImmune, CD73, a variety of potential combination partners, it's a very rich pipeline.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

So of course, it's a very attractive financial construct. But the most important piece is going back to Sachin's question, the most important aspect of this collaboration is the creation of additional value. The increase in NPV of Lynparza NPV and the collaboration with a company, Merck, that shares our value, shares our focus on science, and certainly a company we've collaborated with very successfully in the past and that we look forward to working with again in the next few weeks and months. So moving to Seamus Fernandez at Leerink.

Seamus Christopher Fernandez - Leerink Partners LLC, Research Division - MD, Major Pharmaceuticals and Biotechnology

So my question is just one. Can you guys categorize the percentage of profit that the externalization strategy will contribute to your earnings this year? And then separately, as we look at the externalization strategy, how sustainable is that over the next, call it, 3 to 4 years? Because I think, again the sustainability of the dividend with a 50% cover is one question. But the sustainability of the dividend relative to your current cash flow dynamics, given the core EPS dynamics, I think is a key question for investors right now.

Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

So I'll ask Marc to answer that question. But I don't think we want to answer percentages, give you percentages. What we can do is, we can confirm the guidance and the element that we put in the guidance that relate to externalization. Marc, do you want to cover this (inaudible)?

Marc Dunoyer - AstraZeneca PLC - CFO and Executive Director

Yes, I want to repeat the 2 indications that we've provided, that for 2017, the sum of external revenue and other income will be greater than the equivalent in 2016. And the other indication we have provided that the path that is sustainable and repeatable is going to grow over time. These are the two indications we've provided. And where we stand today, we have -- we're reconfirming these two guidance.



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

So moving to Keyur Parekh at Goldman Sachs.

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

I just want to try and understand the source of your comfort around your ability to pay the dividend? If I understand your numbers correctly, you generated 334 -- \$338 million in cash flow from operations in the first half of this year. Your dividend payment is \$3.6 billion a year. And you owe \$1.5 billion to Acerta at 2018, if not before that. What drives your confidence in generating enough cash flow to cover the dividend given your debt is already 50% higher than where it was December last year?

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

I'll just make a couple of quick comments, and then Marc can be more specific. I think you have to consider the growth that will come out of Tagrisso for instance. And very, very profitable growth. This is a product that has very strong clinical data, including in first line, and will generate very strong growth over the next 2 to 3 years. And as I said, very profitable growth because there's no competition in that segment at this stage. Second is, should not underestimate the growth that will come from PACIFIC. Not as big as Tagrisso overall, but certainly a substantial opportunity. And again, no competition for the next couple of years in that specific -- stage III unresectable lung cancer. And then China is growing rapidly. I mean we're reporting an 8% growth rate. For the underlying growth rate, if you adjust for divestments, it is in fact, 17% in China. So as soon as we get out of these divestment part, we'll return to this very high growth rate in China. So we have a business that is starting to make a difference in China. It's very big. So those are all -- and the platform, the growth platforms are overall growing. We believe that this is certainly going to drive sales but also profit improvement. We have seen headwinds in the last 2, 3 years with patent expiries. Those very soon will be behind us. Marc, do you want to be...

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

Maybe two additional information. First of all, this is, we have a pattern of cash flows, which is different between the first half of the year and the second half of the year. So we have projection for second half 2017, which are going to be much better than the first half of the year. And then on the table that you were quoting, which is page 44 of our press release, there is a reclassification of disposal of intangible assets, which goes from -- I would say the top of the table and goes to the investing activities. So, in fact, you have -- you should count also the \$728 million together in a way with the \$338 million. This being said, we have just announced today a deal that is going to bring in a substantial amount of cash. So that should help us with all the cash needs of the company.

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

So we move to question from James Gordon of JPMorgan.

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

The question was about confidence in PARP combos versus CTLA combos. How does the MYSTIC PFS result impact your confidence in showing a significant OS result in MYSTIC and also to the DANUBE and KESTREL studies? And just your relative confidence in CTLA-4 versus PARP as a combo approach?

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

Did you say relative confidence of CTLA-4 versus what?



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

PARP.

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

Okay. Sean, maybe you want to comment on this. I mean, the confidence for MYSTIC, we have clearly to wait until we see the final OS analysis. But as we said before, there are quite a number of studies that have shown an overall survival benefit, without showing a PFS benefit, and very strong overall survival benefit (inaudible) in lung cancer. We also have our own internal data. And some of those data we'll present in Q4. We're looking at what is the best way to present this data. We have internal data showing, in separate study, looking at some of the suspects that gives us confidence. But in the end, until we have the final OS analysis, we really cannot say much. Do you want to comment for this, Sean?

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

Yes, I guess, so two things I would say, starting CTLA-4 which is the much more mature hypothesis being tested. We're really awaiting the outcome in MYSTIC. Again, I'll add, these are things we've been saying for over a year, but we do believe overall survival is more -- it's obviously clinically meaningful but also the one that better shows benefit from I/O therapies. MYSTIC is designed to show Imfinzi plus tremetuzumab versus standard of care chemotherapy or Imfinzi monotherapy versus standard of care chemotherapy. So that's how we get a positive trial. I think then it's a more complex equation about level of additional benefit if seen for the CTLA-4 combo, and then benefit risk when we figure out whether there's a possibility of moving forward and changing practice and getting registration. That's a matter of waiting. The two don't -- the PARP combo and the CTLA-4 combo with PD-1, PD-L1 really don't inform each other. They're very different therapeutic hypotheses with CTLA-4 basically removing an immunosuppressive signal, and hopefully intensifying the activation of the immune system against the tumor. PARP is very different, derived from the observation that high mutational burdens seen in the tumor seems to correlate with greater sensitivity to immunotherapy agents, and as well, homologous recombination, repair defects and other DNA repair defects correlating with the high mutational burden and then how in PARP do you enhance that effect in the context of I/O. So they are very, very different. I would say really unrelated mechanisms. And so their probability of success is very much not informative of each other.

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

Thanks, John. Jack Scannell with UBS. Jack, go ahead.

Jack Scannell - *UBS Investment Bank, Research Division - Co-Head of Pharmaceuticals Equity Research and MD*

Two questions. I guess, you have -- you said that capital allocation principles. And you've also said you have a risk-adjusted plan. Does that effectively mean that thoughts about capital allocation in practice change when the risk adjustments in the plan change? So investors shouldn't expect to see any changes in dividend policy or externalization revenue or so forth, unless or until we saw more data on the various lung programs, for example?

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

Hopefully, I get your question, Jack. But maybe I don't, in which case please, please come back and ask again. What I think I said -- what I said was that, our plan is a risk-adjusted plan. So we take all our projects, we risk-adjust them and that's what we use to long-range forecast and look at our long-range sales for us and cash flow forecast. So what we're going to do now with those results is, we're going to put, let's say, 100% soon enough hopefully of PACIFIC into the plan, the same for Tagrisso including first line. And then we'll adjust MYSTIC. The PFS endpoint in our long-range plan had a low probability in our plan because we've always believed, as we told you, we've always believed that it is an OS gain more than a PFS gain. And that's why we put the majority of the statistical power in the OS analysis. So in our long-range plan, we had lower probability for the PFS endpoint to read out. And now we're moving to OS. So what I was saying earlier is, we'll redo our long-range plan with all these elements. From



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what we can see today, there is no reason for us to change our long-range forecast, including our cash flow forecast, and therefore, to have a different approach to our dividend policy. Of course, the next 6 to 8 months will be very informative because the competitive landscape will clarify. As you know, there is a number of other studies that will read out. Depending on the outcome of these competitive studies and also the outcome of our own ongoing studies in other indications and into next year the OS analysis, until then, it would be difficult to be clear on the total potential for durvalumab. But based on what we know today, I think what I said earlier, is that we have no reason to have a different view of our future. Does it answer your question or did you have anything else in mind?

Jack Scannell - *UBS Investment Bank, Research Division - Co-Head of Pharmaceuticals Equity Research and MD*

I had a terrible echo in my line, which may have made my question less coherent even than usual. But actually you answered it precisely.

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

Jo Walton at Credit Suisse.

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

My question is about the turning point for AstraZeneca and longer-term margins. Mark showed us a slide showing really very stable 30-odd percent margins. Of course, some of that is being helped by disposable gains within that. So it isn't all truly operational from an underlying perspective. I wonder if you could confirm whether you think that 2018 still will be the turning point year? And what sort of operating margins do you think would be a sustainable level given the mix of business that you would expect to have in the next few years? Some really fancy new drugs, but also a growing emerging market presence. So I wonder you could just help us on that longer-term margin objective?

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

Thank you Jo for these 2 questions. Regarding the operating margin, I think we have said, and we said this I think several years ago, that the profit will grow slightly faster than our sales. And we also said that from 2018 onwards we would return to growth. I think these two elements stay the same. At what level the operating margin will stabilize, I think it may be a bit early to comment. But I think over time, as we move towards specialty care and oncology taking a greater share in our business, the operating margin is definitely going to increase.

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

Thank you, Marc I will conclude, by the way, the Emerging Markets business is a low profitability business. It is a business with quite a reasonable profitability actually and it's growing. What has really been a burden for us in the last 3 years is patent expiries and losing products that were incredibly profitable like Crestor, Nexium that were at the end of their life cycles, with limited promotion and big scale, and therefore, very profitable. At the same time, as we had to invest in rebuilding our pipeline and rebuilding our future. So that's really what has been a burden more than the emerging markets that are actually growing and delivering reasonable profitability. But as Marc said, as we move forward and suddenly our specialty care business grows, we're launching benralizumab at the end of the year or early next year. And then we launch future products, the margin should, over time, improve. But it's too early yet to give you a target as to what that margin could be. We need still more understanding of what the pipeline looks like. Should we move to Emmanuel Papadakis of Barclays? Emmanuel, go ahead.

Emmanuel Papadakis - *Barclays PLC, Research Division - MD*

Can you hear me?



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

Yes.

Emmanuel Papadakis - *Barclays PLC, Research Division - MD*

Apologies. Couple of follow-ups. One is for Marc, if we could perhaps pin you down a down touch further on cash flow. I think when I asked the question with the Q4 results, you had indicated 2017 would be in line with 2016 on cash flow from operations. And it's clearly running significantly below that. I know you said H2 will be better, but perhaps you can confirm that comment you made earlier? And then the second was for Pascal, it just to follow-on on from your comment that, I don't know whether it was intentional, for you just remarked that the PACIFIC opportunity would not be as large as Tagrisso and if I recall correctly your 2014 un-risked guidance for what was then [90, 91] was around \$3 billion. So perhaps you'd just like to clarify that or quantify that?

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

Let me try this one, and Marc, maybe you can cover the cash flow questions. Hopefully I address -- I will address your question and you will otherwise let me know. But what I meant to say is that PACIFIC is a large opportunity, but Tagrisso as a whole is a bigger opportunity. We see Tagrisso being now with the kind of data we have a \$4 billion-plus opportunity, including first line, and it could go even beyond that if we have a successful adjuvant outcome. So PACIFIC is large. The stage III unresectable lung cancer is not as large as the stage IV lung cancer. But in the near term there will be no competitor, because we are the only product with data in that setting. So it's a large opportunity for us. But still smaller than the sort of \$4 billion we see in PACIFIC. That's what I said. Hopefully that addresses your question. And Marc, you want to cover the cash flow?

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

Yes, I can only say that as I indicated earlier on, the pattern for cash flows between the first half and the second half is very similar between 2016 and 2017. And as far the overall for the year, we estimate today, as I indicated earlier, that it would be of a similar quantum for '17 as for '16. A similar pattern, similar numbers.

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

So, Emmanuel, did that cover your question regarding the potential of Tagrisso? Maybe one thing I could also add is that, 2, 3 years ago, we gave an indication of the potential of Tagrisso, and then we had a forecast in our plan for Tagrisso, but that forecast we had in our plan was a risk-adjusted forecast. And as we have progressed, two things happened. First of all, the risk has been removed, and the probability of success is now close to 100% for all those indications. And two is the product profile has improved. We now have very good data and in first line we have data in brain metastasis. The product penetrate the blood-brain barrier. We didn't expect that 3 years ago. We hoped it might be the case but we did not have the data. So we didn't have that in our product profile. So -- and finally the competitors have left the scene. So essentially as we progressed, the product has looked better. The competitors have disappeared. And the probability -- the risk has been removed. So all of that has driven Tagrisso up and up and up. So now it is very large. So we move to Mark Purcell at Redburn, who is asking us an e-mail question. Please could you explain your confidence in MYSTIC overall survival data reading at first half '18 as opposed to full year '18? Is this based on even rates of curve separation, which was seen relatively late, we scheduled that in Keynote 21G. Sean, for you.

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

Sure. So the anticipated readout is based on event rates with a level of maturity that triggers the final overall survival analysis. And the reason that we're refining it is because we're getting closer and we're better able to estimate when we will -- to narrow down from 12-month period to a 6-month period. It doesn't -- it's not an inference from another trial, it's just standard clinical trial design and execution.



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Pascal Soriot - AstraZeneca PLC - CEO and Executive Director

Thank you, Sean. So we'll now actually end the Q&A. And I would like to thank you very much for your great questions and conclude again. And just kind summarize where we are again for you. First of all, first half financials are in line with expectations. And New AstraZeneca sales grew by 4%. Our financials are on track. We reconfirm our guidance. Pipeline, very importantly, the pipeline is advancing at pace. 12 new potential medicines in Phase III and under registration. In particular, our pipeline in oncology is progressing with Tagrisso and Lynparza looking really good. In particular, just recent Tagrisso news makes us very confident that it is going to be the big product we were hoping it would become. On the I/O front, MYSTIC, of course, is a disappointment. But please consider the number of studies that had PFS endpoint not met, but still there is otherwise benefit. So let's wait a little bit longer. But we do recognize MYSTIC is certainly a disappointment, but we also have to recognize that PACIFIC was certainly not expected. It's a positive surprise and it has a lot of potential and a very profitable potential. I would like to underline this. And considering the limited competition in that segment. We're looking forward to sharing further news flows over the next few weeks and months. And we think that we have the potential to reach a meaningful step-change for AstraZeneca in the next few month. In particular, when we present the details of the PACIFIC and FLAURA Phase III trials in lung cancer. So thank you again for your support and your interest. Have a good rest of the day.

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