# Simon Lowth Q1 12 Analyst Final Script 26 April 2012

Thank you David.

I will focus on 5 topics:

First, I'll summarise the headline numbers.

Then, I'll cover the revenue performance by region and for selected brands.

Third, I will turn to the Core operating performance ...with an emphasis on the key drivers of operating profit and margin.

I'll briefly touch on cash distributions to shareholders.

And finally, I will close with our thoughts on guidance for the full year.

#### **Headline Results: First Quarter**

So, on to the headline results.

Total Company revenue was \$7.3 billion in the quarter, an 11 percent decline in constant currency terms. Exchange rates were neutral to first quarter revenue.

Now the dominant feature of our revenue profile for the year will be the impact from the loss of exclusivity on several brands...and in the first quarter 8 percentage points of the revenue decline is attributable to generic erosion—chiefly for Nexium in Europe, Arimidex and Merrem globally, and for Seroquel IR in the US. Generics for Seroquel IR launched at the end of March. In line with our established practice following a generic launch, a returns reserve was taken against the estimated trade inventories, and this amounted to \$223 million. So although the prescription declines won't affect the product until the second quarter, we have already experienced some of the impact in first quarter revenue.

The disposal of Astra Tech accounted for 1.7 percentage points of the revenue decline, as there was \$141 million in revenue in the first quarter of last year.

We had a small impact on revenue, just under 1 percent, from disruptions in our supply chain associated with the implementation of a new enterprise resource planning system at our plant in Sweden. Though the underlying problems have now been largely resolved, we anticipate further limitation in the supply chain in some markets in the second quarter, as production responds to ongoing demand, fulfilling back orders and restoring normal inventory levels.

Government interventions continue to impact AstraZeneca and the biopharma industry overall. We estimate our revenue impact at around \$370 million in the guarter.

I'll discuss the regional and brand revenue performances shortly, but let's continue with the headline numbers.

Core operating profit in the quarter was down 18 percent in constant currency to \$3 billion, chiefly on the revenue decline. But also, Core gross margin in the first quarter last year benefited from a \$131 million gain from settlement of some patent disputes with PDL BioPharma.

Core earnings per share in the quarter were \$1.81 compared with \$2.23 last year. That is a 19 percent decrease in constant currency terms. Again, a large one-off in the prior year period has a big impact. Last year's first quarter benefited by \$0.39 as a result of agreements reached between the UK and US governments over certain tax matters.

If we exclude the one-offs in gross margin and tax from the prior period, Core EPS in the first quarter would have increased by 2 percent versus last year.

Adjustments to Core earnings are significantly higher in the first quarter 2012 due to the restructuring charges, so the 19 percent decline in Core EPS becomes a 39 percent decrease in Reported EPS.

So, those are the headlines for the first quarter.

## Q1 Revenue performance

Returning to the first quarter revenue performance, when I refer to growth rates, they will be on a constant currency basis.

Revenue in the US was down 12 percent compared with the first quarter last year. I already mentioned the Seroquel returns provision. US healthcare reform had a \$205 million impact. This includes around \$38 million adjustment in the Medicare coverage gap discounts related to 2011 utilisation...we had been accruing based on estimates, and now that the actual utilisation is known, we need to make a catch-up provision.

Revenue in Western Europe was down 19 percent in the quarter, largely due to further penetration from generics for Nexium, Arimidex and Merrem, and downward pressure on prices from government interventions.

Revenue in Established Rest of World was down 9 percent. Japan was down 10 percent, on general destocking ahead of the biennial price reductions and the quarterly phasing of shipments to marketing partners for Crestor and Symbicort--the in-market demand for both products was up year on year. Canada's 8 percent decline is largely due to generic competition for Nexium and Atacand.

Revenue in Emerging Markets was up 1 percent in the quarter. You will recall in our Full Year Results in February that we expected a weak first quarter in Emerging Markets.

China was up 13 percent. Three markets--Brazil, Turkey and Mexico--account for more than 40 percent of the shortfall from recent double digit growth trends. Brazil is down 15 percent on loss of exclusivity for Crestor and Seroquel IR. Turkey is down 18 percent, chiefly on government price interventions. Mexico is down 25 percent, on challenging market conditions.

We expect a rebound in Emerging Markets over the remaining three quarters of the year, but whether we will be able to claw back all of the first quarter shortfall and achieve double-digit growth for the full year is hard to call at this point, but there is no question that it will be a challenge.

#### **Brands**

This slide provides a snapshot of revenue for key brands.

We grew revenues for the key brands that retain market exclusivity...except for Symbicort, which would have been up were it not for the phasing of shipments in Japan.

Crestor was up 2 percent, to \$1.5 billion.

We had double-digit growth for Seroquel XR. Onglyza revenue more than doubled.

But, as you can see on the bottom of the slide, loss of exclusivity has taken its toll on Nexium, Seroquel IR, Arimidex, Toprol-XL and Merrem.

Detailed commentaries on brand performances are in the press release. I want to provide some additional colour on two products...Crestor's performance in the US following the launch of generic atorvastatin, and an update on the Brilinta launch.

First, Crestor.

We now have 4 full months of data on the statin market post generic Lipitor, and in its wake Crestor's performance has remained resilient. Crestor total prescriptions in the first quarter 2012 were up 2.1 percent, which is slightly higher than the 1.8 percent increase in the total statin market.

And this is largely due to stability in the 94 percent of the Crestor volume that is continued therapy. We thought that there would not be significant switching for patients who are doing well on Crestor, and that has been our experience to date.

We thought there would be some churn in the 6 percent of the volume which is dynamic—around 4 percent from new starts and around 2 percent from patient switches from other therapy. That is the thin sliver at the bottom of the first chart, which we have blown up into a larger scale on the next slide.

Crestor volume of patients who are new to statin therapy is holding up very well, which is the area in red. The purple wedge is switches to Crestor, and that has eased somewhat as some of the pool of patients that used to switch to Crestor from simvastatin has moved to atorvastatin. As we expected, at the outset there was some increase in patients switching from Crestor to atorvastatin on economic grounds, but there has been some recovery in that trend in recent weeks.

All in all, the market is evolving in line with our expectations. A quick note on the ex-factory sales in the US...they were flat in the quarter, with the increase in prescriptions offset by a slight decline in realised prices that is attributable to the Medicare discount adjustments I mentioned earlier.

Turning to **Brilinta**, sales were \$9 million in the quarter.

Brilique is really starting to pick up steam in Germany, which is the major market with the most launch experience. Brilique is reported to be on protocol in 79 percent of target hospitals in March. The latest market research data indicates that in these hospitals we are now the leading product for initial therapy for ACS patients, with a market share of 37 percent of new starts.

In the US, there were no reported ex-factory sales, as we continue to work down the launch stocking that remains in the channels; but we continue to make steady progress on the leading indicators. Brilinta is now on formulary in 68 percent of the top 400 target hospitals. Protocol access in these institutions is now 20 percent, up from 14 percent. Trial rates among all interventional cardiologists have increased to 15.4 percent.

As you can see on the left hand chart, since we rolled out the full complement of promotional materials in November of last year, understanding of our key differentiating attribute—Cardiovascular mortality reduction—is starting to gain traction. Our latest market research indicates that 17 percent of interventional cardiologists rank Brilinta as providing the greatest cardiovascular mortality benefit of any oral antiplatelet agent.

We know from our experience in Germany that as awareness and belief in this differentiating attribute increases, trial and adoption follow.

On the right side of the slide, in the first quarter we have seen an encouraging inflection point in Brilinta total prescriptions from the trend-line upon which we exited 2011.

Based on the PLATO data, Brilinta has the potential to save thousands of lives if used instead of the current standard of care, so we would have liked to have seen a faster uptake. But because of the complex steps to achieve hospital access, we knew this would be a slow journey to adoption. Having worked with many key institutions in the US, we know that it can take up to a year to ensure a new medicine is widely available for use in a particular institution. The process friction is real, but so is our belief that Brilinta's clinical profile will ultimately drive strong usage.

You will have seen yesterday's announcement of our collaboration with The Medicines Company, starting with a co-promotion agreement in the US. They are a respected organisation with a strong network in interventional cardiology, and we look forward to their support of our promotional efforts.

### **Operating Profit and Margins**

I will now turn to the first quarter P&L. I will focus here on Core margins and profit. The press release does, of course, contain the statutory numbers and a detailed reconciliation to the Core measures. As with sales, when I refer to growth rates, they will all be on a constant currency basis.

Core gross margin in the quarter was 82 percent of sales. That is down 190 basis points compared with the first quarter last year...more than 80% of this is related to the PDL settlement.

Core SG&A expense was down 9 percent compared with the first quarter last year, as restructuring benefits and overall lower sales and marketing expenses in developed markets more than offset selective investments in Emerging Markets and a [slight] increase in the excise tax from US healthcare reform.

Core other income was 25 percent higher than the first quarter last year. This is largely the result of the Zomig deal in the US, where marketing rights have been licensed to Impax Laboratories. As a result, we now recognise the commercial contribution from Zomig in other income, not sales.

That leads to a Core Pre-R&D operating margin of 55.5 percent of revenue, above the top of our 48 to 54 percent planning range, but this is down 170 basis points compared to first quarter last year. Lower revenue and gross margin was only partially offset by lower SG&A expenses and higher other income

Core R&D investment in the quarter was just under \$1.1 billion. That is a 2 percent increase, largely attributable to a net increase in intangible asset impairments compared with last year. We took the remaining \$50 million impairment related to TC-5214 in the first quarter 2012. For the full year, I expect Core R&D expense will be lower than last year in constant currency terms, both on an overall basis and if you exclude the impact from intangible impairments from both periods.

This leads to a Core operating profit of \$3 billion in the quarter, 18 percent lower than last year. Core operating margin was 40.8 percent of revenue, down 360 basis points.

## Productivity/Restructuring

Turning to our Productivity programme, one third of the projected \$2.1 billion total cost for phase 3 of restructuring was taken in the first quarter...an indication of the pace at which the organisation is implementing these plans...in particular R&D, which accounted for \$445 million of the \$702 million charged in the quarter.

Most of the restructuring costs will be taken in 2012, and we remain on track for delivering the estimated \$1.6 billion in annual benefits by the end of 2014.

#### Cash

Cash generated from operating activities was \$1.5 billion compared with \$1.9 billion in the same period last year. With the benefits arising from our disciplined management of working capital we were able to partially offset the reduction in operating profit and the \$500 million contribution to the pension fund.

Net cash distributions to shareholders in the first quarter were more than \$3.4 billion, through payment of \$2.5 billion for the second interim dividend from 2011 and net share repurchases of \$912 million...which is broadly in line with the pace required to complete the \$4.5 billion target for the full year.

Another potential call on cash in 2012 is the Merck Shares option, or the Second option at it is also known by. Beginning in May we have a 6 month window to exercise the Shares Option...the first of 3 opportunities to do so. A notice of exercise would trigger an appraisal process to establish the value, payable on closing of the option, which is largely based on the net present value of the future annual contingent payments on Nexium and Prilosec in the US and some other items.

We have not yet decided whether we will exercise this year, or not. From a pure "strategic freedom to operate" perspective, our preference would be to exit the arrangement at the earliest juncture, but ultimately a decision as to whether we exercise in 2012 will be informed by whether the range of values that will emerge from our modeling of the various appraisal scenarios are attractive in economic terms.

#### **Future Prospects/Guidance**

Finally, turning to guidance.

We knew that it was going to be a challenging year, with the main element of the revenue profile being the loss of exclusivity on several products, particularly Seroquel IR. And the disposal of Astra Tech and ongoing disposal of the Aptium business also contribute to the decline in revenue. There are several other factors however, which, while individually not large, collectively exert downward pressure on our revenue expectations for the full year.

We certainly expected government interventions on pricing to continue, but they are now looking to be at the upper bounds of what we anticipated, both in Europe, as well as the impact in the US from the Medicare coverage gap adjustments.

We continue to have confidence in, and will vigorously defend our intellectual property. We prevailed in the US trial on the Seroquel XR patent, but we have also had an adverse judgment in the UK, we have had some at risk launches in Europe, and we have rulings in other jurisdictions pending.

We expected the revenue trends in Emerging Markets revenue to be phased towards a weak Q1, and I have called out the three markets that are the main drivers of the variance. While we are aiming for double digits for the full year, it will be a challenge to get there.

Finally, we have seen an impact from our supply chain issues in the first quarter, and there will be some carry-over of this into the second, and possibly the third quarter.

That is why, on balance, we have revised our revenue expectations to now be in the range of a low to mid-teens decline in constant currency terms, rather than the original low double- digit guidance. The second and third quarters are likely to be the toughest.

Against the backdrop of this challenging revenue picture, we are proceeding apace with the third phase of the restructuring, and we will, of course, exert discipline in our operating expenses. We expect Core Pre-R&D margin to be in the upper half of our planning range, but below last year.

But we will not compromise on the investments that will drive value.

We will continue to make sales and marketing investments behind new launches and in growth markets.

We will continue to invest to progress the late stage pipeline and in business development opportunities. We are counting on productivity and restructuring benefits to mitigate the investments behind these projects, which is why I expect R&D expense to be down in constant currency terms for the full year.

Finally, we will also invest to rebuild inventories in the supply chain following the implementation of the enterprise resource system in our plant in Sweden.

There is a change to the tax rate, which is now expected to be lower than the 24 percent that we projected at the beginning of the year. We are now estimating a 22 percent effective tax rate for the full year, the result of a UK tax rate reduction, resolution of tax audit issues in the first quarter and variations in the levels and mix of profitability in different jurisdictions.

However, the delivery on restructuring, ongoing discipline on operating expenses and the lower tax rate will only partially mitigate the downward pressure on revenues. As a result, we have felt it prudent to lower our Core EPS target for the full year to the range of \$5.85 to \$6.15 per share.

Currency was neutral to the first quarter Core EPS. But I would remind you that the forward look is based on the January 2012 average exchange rates upon which our guidance was based...it takes no account of the likelihood that average exchange rates for the remainder of the year may differ materially from the January 2012 average.

**In summary**, it has been a tough quarter as we face the challenges of generic competition and government action on pricing and the other factors I just discussed. But we continue to drive the performance of brands that retain exclusivity. We are quickly implementing the third phase of restructuring. And our resilient cash generation supports investment in innovation as well as strong cash distributions to shareholders.

And in the last few weeks we have announced a significant collaboration with Amgen, and an agreement to acquire Ardea Biosciences—examples of the kinds of opportunities that we will continue to pursue to create value.

Now we would be delighted to take your questions.

For those who are taking part via the telephone you press \*1 on your keypad to alert the operator that you wish to ask a question.

For those listening via the webcast you will find a text box on the webcast page to type your question. We will try and answer as many questions as possible.

Can we have the first question please.

#### Q&A

Thank you for joining us on today's call.