

Simon Lowth Q3 09 Results Script

Thank you Jonathan and good afternoon everyone.

Today I am pleased to present another strong set of quarterly financial results for AstraZeneca fuelled by sales growth and operating leverage.

We have also made some progress on the pipeline. Since the half-year results, we received US and European approvals for Onglyza and have already launched in some markets. We have submitted our first regulatory application for Brilinta in Europe and we announced two more important collaborations for late stage development projects with Forest Laboratories and Nektar Therapeutics. Of course, this progress is somewhat tempered by the withdrawal of the regulatory submissions for Zactima.

On today's call, I will focus on five topics:

First, the headline numbers for the Third Quarter and the Nine Months.

Then, I'll cover the third quarter revenue performance by region and by our key brands.

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

I'll briefly touch on cash performance and our steadily improving net debt position.

And finally, I will explain the increase in our Core EPS target for the full year.

Headline Results: Third Quarter

Turning first to the headline numbers for the third quarter, we achieved revenue of \$8.2 billion dollars, a 10 percent increase in constant currency terms. You will have also seen that the adverse impact of currency movements on the top line reduced the reported revenue growth rate to 5 percent.

As I noted last quarter, in addition to good underlying operating execution, there are clearly some unanticipated revenue upsides that are contributing to our strong revenue performance in Q3, including the upside from Toprol-XL in the US, which accounted for \$221 million of constant currency revenue growth in the quarter and revenue from US government orders for our H1N1 influenza vaccine, which was \$152 million. Excluding these two items, global revenue growth was 5 percent in the quarter in constant currency terms.

Core operating profit for the quarter was up 29 percent at CER to \$3.6 billion, chiefly as a result of the increased revenue. The added contribution from improved gross margin and lower R&D expenditures was partially offset by higher SG&A expense and slightly lower other income. I'll return to these when I discuss third quarter operating margin.

You will also note that currency provided a 1 percent boost to Core operating profit, in contrast to the 5 percent drag on revenue, as the mitigating effect on our operating costs more than offset the negative revenue impact in the quarter.

Core Earnings per share in the quarter were \$1.68 compared with \$1.32 last year. This is a 27 percent increase at constant currency.

Making the bridge from Core EPS to Reported EPS in the quarter, we have the usual adjusting items—restructuring, MedImmune and Merck related amortisation, as well as an intangible impairment. These were broadly similar in both the current and prior year periods.

Additional core adjustments this quarter include legal provisions totalling \$108 million, or 7 cents per share, which have been taken with respect to various federal and state investigations and civil litigation matters relating to drug marketing and pricing practices. This brings the total legal provisions to \$538 million for the nine months. As we noted in the press release, we have reached an agreement in principle with the US Attorney's Office in Philadelphia to resolve its investigations related to Seroquel sales and marketing practices. This accounts for \$520 million of the \$538 million provided for in the nine months.

Net of these adjusting factors, Reported EPS increased by 22 percent at CER to \$1.46.

Headline Results: Nine Months

For the nine months:

Revenue increased by 8 percent at CER, 5 percent excluding Toprol XL and the H1N1 vaccine. Core operating profit was up 29 percent and Core EPS was up 28 percent.

I will turn now to our third quarter revenue performance. For the avoidance of doubt, when I refer to revenue growth rates, it is on a constant currency basis.

Third quarter revenue: Regional performance

Looking at our 10 percent worldwide revenue growth in the third quarter on a regional basis.

Revenue in the US was up 14 percent, or 3 percent stripping out Toprol-XL and H1N1 flu.

Revenue in the Rest of World was up 7 percent.

In our Established Markets, revenue in Western Europe was up 3 percent. Revenue in Japan was up 9 percent, chiefly on growth for Crestor and Seroquel.

We continue to drive good growth in our Emerging Markets business, where revenue was up 15 percent in the third quarter. We expected this rebound from the 8 percent growth reported in Q2, and we remain on track for double-digit revenue growth in Emerging Markets for the full year.

Key Brand Highlights

Turning now to our key brands, beginning with Nexium. And again, in all instances the growth rates will be in constant currency terms.

Nexium

Nexium revenue in the third quarter was down 1 percent to \$1.24 billion.

Revenue in the US was down 12 percent to \$689 million. Dispensed retail tablet volume decreased by around 1 percent in the quarter. Average realised prices were down by around 13 percent in the quarter and for the nine months they are down around 9 percent, in line with our expectations for a high single-digit price decline for the full year.

In the fourth quarter, we will of course be watching the market closely for the potential impact that the launches of OTC lansoprazole and the first generic entry against Prevacid may have.

In the Rest of World markets, Nexium revenue was up 13 percent to \$554 million. Revenue in Western Europe was up 11 percent. Revenue in Emerging Markets was up 30 percent, including a 55 percent increase in China.

Seroquel

Turning to Seroquel, third quarter revenue was up 12 percent to \$1.23 billion.

In the US, Seroquel revenue was up 14 percent to \$851 million. Total prescriptions for the Seroquel franchise increased by 2.4 percent in the quarter, with all of the growth attributable to the Seroquel XR formulation. The launch of XR has driven our dynamic share in Bipolar disorder—which is the focus of all of our promotional efforts now—by 440 basis points since the beginning of the year.

As we have completely transitioned our commercial efforts to be 100 percent behind XR and the bipolar indications rather than Seroquel IR, we have seen the IR formulation lose some ground whilst Seroquel XR accelerates and grows faster than the market. We are pleased that the net effect was that Seroquel franchise share increased in the third quarter by around 12 basis points.

Our ability to drive Seroquel XR growth faster than the decline in Seroquel IR would, of course, be strengthened by the addition of an approval in Major Depressive Disorder. We continue to look for FDA action on our response to the CRL around the end of the year.

Seroquel revenue in the Rest of World was \$380 million, up 9 percent despite the 73 percent decline in Canada due to generic competition. The bipolar indications and the Seroquel XR formulation are driving this growth. On September 29 we received approval under the European Mutual Recognition Procedure for the bipolar maintenance indication for both Seroquel and Seroquel XR. Revenue in Western Europe was up 17 percent, and revenue in Emerging Markets was up 15 percent.

Crestor

Crestor revenue was up 30 percent in the quarter to over \$1.1 billion.

Revenue in the US was up 25 percent to \$523 million. Crestor total prescriptions increased by 25 percent, compared with 6 percent growth for the US statin market. Crestor share of total prescriptions in the US continued to increase, reaching 11 percent in September.

Crestor revenue in the Rest of World was up 34 percent to \$624 million. As in the US, we are growing share at a pace that is 3 to 4 times the statin market in both Established and Emerging Markets.

There was good growth in Western Europe, Canada, Australia and Japan.

Looking forward, Regulatory filings for a label change to include outcomes data from the JUPITER trial are now under review in the US and in Europe. We have been informed that the US supplemental NDA will be discussed at an advisory committee meeting on 15 December 2009.

The last of the key brands I want to cover is Symbicort.

Symbicort

Symbicort revenue in the third quarter was up 22 percent to \$562 million.

Revenue in the US increased by 95 percent to \$125 million. Symbicort accounted for most of the nearly 8 percent growth in prescriptions for fixed combination products in the quarter, paced by continued penetration of the asthma market as well as the launch of the COPD indication.

Symbicort share of new prescriptions for fixed combination products increased by 270 basis points in the quarter, reaching 16.6 percent share in September. Market share of patients new to fixed combination therapy is now over 26 percent.

In the Rest of World, Symbicort revenue increased by 11 percent to \$437 million. Revenue in Western Europe were up 8 percent; revenue in Emerging Markets were up 22 percent.

Onglyza

A few words on Onglyza in the US.

In the third quarter, we recorded \$9 million for Onglyza revenue, from US stocking following US FDA approval on 31 July. Just a reminder, this is recorded as "Alliance Revenue" in our P&L. Our partner, Bristol-Myers Squibb, manufactures Onglyza and books ex-factory sales, so our Alliance revenue recognises our share of the gross profit in the collaboration.

We have made good progress to date in the US. We are steadily building brand awareness, trial usage, and intent to prescribe. Managed care access is also progressing well—with access to around 75% of covered lives, with 28% already at Tier 2.

And we are growing Onglyza's share of new patient starts for DPP4 products, around 7 percent in the week ending 9 October.

Outside the US, we have launched in Mexico, the UK and Germany, with more to come in the near future.

There are 4 other products that are also worth mentioning-- to provide the complete context of performance in the quarter as well looking forward.

Toprol XL

I've already mentioned Toprol-XL in the US and its contribution to revenue growth in the third quarter. As you may know, Watson received approval for their generic version on 3 August, just days after we reported our first half results. However, they only received approval for 2 dosage strengths—the 25 and 50 mg tablets. Those strengths account for around 70 percent of total prescriptions for Toprol-XL and less than that on a revenue basis. So, based on their limited range and their market penetration to date unless one of the other players—either KV or Sandoz—return to the market soon, we are probably still looking at some upside compared to the scenarios we were modelling at the half year.

H1N1 Influenza Vaccine

For H1N1 influenza vaccine, you have seen that we booked \$152 million dollars in revenue in the third quarter from our contract with the US government. We now have orders for more than 40 million doses, with a total contract value of \$453 million. Again, that is right at the top of our "finish and fill" capacity expectations when we recast guidance at the half-year, and it also looks like, based on scheduled production, that most of the revenue will be recognised in 2009.

Casodex

You can see in the third quarter numbers that we are now experiencing the rapid erosion expected when an oral dosage form loses exclusivity in the US market. As a consequence, US sales in the third quarter were down 80 percent, to \$14 million, compared to \$71 million in the third quarter last year. That said, the generics were approved in July, so compared to our planning assumption of generic entry in April, we are probably \$80 million dollars ahead of where we thought we would be. Again, I offer this observation chiefly to help you construct the appropriate 2009 base from which to refine your 2010 forecast modelling.

Pulmicort Respules

Finally, Pulmicort Respules in the US. For the nine months, revenue was just under half a billion dollars, and that is down 23 percent as a result of the inventory overhang in the market from Teva's "at risk" launch back in November last year, before we settled our patent litigation. Just a reminder that under the licensing agreement negotiated last year, Teva begins sale of its generic budesonide starting 15 December of this year. Going forward, we will continue to book and report AstraZeneca's branded US Pulmicort Respules

sales in the Pulmicort family sales line. However, the revenue we earn from the royalties on Teva's sales will appear in the "other income" line of the P&L.

Third quarter: Operating Profit and Margins

I will now turn to the third quarter P&L, and the drivers of the growth in Core operating profit. 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, at 84.9 percent of sales, was a 270 basis point improvement over the third quarter 2008. The usual contributors to our improved gross margin in 2009 are at work here--lower Merck payments, efficiency gains and favourable product mix—partially offset by higher royalty payments. But there is another factor driving the positive variance in the third quarter. During the quarter we successfully resolved an issue related to a third-party supply contract, which triggered the release of a related balance sheet provision that was being held whilst the issue remained open. This provision accounted for two-thirds of the margin improvement in the quarter.

I now expect Core gross margin for the full year to be up to 200 basis points higher than 2008 on a constant currency basis.

Core R&D expenditures were 9 percent lower in the quarter. Increased investment in biologics was more than offset by continued productivity and efficiencies in R&D. The third quarter 2009 spend also reflects lower intangible asset impairments compared with the third quarter 2008, as well as lower spending related to those projects that have advanced from active Phase III development to pre-registration status this year.

Core SG&A expense was 7 percent higher than the third quarter last year, but I would look through the quarterly phasing and call attention to the nine month increase of 1 percent as more indicative of the full year trend. We continue to drive efficiencies in our underlying SG&A costs in order to release the resources to invest in growth in Emerging Markets and to fund the launch preparations for new products.

I still expect the combination of R&D and SG&A to come in broadly flat in CER terms for the full year.

Core other income for the third quarter was \$143 million, just slightly below the \$162 million in the third quarter 2008. As I flagged at the half year, most of the "year-on-year" increase in other income is now behind us. I still expect Core other income for the full year of around \$900 million.

Core operating margin for the quarter was 44.0 percent of sales compared to 35.7 percent in the third quarter 2008. 220 basis points of the improvement were related to currency. Operating margins therefore improved by 610 basis points on a CER basis, as a result of efficiencies and increased operating leverage against the strong 10 percent revenue growth.

Productivity/Restructuring

Turning to our Productivity programme, we have taken restructuring charges of \$112 million in the third quarter, bringing the year to date total to \$374 million.

The programme is on track for both costs incurred and benefits being realised.

Cash/Capital Structure

Let me now turn to cash flow

Cash generated from operations increased by \$1.9 billion in the first nine months of 2009 compared with last year, driven by strong underlying operational performance and improved working capital management.

Cash distributions to shareholders were nearly \$3 billion through payment of the second interim dividend from 2008 and the first interim dividend for 2009.

Net debt, at \$3.2 billion, is down almost a billion dollars from the half year, and by nearly 4 billion since 31 December 2008.

Future Prospects/Guidance

Finally, I will explain the factors behind the increase in our Core EPS guidance for the full year.

As I said at the half year, business performance, in the context of tough global economic conditions, has been better than we anticipated. This, together with good operating execution and some unexpected revenue upsides—including Toprol-XL and delayed generic entry for Casodex in the US—combined to drive our strong performance in the first half.

This trend has continued in the third quarter, including an uplift from initial revenue from H1N1 influenza vaccine.

The outlook for the remainder of the year has been boosted by several factors.

As I already mentioned, Watson's approval of only 2 strengths of Toprol.

The additional orders, now totaling some 40 million doses, for H1N1 influenza vaccine—that's at the top of our estimate, and with a production schedule that will put most of the revenue into 2009.

The release of the provision within Cost of Sales, which further benefited gross margin in the third quarter.

And the 29 percent tax rate for the full year, which is a 50 basis point reduction in our earlier guidance.

For revenue, we now anticipate CER growth in the mid to high single-digits.

And for Core EPS, we now anticipate Core earnings in the range of \$6.20 to \$6.40 per share.

Now if you take this and solve for the fourth quarter, it implies some deceleration on the top-line and thus EPS compared to the nine month run rate.

As you'd expect, the uplift from Toprol-XL, although still positive, should be substantially lower than the average over the first 3 quarters.

The same goes for Casodex in the US.

I've already flagged the increased generic competition looming in the US PPI market for Nexium.

The other variable is anticipated stocking levels in the US as we exit the year. We have renewed our distribution agreements with all of the major wholesalers in the US. Under the revised terms of these agreements, they will be permitted to carry lower levels of inventory than before. If they choose to fully implement this change in Q4, then there will be a destocking impact, compared to the typical inventory build seen in the fourth quarter last year. It is difficult to call, but we are assuming that reported US revenue growth in the fourth quarter will be adversely affected by inventory movements.

As is our usual practice, this guidance is on the same currency basis we have used all year, that is, the January 2009 average rates.

So far in 2009, despite the volatility, currency has been broadly neutral to that assumption.

We are, of course, taking no view of the future movements for currency, so going forward, this guidance takes no account of the likelihood that average exchange rates for the remainder of the year may differ materially from the January 2009 average. As usual, I would point you to our currency sensitivity chart to help you flex your own estimates on the currency impact to sales and earnings.

I think I will wrap up my formal remarks here, and turn the call back to the conference operator to begin the question and answer session.