

Simon Lowth **Q1 13 Analyst Script 25th April**

Simon Lowth

Thank you Operator, and good afternoon everyone.

Let me start by saying that we have posted a set of slides on the investor page of our web site that will follow along with my presentation, and I will try and cue the slide numbers as we go along.

So, turning to the first content slide, which is slide number 4 in the pack...

It has been a few short weeks since our Investor Day on the 21 of March. At that meeting, Pascal and the AstraZeneca management team laid out a clear articulation of our strategic priorities:

Achieve Scientific leadership.
Return to Growth
Be a Great place to work

The energy of the entire organisation has been marshalled to undertake the important task of executing on these priorities.

And over the last few months, in the run up to and following that meeting, we have made good progress:

Our drive towards scientific leadership has been enhanced by 4 important business development agreements: Moderna Therapeutics, Karolinska Institute, Alphacore Pharma and Bind Therapeutics, all of which put us at the cutting edge of important new technologies to bring important new medicines to patients.

Our 5 growth platforms: Brilinta, the Diabetes franchise, Emerging Markets, Respiratory and Japan—all contributed incremental growth in the first quarter, although clearly they couldn't make up for the expected revenue loss from patent expirations in the quarter.

And we are working at pace to simplify our business and drive continued productivity, as evidenced by the quick start to Phase 4 of our restructuring programmes.

But our focus today, of course, is the first quarter results.

I plan to cover 5 topics:

First, I'll summarise the headline numbers.

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

Then, 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 restructuring and cash.

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

Headline Results: First Quarter

So, on to the headline results, on slide 5.

Total Company revenue was \$6.4 billion in the quarter, a 12 percent decline in constant currency terms. Revenue declined by 13 percent on an actual basis as a result of the negative impact of exchange rate movements, chiefly the Japanese yen.

Once again, the dominant feature of our revenue profile in the first quarter is the loss of exclusivity on several brands—Seroquel IR and Atacand in many markets, and Crestor in Canada. These 3 products were down more than \$900 million dollars compared to last year.

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 21 percent. Core operating expenses were 4 percent lower than last year in constant currency terms, but revenue was down more, and together with the impact of lower Core other income, this drove the Core operating profit decline.

Core earnings per share in the quarter were \$1.41 compared with \$1.87 last year. The 21 percent decrease in constant currency terms is in line with the decline in Core operating profit, as the benefit from a lower number of shares broadly offset the higher tax rate in the quarter.

Adjustments to Core financial measures, at \$0.60 per share, were the same for both periods, although with a different mix: higher restructuring last year, and higher amortisation this year. When applied to the lower Core EPS base in 2013, this resulted in a larger decline for reported EPS compared to Core earnings.

Therefore, reported EPS was down 31 percent to \$0.81.

So, those are the headlines for the first quarter.

Q1 Revenue performance

Slide 6 returns to the first quarter revenue performance, when I refer to growth rates, they will be on a constant currency basis.

The first thing to mention on revenue is that we have made a slight boundary change to our regional breakouts for revenue. What is reported in Europe is now revenue from Western Europe combined with many markets that were previously reported under Emerging Markets.

We have provided 8 quarters of restated history to help you recalibrate your models, and they can be found on the investor page of our web site.

So with that bit of housekeeping out of the way, let's look at revenue.

Revenue in the US was down 16 percent compared with the first quarter last year, driven by loss of exclusivity for Seroquel IR... excluding Seroquel IR, the rest of the portfolio increased by 3 percent in the quarter. First quarter revenue includes \$78 million related to our share of sales of the Amylin diabetes portfolio which was not in the prior period. And there was growth contribution from Symbicort, Brilinta and the Onglyza franchise.

Revenue in Europe was down 16 percent in the quarter, chiefly due to the loss of exclusivity for Seroquel IR. There was also generic erosion on Seroquel XR following some adverse patent judgments and "at risk" launches, particularly in Germany. The continued impact from the loss of exclusivity for Atacand and Nexium also fuelled the revenue decline.

Revenue in Established Rest of World was down 17 percent, and it is largely a Crestor story—loss of exclusivity for Crestor in Canada, and pricing pressure in Australia. Revenue in Japan was up 5 percent, on good growth for Nexium, Crestor and Symbicort.

Revenue in Emerging Markets was up 9 percent in the quarter, an improvement from our exit rate in the fourth quarter of 2012. Although increases in Saudi Arabia and stable revenue in Brazil and Turkey played their part, it was the 21 percent increase in China that was the primary driver of performance. China sales were fuelled by good growth for Seloken, Nexium, Crestor and Iressa. Looking toward the rest of the year, in addition to continued growth in China we expect to see a broader set of markets contribute to our Emerging Markets performance.

Brands

Slide 7 provides a snapshot of revenue for key brands.

In addition to the regional growth platforms of Emerging Markets and Japan, as you can see here, our brand growth platforms: Brilinta, the diabetes franchise and Symbicort, all contributed incremental revenue in the quarter.

Crestor was down 11 percent, but it would have been flat except for the generic erosion in Canada. And on the bottom of the slide, you also see the significant impact from loss of exclusivity for Seroquel IR and Atacand.

Detailed commentaries on brand performances are in the press release. I want to provide some additional colour on our three growth platforms: Brilinta, the diabetes franchise, and Symbicort...but I will also touch on Crestor.

First, **Brilinta**, which is slide 8...

Sales were \$51 million in the quarter, with \$30 million in Europe and \$15 million in the US.

We continue to implement our plans to build this important brand that we outlined in our Investor day a few weeks ago.

On slide 9, we have rolled forward this graph of Brilinta's "New to Brand" performance in the US for the most recent weekly data, and it shows a continuation of the growth trend from January, with the usual dip for the Easter holiday week. We exit the first quarter with weekly New to brand volumes up 30 percent compared to the entry point in January.

Performance outside the US continues to build. We can increasingly use the regular IMS data to track progress instead of relying on survey data...and as you can see on slide 10 these graphs show steady progress in markets like Germany, Italy, the UK, and Australia.

Turning to the **diabetes franchise**, on slide 11.

Revenue for Onglyza was up 27 percent to \$90 million in the quarter.

Alliance revenue in the US was \$64 million, up 19 percent.

Total prescriptions growth for DPP4's in the US has slowed, but was still double digits in the quarter, up 10 percent.

Total prescriptions for our franchise of Onglyza plus Kombiglyze XR were up 9 percent. We did lose share during the quarter. Our market share of TRx's was 16.1 percent in March, and that is off by 170 basis points from December 2012. This is an increasingly competitive category. We have experienced some losses of preferred formulary positions in managed care plans, and have experienced a decreased share of voice relative to competitors. We are focused on pulling through volume where we have strong access, and we will continue to compete vigorously in the market.

Outside the US, our share of alliance revenue for Onglyza was \$26 million, up 53 percent.

And there have been further European launches of Kombiglyze during the quarter.

Moving on to slide 12,

First, the GLP-1 franchise. The first quarter includes \$69 million in revenue from our share of the alliance's Byetta and Bydureon sales in the quarter. The re-launch of Bydureon by the alliance has driven weekly new to brand volumes to a 15 percent increase compared to their October baseline, with new to brand share up 1.5 percentage points in that time. And starting April 1, the Alliance has assumed responsibility for the exenatide products outside the US.

Forxiga revenue was \$1 million in the quarter, reflecting the fact that the launch rollout is in its very early stages following approval in November of last year. The initial feedback we are getting from physicians is quite positive towards this new treatment modality.

Symbicort

As seen on slide 13, Symbicort sales were up 14 percent to \$826 million.

Sales in the US were up 32 percent. Symbicort's total prescriptions were up 15 percent compared to just 3 percent for the fixed combination market. And our share of total prescriptions and share of new patient starts were both up during the quarter.

Sales in the Rest of World were up 7 percent on growth in Europe and continued market share penetration in Japan on the back of the launches of Symbicort SMART and the COPD indication.

Finally, turning to **Crestor**, slide 14.

Sales were down 11 percent in the quarter to \$1.3 billion, due to the loss of exclusivity in Canada; otherwise sales would have been flat.

Sales in the US were down 4 percent to \$652 million.

Total prescriptions were down 7 percent compared to the first quarter last year. Realised prices were up, but that is attributable to the Medicare coverage gap adjustments that were put through in the first quarter last year, otherwise realised prices would have been slightly lower in the quarter, and we continue to expect lower pricing for the balance of the year.

Sales in Rest of World were \$671 million, down 16 percent; excluding Canada, Rest of World sales were actually up 5 percent, on some good growth in Japan and China.

As you model Crestor revenues for the rest of the year, you will be reminded that a ruling from the Court in Australia invalidated three patents, and we would expect that generics will achieve listing for reimbursement around mid-year.

Operating Profit and Margins

I will now turn to the first quarter P&L, which is on slide 15. 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 82.2 percent of sales. That is up 90 basis points compared with the first quarter last year. Product mix was unfavourable, however Core gross margin benefited from benefited from lower Core Merck expense related to the Second Option amendments implemented in the middle of last year.

Core SG&A expense was down 2 percent compared with the first quarter last year. Benefits from restructuring programmes and overall lower selling and marketing expenses in developed markets more than offset selective investments in support of Emerging Markets and Brilinta, as well as taking on our share of the selling costs for Byetta, Bydureon and Symlin.

Core other income was 36 percent lower than last year, on lower Zomig royalties and the absence of some one-offs in the first quarter of 2012.

That leads to a Core Pre-R&D operating margin of 51.5 percent of revenue, 350 basis points lower than last year, as the slightly higher Core gross margin as a percentage of revenue is offset by the lower Core other income and higher SG&A expense as a percentage of revenue.

Core R&D investment in the quarter was \$963 million. That is 7 percent lower than last year. We continue to realise savings from restructuring programmes. The phasing of clinical project costs also drives the favourable variance—as spending winds down on Phase III trials for projects like fostamatinib and naloxegol.

These savings provided more than enough headroom to accommodate the spending for new in-licensed, acquired or partnered projects.

You will recall that we have guided to Core operating costs—that is combined Core SG&A and R&D costs—being held to a slight increase in 2013 in constant currency terms, and that is indeed our expectation, so I would view the 4 percent decrease in these costs in the first quarter as a matter of phasing—we will continue to make the investments behind the growth platforms and pipeline through the course of 2013.

Core operating profit was \$2.3 billion in the quarter, 21 percent lower than last year. Core operating margin was 36.4 percent of revenue, 4.4 percentage points lower than last year.

Productivity/Restructuring

Just a brief word on restructuring. On slide 16, you can see the scope of what we are now referring to as Phase 4 of restructuring, which combines the initiatives newly announced last month together with the actions that remained to be implemented from the Phase 3 programme that we announced back in February of 2012.

Total programme costs are estimated to be \$2.3 billion, and as you can see here we have charged \$543 million to the P&L in the first quarter.

Cash

Turning to slide 17, Cash generated from operating activities was \$2.2 billion in the quarter, compared with \$1.5 billion in the first quarter of 2012. Lower tax and interest payments partially offset the lower operating profit in 2013, whilst a one-off pension fund contribution drove higher outflows in the first quarter last year.

And we paid the second interim dividend from 2012 in the quarter, which amounted to \$2.3 billion.

Future Prospects/Guidance

Finally, turning to guidance, slide 18 in your pack.

We continue to expect a mid-to-high single digit decline in revenue in constant currency terms for the full year.

We will continue to face headwinds from loss of exclusivity. Indeed, since the start of the year we have received an adverse ruling on Crestor patents in Australia. We will see continued erosion of Seroquel IR, Atacand and for Crestor in Canada, however the prior year comparisons will improve as the 12 month anniversaries are met. So despite the new challenges and the double digit revenue decline in the first quarter, we maintain our revenue guidance for the full year.

It is a similar story on costs. Despite the 4 percent decline in combined Core SG&A and R&D expense in the quarter, this is a matter of phasing, and we continue to expect a slight increase in Core operating costs for the full year in constant currency terms.

With a revenue and cost profile in line with guidance, we continue to expect Core EPS to decline at a rate significantly higher than the decline in revenue this year.

One final item. As you will recall, on 1 April the US District Court for the District of New Jersey ruled one of our patents protecting Pulmicort Respules invalid, and further ruled that the generic defendants do not infringe a second patent. In that announcement we disclosed that revenues for Pulmicort Respules in the US were \$135 million in 2012, and royalties represented an annualised value of approximately \$260 million under Core other income. There is currently a temporary restraining order in place while the US Court of Appeals for the Federal Circuit considers our pending motion for a longer injunction pending appeal. We have no further news to report at this time, but just to remind you that should additional generics enter the market, both Pulmicort sales revenue and royalty income will come under significant pressure, and I am sure you will want to adjust your models accordingly.

As for currency, exchange rate movements created a 4 percent negative variance to Core EPS compared to last year, but was neutral to Core EPS versus our January 2013 guidance rates in the quarter. But I would remind you that our guidance takes no account of the likelihood that average exchange rates for the remainder of the year may differ materially from the January 2013 average.

We will now move on to the Q&A session. And I'll ask the operator to come on and provide the instructions.

Q&A

Post Q&A Summary

Thank you operator, and thanks to everyone for joining us today.

As expected, the first quarter results reflect the continued impact from loss of exclusivity for several products, and our outlook for the year is unchanged. We are working to a clear set of priorities, including returning to growth and achieving scientific leadership. In the quarter, all 5 of our growth platforms contributed incremental revenue, and our recent business development activities reinforce our commitment to invest in distinctive science to bring new medicines to the patients we serve. And with that, I bid you all good day.