# Q2 2013 Analyst presentation Pascal Soriot script

Slide 1: 2Q and Half Year Results

Slide 2: Safe Harbour statement

Slide 3: Pascal Soriot, Chief Executive Officer

Slide 4: 2Q Highlights

I would like to start by first giving you a high level summary of the highlights for the quarter as I see them.

Second quarter revenue was down 4 percent, largely on the back of a nearly \$500 million impact from brands that have recently lost exclusivity, which is very much in line with our expectations.

Despite this, we saw good double-digit increase from our 5 growth platforms, which provided in aggregate of more than \$400 million of incremental revenue in CER terms.

Our late-stage pipeline is growing, with:

- -2 NDA submissions
- -1 Phase III start
- -and we added 3 late-stage projects to the portfolio through business development transactions.

Slide 5: Headline results 2Q 2013

First, let me give a quick overview of the headline results for the second quarter. Simon will, of course, make more detailed remarks on the P&L in his presentation.

Revenue in the second quarter was down 4 percent in constant currency terms, to \$6.2 billion.

Core operating profit was down 10 percent, as we continue to invest behind our growth platforms and our pipeline.

Core EPS was down 21 percent at CER, with the main driver beyond the operating profit line a higher tax rate in the quarter compared to last year, where we had a \$0.19 per share benefit from tax settlements.

And, after the usual Core adjusting items, reported EPS was \$0.66.

Slide 6: Revenue impact from LOE moderating

If we look at the evolution of our revenue profile, you can see a steady moderation in the rate of revenue lost from products recently experiencing loss of exclusivity—from nearly \$1.4 billion in the fourth quarter 2012 to now just under \$500 million this quarter.

The rest of the portfolio has been showing some growth, but obviously it has been swallowed up the generic erosion.

Still we grew the rest of the portfolio by \$232 million dollars, or around 4 percent. And as I mentioned in my introduction, this has been fuelled by a double-digit increase for our 5 growth platforms—which combined for more than \$400 million in incremental revenue in the quarter.

## Slide 7: 5 key growth platforms

I will now look at the revenue performance in a bit more detail, and I will highlight the performance of these 5 growth platforms as I do.

Looking first at revenue on a regional basis.

## Slide 8: Regional revenue performance

The US was down 4 percent, chiefly on Seroquel IR and further erosion of the Toprol-XL franchise. Excluding these, the rest of the portfolio was up 4 percent.

Revenue in Europe was down 13 percent, as the exclusivity losses continue to take their toll.

In the Established Rest of World, Japan—which is one of our 5 growth platforms-had a revenue increase of 10 percent. Now some of this increase is the result of a very soft comparator for Nexium, where the second quarter last year only had \$1 million in sales, as we were still working of launch stocks. Japan is a market where we have a number of partnered products, so there is some revenue volatility based on ordering patterns by our partners, but we are also seeing strong underlying inmarket demand for Nexium, Crestor and Symbicort.

Revenue in Emerging Markets was up 12 percent in the quarter.

#### Slide 9: Good performance in Emerging Markets

If we look at the quarterly revenue progression over the last 6 quarters, it is quite a good picture. However, I do want to point out that the growth rate in the second quarter is flattered by the comparatively weak second quarter last year, when we were still working through the supply chain issues that impacted revenue.

As we said back in March, we expect to be able to achieve high single digit revenue increases in Emerging Markets for the foreseeable future, so I think it is important to put that 12 percent figure in perspective.

The other point to note is that we had a very balanced profile in terms of growth in Q2. In contrast to Q1 when it was essentially all driven by China, our growth in the second quarter is almost 50/50—Sales in China are up 21 percent, combined with a 9 percent increase in our other Emerging Markets.

I will now turn to the 3 product franchises among our 5 growth platforms, first Brilinta.

#### Slide 10: Brilinta

Brilinta revenue in the quarter was \$65 million, up from \$18 million last year.

We are executing on all of the new programmes and increased investment according to the plans we laid out in March, including the July start for the Transition of Care nurses.

As we said, we don't expect the fruits of these investments to effect a meaningful uplift in the growth trajectory of the new to brand share until the back end of this year.

Sales in the Rest of World were \$49 million in the quarter. In Europe, we are at or now closing in on the number 2 position in volume share of the total OAP market in Germany, the UK and Italy. We also continue to make steady progress in France.

#### Slide 11: Brilinta US steady growth

This chart shows the steady progress we are making in growing our "New to Brand Share" in the US market, which is closing in on 6%, and that is all OAP usage, not just the ACS indication.

This has been accompanied by a steadily increasing total prescription trend, where TRx in the second quarter are 33 percent higher than the first quarter of this year.

#### Slide 12: Brilinta ROW charts

And here is the market share trend in volume terms for the OAP market in the major markets in Europe.

#### Slide 13: Diabetes franchise

Revenue from our share of the diabetes alliance reached \$200 million in the quarter. Of course, the growth rate compared to last year is flattered by the absence of Byetta, Bydureon and Symlin revenues in the prior year.

Onglyza revenues were up 29 percent in the US, although some of this was due an adjustment related to returns reserves.

The market itself looks to settling in to a high single digit growth trend in prescription terms, as the feeder of switches from the TZD products has run its course

Our Onglyza franchise market share has stabilized following the formulary changes that affected our first quarter performance.

Outside the US, Onglyza franchise revenue increased by 23 percent.

Of course, the other Onglyza news in the quarter was the announcement of the headline results for the SAVOR trial, where Onglyza met its primary safety objective of non-inferiority and did not meet the primary efficacy objective of superiority for a composite endpoint of cardiovascular death, non-fatal heart attack or non-fatal stroke, versus placebo when added to the current standard of care. The results will be presented at the European Society of Cardiology meeting in September

For the GLP-1 franchise, US revenue for Byetta and Bydureon was \$63 million in the quarter, and we recorded \$22 million in the Rest of World following the assumption of these products from Lilly in April of 2013.

Market share for Bydureon prescriptions in the US market continues to grow, although with the declines in Byetta, market share for the total franchise is down.

Of course, the breaking news for Forxiga is that we have resubmitted the NDA in the US, and the application has been assigned a PDUFA date of January 11 of 2014.

It is still very early days for Forxiga, where we started launching in Europe in November of last year, so revenue is just \$3 million in the guarter and \$4 million for the first half.

The trajectory of the launch uptake in the first 6 months in Germany and the UK is tracking to previous launches in the diabetes markets, including Januvia.

I'll now briefly show you some of the charts that illustrate the trends I just spoke to.

#### Slide 14: Onglyza US franchise share stabilized

Here is the Onglyza franchise market share, which has now stabilized, with share of total prescriptions at 16 percent, down just 10 basis points since March.

#### Slide 15: Bydureon/Byetta US TRx trends

And here is our GLP-1 franchise in the US. Market share for Bydureon prescriptions in the US market continues to grow, although with the declines in Byetta, market share for the total exenatide franchise is down.

#### Slide 16: Forxiga launch uptake in Germany and UK

And here is the launch uptake for Forxiga in Germany and in the UK. And you can see that it is tracking to previous launches in the diabetes markets, including Januvia.

In terms economic assessments, in the UK, we have had a favourable review by NICE, whereas in Germany we will have to negotiate pricing in the context of a GBA finding of "no additional benefit" compared with the existing standard of care.

## Slide 17: Symbicort

Turning now to Symbicort, the current anchor to our Respiratory franchise, sales in the second quarter were up 8 percent to \$842 million.

This performance is fuelled by the 16 percent revenue increase in the US market, where Symbicort prescriptions were also up 16 percent, compared to just 2 percent for the fixed combination market.

Symbicort sales in the Rest of World were up 4 percent. Sales in Europe were up 2 percent. We continue to drive a good in-market performance in Japan, on the back of approvals for SMART and COPD, although this is not reflected in reported sales in the quarter due to partner ordering patterns.

#### Slide 18: Symbicort US market share trends

Here is the Symbicort market share trend in the US. Our share of total prescriptions has grown to 24.1 percent...that is up 1.8 points since December...and we have reached an all-time high of 30.7 in share of patients new to combination therapy. An excellent performance

#### Slide 19: Achieve Scientific Leadership

I'll spend the next few minutes outlining progress we are making on our priority to achieve scientific leadership.

Our strategies to achieve this:

Focus on our distinctive science in 3 core therapy areas: Cardiovascular and Metabolic disease, Oncology, and Respiratory/Inflammation and Autoimmune diseases.

We are prioritizing and accelerating our pipeline, both in our internally sourced projects, but also with business development.

And we are driving to transform our innovation culture and model.

## Slide 20: Recent pipeline news

These are the key items of newsflow on our pipeline since the last quarter.

As I mentioned earlier, we have resubmitted the NDA for Forxiga in the US. The FDA has acknowledged receipt of the file, and has assigned a January 11 2014 PDUFA date.

Just before the ASCO meeting we announced that the first patient has been enrolled in the Phase III clinical trial for moxetumomab pasudotox in the treatment of adults patients with hairy cell leukemia who have not responded to or relapsed after standard therapy.

In June, we and our alliance partner, Bristol-Myers Squibb, announced the top-line results for the SAVOR trial for Onglyza. AS you know, Onglyza met the primary safety objective of non-inferiority,

but did not meet the primary efficacy objective of superiority for a composite endpoint of CV death, non-fatal MI or non-fatal ischemic stroke, when added to standard care, as compared to placebo.

The SAVOR trial will be presented at the European Society of Cardiology in September.

The US FDA has designated our NDA for metreleptin for priority review. This drug is a treatment for metabolic disorders associated with inherited or acquired lipodystrophy, a rare disease estimated to affect a few thousand people around the world.

The disappointment in the quarter was the completion of the fostamatinib OSKIRA programme, and based on the totality of results for the programme, we made the decision not to proceed with regulatory filings and return the asset to Rigel.

And our growing portfolio of late-stage projects was strengthened by the acquisitions of Omthera and Pearl, as well as by the collaboration with FibroGen that we announced yesterday.

#### Slide 21: Growing late-stage pipeline

And here is the snapshot of where our portfolio stands at the half year, with 81 projects in clinical development and a growing late-stage pipeline.

As you can see on the right hand side of the chart, we now have 8 New Molecular entitiy projects in Phase III or registration. This is the result of the moxetumomab Phase III start combined with the additions of Omthera's Epananova for high triglycerides and Pearl's LABA/LAMA combination for COPD. There are 5 others that still await regulatory approval in one of our major markets.

During the period there were 5 additions to the clinical development pipeline from Discovery research, 6 projects successfully progressed to their next phase of development alongside the 2 external additions, and 10 projects were discontinued.

## Slide 22: Business Development aligned with priority TA's

We have also made excellent progress on the business development front.

Here are just some of the key transactions we have completed in the last 9 months or so, mapped across all 3 of our core therapy areas.

There is also a good spread between investments in Discovery Research—such as Moderna, BIND, and NGM, just to name a few—and later stage or close to market assets, which came by way of acquisition of Omthera Pharmaceuticals and Pearl Therapeutics. And yesterday we added another late-stage project with the collaboration with FibroGen for FG-4592 for the treatment of anaemia associated with chronic kidney disease and end-stage renal disease.

## Slide 23: Cambridge Biomedical Campus (aerial photo)

I think the biggest piece of news in the quarter, at least in the way of long-term implications for transforming our innovation culture, is our decision to locate our new UK based global R&D and headquarters center on the Cambridge Biomedical Campus

This campus is a vibrant hub for biomedical innovation

It is home to leading research, academic and healthcare organizations, including:

- -- University of Cambridge School of Clinical Medicine
- --Addenbrooke's hospital
- -- The MRC Laboratory of Molecular Biology
- -- The Wellcome Trust-MRC Institute of Metablolic Science
- -- and the Cancer Research UK Cambridge Institute.

In July we announced two-year collaboration on three pre-clinical and clinical oncology projects with the University of Cambridge and Cancer Research UK. The first of what we envision will be numerous opportunities for collaborations with all of the world-class centres that will be our new neighbours.

# Slide 24: Simon Lowth

I am going to stop here, and turn over to our Simon, who will take you through the second quarter financial performance, after which we will hold a Q and A session. Simon, over to you.