

Shire Plc (SHPG) Flemming Ornskov on Q3 2015 Results - Earnings Call Transcript

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About: [Shire PLC \(SHPG\)](#)



Operator

Good morning and good afternoon, ladies and gentlemen, and welcome to the Shire Q3 2015 results call, "Progressing our transformation to a leading global biotech." Throughout the call, all participants will be in listen-only mode, and afterwards there will be a question and answer session. Just to remind you, this conference call is being recorded. Today I'm pleased to present our speaker for today's call. Please go ahead.

Matthew Osborne - Global Head-Investor Relations & Vice President

Thank you. Good morning and good afternoon, everyone. Thank you for joining us to discuss the press release Shire issued earlier today announcing our 2015 third quarter results. You should have received our press release and should be viewing our presentation via our webcast on Shire.com. If you are unable to access the press release or presentation on our website, please contact Souheil Salah on our Investor Relations team at +44-1256-894-160, and he will be happy to assist you.

Our speakers today are Chief Executive Officer Dr. Flemming Ornskov and Chief Financial Officer Jeff Poulton. We are also joined today by Dr. Phil Vickers. Phil is Shire's Head of Research and Development and will be available to answer questions related to our pipeline during the Q&A portion of the call.

Before we begin, I would refer you to slide 2 of our presentation and remind you that any statements made during this call which are not historical statements will be forward-looking statements and as such will be subject to risks and uncertainties that if they materialize could materially affect our results.

Following our presentation today, we will also open up the call to your questions. We request that you ask only two questions so that everyone has a chance to participate. We will also be available to follow up with you after the call. I will now hand the presentation over to Flemming.

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Flemming Ornskov - Chief Executive Officer & Director

Thank you, Matt, and hello, everyone. It's good to be with you today to discuss our third quarter results. Over the next 30 minutes or so, I'll give you a greater understanding of our progress towards becoming a leading global biotech company, with a focus on rare diseases and other specialty conditions. I will then hand over the call to Jeff to take you through what was a strong Q3 financial performance. I'm sure you're also interested in an update on Baxalta, and I will make some comments in regards to the combination we proposed at the conclusion of this call before we go into Q&A.

Let's now all turn to slide number 4. As you're aware, we've been on a journey to build a leading global biotech company focused on rare diseases and other specialty conditions. Our initial priority was getting the basics right:

know, 2015 is a year of further investments that will allow us to continue to drive future growth to meet our 10x20 plan which we are well on our way towards achieving.

Let me now move on to slide 5 and take you through some of the highlights from the third quarter. During the third quarter, we delivered 12% year-over-year sales growth at constant exchange rates from our core products when you exclude INTUNIV. This was the result of growth from VYVANSE, CINRYZE, and FIRAZYR, as well as GATTEX or REVESTIVE and NATPARA as we continue to leverage Shire's rare disease platform.

As you will recall, last quarter we increased our full-year guidance for non-GAAP diluted earnings per ADS to mid to high single digit growth, and we are reiterating this guidance today as we continue to invest in our innovative pipeline and support the recent launches of VYVANSE in binge-eating disorder in adults, NATPARA and GATTEX or REVESTIVE ex-U.S.

We continue to see the benefit of investing in innovation, with progress this quarter in several areas of our pipeline. During the quarter, we received European approval for INTUNIV for the treatment of ADHD in children and in adolescents for whom stimulants are unsuitable, ineffective, or not tolerated. Patients in Europe can now benefit from having an additional choice of treatment.

As we announced last week, the FDA requested additional information in response to our application for lifitegrast as a potential new treatment for the signs and for the symptoms of dry-eye disease. We have recently completed another Phase 3 study of lifitegrast called OPUS-3, and we expect top line results sometime during the fourth quarter of this year. If the data from this study are positive, they are expected to support resubmission to the FDA in the first quarter of 2016. I will have more to say on lifitegrast in just a few minutes.

We are ahead of schedule with recruitment for the Phase 3 pediatric study of SHP465, and we also expect to initiate multiple Phase 3 studies with other pipeline assets by the end of this year or early next year. And we're truly excited by FST-100, which we now call SHP640, which is a potential therapy for the treatment of infectious conjunctivitis, which we bought into the company through the acquisition of Foresight Biotherapeutics. I'll come back to this acquisition later in this presentation.

But let's now all move to slide number 6. Our core products when you exclude INTUNIV grew 12% at constant exchange rates over the third quarter of last year. As expected, INTUNIV sales continue to decline due to the entry of generics, but at the same time we're still dealing with foreign exchange headwinds. These factors combined reduced reported product sales by 10%, with 6% of that due to the decline in INTUNIV and 4% related to foreign exchange headwinds.

I'm pleased to say that we grew our non-GAAP earnings per ADS by 11% on a reported basis and by 15% on a constant exchange rate basis, which benefited also in part from a lower tax rate this quarter. We delivered these results while we continue to invest in the launches of VYVANSE for binge-eating disorder in adults, the launches of GATTEX or REVESTIVE and NATPARA, and in preparation for the potential launch of lifitegrast in the U.S. initially. And as noted, I'm very pleased to reiterate our mid to high single digit growth in non-GAAP diluted earnings per ADS guidance for the full year, which we gave last quarter.

Let's now all move on to slide number 7. The investments we have made in recent years to bring innovative products to patients are now driving the growth of our portfolio and will continue to do so well into the future. Our focus – our keen focus, I would even say – on commercial excellence has led to the continuing performance of our newest inline products. I'm very pleased with the double-digit growth we saw across several of our products during this quarter, and Jeff will go into further detail on what's driving this growth when he presents later today.

One particular highlight worth noting was the VYVANSE IP victory, where the Court of Appeals affirmed the District Court's summary judgment ruling that 18 patent claims from four of the FDA Orange Booklets, the patents for

which further confirms that Shire has strong patents protecting VYVANSE.

Let's look at slide 8 and subsequently slide 9. That deals with our pipeline progress. On slide 9 you will see this progress. We continue to advance our pipeline of innovative programs, and we have a very good mix of near- and longer-term growth opportunities. Our view is that a deep and innovative pipeline is at the core of becoming a leading biotech company. As you can see, we've come a long way in the last two years based on the robustness of our pipeline, a majority of which is focused on rare disease programs.

Let's go through some of the key changes over the last quarter. In September, we received European approval for INTUNIV, which also triggers 10 years of exclusivity in the EU. SHP640 for infectious conjunctivitis is now ready for Phase 3. We discontinued our Phase 3 program for FIRAZYR in the treatment of ACE inhibitor induced angioedema. This decision follows recent top line data demonstrating the study did not meet its primary or secondary efficacy endpoints. While these results were disappointing, FIRAZYR continues to be an effective treatment option for acute hereditary angioedema attacks in adults aged 18 or older.

Now turning to the next few slides, I'll provide an update on a few of our key pipeline assets. Slide 10. Let's first talk about lifitegrast. As you're well aware, on October the 16th, the FDA requested an additional clinical study as part of the complete response letter to our new drug application for lifitegrast for the signs and symptoms of dry eye disease in adults. At the same time, we announced the recent completion of another Phase 3 study of lifitegrast called OPUS-3, which we expect to be the basis of Shire's response to the complete response letter from the FDA. We do indeed expect top line results of OPUS-3 sometime during the fourth quarter of this year, and, if positive, we plan to provide these data as part of a resubmission to the FDA during the first quarter of 2016. During their product quality review, the FDA also requested more information related to lifitegrast and its formulation, which Shire is confident it can also address as part of its resubmission to the FDA.

I want to emphasize Shire's commitment to working closely with the FDA to provide the evidence required to deliver a new prescription treatment option for the 29 million adults in the U.S. living with this chronic and progressive disease. This is an area of significant unmet medical need for which there has been no new treatment in over a decade.

Let's turn to slide number 11. Along with lifitegrast, our commitment to building an innovative pipeline in ophthalmology continues with SHP640, which we formerly called FST-100, which is a late-stage asset we added to the portfolio through our recent acquisition of Foresight Biotherapeutics, which took place in August. 5.9 million cases of infectious conjunctivitis – by many also known as pink eye – occur in the U.S. each year, and 5.4 million cases in the EU. Unfortunately, existing therapies may not treat the cause of this condition, so many physicians are unable to differentiate between the viral and the bacterial form of so-called pink eye. If approved, SHP640 has the potential to become the first agent to treat both the viral and the bacterial form of conjunctivitis, addressing a significant unmet medical need.

With two Phase 2 studies in adenoviral conjunctivitis already complete, we discussed with the FDA a path forward for Phase 3 studies. We are currently in the trial design phase and anticipate the Phase 3 program to include investigation for the treatment of bacterial conjunctivitis. Overall, we are excited about the potential of SHP640. It's a clear strategic fit with lifitegrast and the overall ophthalmics business unit, treating a serious and highly prevalent eye condition. And as a reminder, we now have three unique clinical programs in ophthalmology: lifitegrast for the treatment of dry eye disease, SHP607 for the prevention of retinopathy of prematurity, and also now SHP640 for the treatment of infective conjunctivitis.

Let's all now move to slide number 12. Starting with INTUNIV, as mentioned, we recently received marketing approval in the EU for the treatment of ADHD in children and adolescents for whom stimulants are not suitable, not tolerated, or have been shown to be ineffective. When we consider the complexities and different manifestations of ADHD in children and adolescents, it is incredibly important that physicians will soon be able to choose a non-stimulant option that may best suit the needs of their patients. We are preparing for launches in the EU in 2016 and expect to make

In the coming months, we also expect to advance four programs into Phase 3, the first time this has occurred in Shire's history. Together, these four products have the potential to generate several hundreds of millions of dollars in sales. This includes plans to initiate this month a Phase 3 trial of CINRYZE in adults with antibody-mediated rejection in renal transplant recipients, representing a potentially new indication for CINRYZE. Earlier this month, the FDA granted fast-track designation for CINRYZE in this important indication. We also hope to initiate a Phase 3 study of the subcutaneous formulation of CINRYZE in the near future, having recently submitted an IND to the FDA.

During the first half of next year, we intend to initiate a Phase 3 program of SHP620, also called maribavir, in cytomegalovirus infection in transplant patients. Finally, we have been in discussions with the FDA regarding a path forward for Phase 3 studies of SHP621, which is our oral budesonide suspension for use in the treatment of eosinophilic esophagitis, which came to us through the acquisition of Meritage Pharma, also earlier this year. We expect these studies to commence by early 2016.

Well, let me now turn the call over to Jeff Poulton, Shire's CFO, to review third quarter financial results in more detail. Jeff?

Jeffrey Poulton - Chief Financial Officer & Director

Thank you, Flemming. Good morning and good afternoon, everyone. As Flemming has highlighted, our core business delivered strong results in Q3 as we continued to position the business for longer-term growth.

Today I'd like to focus on four areas of performance. First, I will provide detail on the drivers of the double-digit sales growth from our core underlying business. Second, I will cover the delivery of a third quarter non-GAAP EBITDA margin of 43%. Third, I will cover our continued strong cash generation. And finally I will reiterate our guidance that was upgraded during our second quarter call to mid to high single digit non-GAAP diluted EPS growth for 2015.

Moving to slide 14, you can see the components of our third quarter performance. Product sales were approximately \$1.6 billion or 6% above the prior year in constant exchange rates. Excluding INTUNIV, product sales were up 12% at constant exchange rates, as our underlying business continues to deliver strong growth. Royalties and other revenues continue to benefit from the SENSIPAR royalty stream acquired as part of the NPS transaction, with royalties increasing approximately \$35 million from the same period in the prior year.

We've delivered non-GAAP EBITDA of \$758 million in the quarter, representing 43% of product sales. Our margins are down slightly from 2014, as we are investing in our future growth drivers, including VYVANSE for binge-eating disorder, GATTEX/REVESTIVE, NATPARA and lifitegrast. The 43% delivered in Q3 represents an increase from our Q2 operating margin as we move beyond the initial launch phase of the VYVANSE BED indication.

Our third quarter non-GAAP dilutive earnings per ADS increased to \$3.24, or up 11% from the prior year. At a constant exchange rate, this represents a 15% increase. Our non-GAAP diluted EPS benefited from a low non-GAAP effective tax rate of 10% in the quarter, due to the timing of quarterly tax charges. However, for the full year, we still expect our non-GAAP effective tax rate to be in the 15% to 17% range. Finally, our cash generation remains strong, and we generated approximately \$600 million of cash in the quarter. I will go into additional detail on this shortly.

Now moving to slide 15, I will cover our product performance and add to comments previously made by Flemming. Starting with our HAE franchise, CINRYZE and FIRAZYR both delivered strong year-over-year growth. For CINRYZE, product sales increased to \$187 million in the third quarter of this year, a 30% increase over the prior year at constant exchange rates. This increase includes the benefit of additional patients on therapy and, to a lesser extent, price increases since the third quarter of 2014. Net sales in the third quarter of 2015 also benefited from approximately \$20 million of stocking, which was slightly above the \$15 million of stocking for CINRYZE in Q3 of 2014. The stocking in the third quarter followed an estimated \$10 million of destock in the second quarter of this year.

since the third quarter of 2014. We remain very pleased with the performance of the HAE franchise, with both CINRYZE and FIRAZYR continuing to perform strongly as we leverage our rare disease expertise following the acquisition of ViroPharma in early 2014.

Turning to our lysosomal storage disease products. ELAPRASE and REPLAGAL sales were down compared to the prior year at constant exchange rates, as Q3 2014 contained a bigger benefit from the timing of large orders in markets that order infrequently. ELAPRASE's year-over-year growth was negatively impacted by approximately \$20 million and REPLAGAL's growth by about \$10 million of less large orders. VPRIV declined 4% at constant exchange rates from the prior year, as the impact of increased competition in the U.S. Gaucher market was only partially offset by our international performance.

Moving on to VYVANSE, we remain pleased with VYVANSE's performance, particularly in the U.S. adult market since the launch of the BED indication in the first quarter of this year. VYVANSE exited the quarter at a 16.8% share of the ADHD market, up 0.5 percentage point from September 2014. As a reminder, BED scripts are not tracked separately, so BED scripts are included in the overall ADHD market basket.

VYVANSE sales grew approximately 22% from Q3 2014 on a constant exchange rate basis. This increase was driven by U.S. script growth of 9% compared to the prior period, outpacing ADHD market growth of 6%. U.S. pricing actions since Q3 2014 and the performance in our international markets also contributed to growth in the quarter. Third quarter net sales also benefited from approximately \$20 million of stocking, which compared with \$10 million of destocking in the same period last year.

Finishing up with our GI products, LIALDA sales were \$177 million for the quarter, up 2% on a constant exchange rate basis. We are pleased with LIALDA's market performance, as we have ended the quarter at a 35.4% market share, up from 33% at the end of 2014, as LIALDA continues to take share from the competition. Resulting increase in scripts versus the prior year, as well as the benefit of a pricing action since the third quarter of 2014, was offset by higher sales deductions as the percentage of product sales and less stocking in Q3 2015 than in the same period of 2014.

The products acquired with our NPS acquisition earlier this year contributed \$50 million of sales in Q3. GATTEX/REVESTIVE contributed \$43 million, and NATPARA contributed \$7 million for the quarter. For GATTEX/REVESTIVE, we are starting to see positive results from leveraging our existing GI sales force to raise awareness of short bowel syndrome and to help identify eligible patients as our 100 LIALDA sales reps in the U.S. began making calls for GATTEX for the first time during the third quarter.

For NATPARA, the number of REMS-certified physicians has increased from approximately 1,900 at the end of the second quarter to more than 2,400 by the end of the third quarter, and we have added approximately 250 new patients onto commercial therapy in the quarter, more than doubling the number of patients on therapy from the end of the second quarter. We are pleased with the performance of both products and believe our rare disease expertise will benefit these products in the same way that we were able to accelerate growth in our HAE franchise.

Lastly, you can see on the far right side of the chart two items that significantly held back reported sales growth this quarter. INTUNIV held back reported sales growth by 6 percentage points, as we've seen the impact from multiple generics, and we were also impacted by foreign exchange headwinds from a stronger U.S. dollar, which held back growth by 4 percentage points.

Moving on to slide 16 and our operating ratios. Non-GAAP R&D has increased 8% year to date as we continue to invest in our pipeline, including the inclusion of NPS's R&D costs. Non-GAAP SG&A has increased 10% year to date as we've invested behind future growth drivers, including launching VYVANSE for BED, NATPARA, and GATTEX/REVESTIVE, as well as the potential launch for lifitegrast. Excluding our investments year to date in BED, NPS, and lifitegrast, non-GAAP R&D and SG&A was broadly flat compared to the first nine months of 2014. Despite

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