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

SA Transcripts

Oct. 23, 2015 1:43 PM ET

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.

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 destination 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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.