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Allergan Management Discusses Q3 2013 Results - Earnings Call Transcript

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Allergan (NYSE:AGN)

Q3 2013 Earnings Call

October 29, 2013 11:00 am ET

Executives

James M. Hindman - Chief Financial Officer

David E. I. Pyott - Chairman and Chief Executive Officer

Jeffrey L. Edwards - Chief Financial Officer and Executive Vice President of Finance & Business Development

Scott M. Whitcup - Chief Scientific Officer and Executive Vice President of Research & Development

Joann Bradley

Analysts

Aaron Gal - Sanford C. Bernstein & Co., LLC., Research Division

Ken Cacciatore - Cowen and Company, LLC, Research Division

Douglas D. Tsao - Barclays Capital, Research Division

Jami Rubin - Goldman Sachs Group Inc., Research Division

Marc Harold Goodman - UBS Investment Bank, Research Division

Seamus Fernandez - Leerink Swann LLC, Research Division

David Risinger - Morgan Stanley, Research Division

Gregory B. Gilbert - BofA Merrill Lynch, Research Division

David W. Maris - BMO Capital Markets U.S.

David G. Buck - The Buckingham Research Group Incorporated

Liav Abraham - Citigroup Inc, Research Division

Annabel Samimy - Stifel, Nicolaus & Co., Inc., Research Division

Vamil Divan - Crédit Suisse AG, Research Division

Operator

Hello, and welcome to the Allergan Third Quarter 2013 Earnings Call. [Operator Instructions] At the request of the company, today's conference is being recorded. If anyone has any objections, you may disconnect at this time.

I would like to introduce today's conference host, Mr. Jim Hindman, Senior Vice President, Treasury Risk and Investor Relations. Sir, you may begin.

James M. Hindman

Thanks, Rebecca. Good morning. With me for today's conference call is David Pyott, Chairman of the Board and Chief Executive Officer; Jeff Edwards, Executive Vice President, Finance and Business Development, Chief Financial Officer; Dr. Scott Whitcup, Executive Vice President, Research and Development, Chief Scientific Officer; and Jim Barlow, Senior Vice President and Corporate Controller.

Before we move ahead, I would like to remind you that certain statements that we'll make in this presentation are forward-looking statements. These forward-looking statements reflect Allergan's judgment and analysis only as of today, and actual results may differ materially from current expectations based on a number of factors affecting Allergan's businesses. Accordingly, you should not place undue reliance on these forward-looking statements.

For a more thorough discussion of the risks and uncertainties associated with the forward-looking statements to be made in this conference call and webcast, we refer you to the disclaimer regarding forward-looking statements that is included in our third quarter 2013 earnings release, which was furnished to the SEC today on Form 8-K, as well as our filings with the SEC referenced in that disclaimer.

We will follow up the question-and-answer session of this call with a short listen-only segment, where we will provide additional miscellaneous information that relates to our business. Under Regulation FD, in order to be able to discuss this information freely during the quarter, we must be sure that it is in the public domain.

This conference call and accompanying webcast are being simultaneously broadcast over the Internet, with replays available for one week. You can access the information on our website at www.allergan.com.

At this point, I would like to turn the call over to David Pyott.

David E. I. Pyott

Great. Thanks, Jim. Good morning, ladies and gentlemen. Third quarter sales increased strongly over Q3 of 2012 by 14.0% to local currencies and by 12.9% to U.S. dollars. We're delighted that this is the highest growth rate we have delivered in the quarter since 2008, and that the expansion was broad-based across many product lines and businesses.

Furthermore, we're benefiting from our global reach in all of our operating regions, namely North America, Europe, Africa, Middle East. Latin America and Asia Pacific achieved at least double-digit growth in local currencies in the quarter. This is reflective of the strong growth being experienced in our product markets, and in general, of Allergan's market share gains as we introduce the steady stream of new innovative products to our customers around the world.

Regarding operating performance, we generated non-GAAP diluted earnings per share of $1.23, an increase of 18% over Q3 of 2012, and well above the outlook provided on the last call of $1.18 to $1.20, thanks to the robust sales. This result was achieved after we continued to invest both into targeted sales and marketing programs to launch products and build our markets, as well as into R&D.

Regarding progress with our pipeline, we're pleased that we're delivering most of the major regulatory approvals we're seeing for this year. Since the last earnings call, we have received FDA approvals for VOLUMA and BOTOX for crow's feet lines, as well as the first positive opinion from the French agency for crow's feet lines, marking the first step in the mutual recognition procedure, which should lead to approvals for this indication across the 27 countries in the European Union, as well as Norway and Iceland.

Furthermore, we secured approvals for BOTOX for overactive bladder in Canada, the U.K. and a positive opinion in France. Also, the Japanese authorities approved our Natrelle breast implant products, including the round, soft cohesive line; the style 410 shaped anatomical line; as well as the tissue expander range. As such, Allergan is the only company to have regulatory approval for both breast augmentation and reconstruction in Japan. We expect to secure reimbursement for reconstruction post mastectomy around the end of the year.

Our global partnership with Medytox, excluding Korea, is a reflection of our long-term efforts to continue to build the facial aesthetics in therapeutic markets for neuromodulators, and should result in us offering an expanded suites of products, including a potential liquid presentation. The Medytox transaction is contingent upon receiving certain government approvals.

Regarding LEVADEX in the U.S., we're on track for filing by year end, all the data required by FDA in its complete response letter, and anticipate approval in Q2 of 2014. Regarding the disposal of the Obesity Intervention business, we're pleased that we have entered into a definitive agreement with Apollo Endosurgery and expect to close the transaction before year end.

Regarding RESTASIS and FDA's draft guidance in generics of cyclosporine, we're encouraged that 22 medical societies, patient groups and consumer groups submitted comments, all raising concerns about public health and patient safety if generics were to be approved of Allergan's complex oil and water emulsion. It is noteworthy that not one single submission was made in favor of the draft guidance. FDA's officials, even within the generics division, have admitted as recently as June 2013 that equivalents of ophthalmic drugs is "an emerging topic" being considered for FDA's regulatory science enhancement initiative.

Allergan has submitted studies of several test emulsions showing that these emulsions that meet the draft guidelines nonetheless significantly differ from RESTASIS. Based on our investigations, FDA has never, in the past, approved an ophthalmic emulsion based solely on in vitro data. In the coming months, the draft guidance has the highest management attention, and we will take every appropriate legal and regulatory action to uphold sound science and patient safety.

Now commenting the performance of the businesses. I'll commence with ophthalmic pharmaceuticals. Allergan sales increased in Q3 by 9.0% in local currencies with mid-single-digit growth in the U.S. being boosted by strong double-digit growth internationally. RESTASIS with 21% growth in local currencies continues to grow very strongly, not only in value, but also in volume, given good response to our increased investment in direct-to-consumer advertising in the U.S. and an expanding base of prescribers in U.S. optometry. In addition, RESTASIS is growing strongly in Canada and Turkey in particular.

In the glaucoma category, we're experiencing a difficult market in the U.S., and low Q3 growth for LUMIGAN given the impact of generics of major patent expired products. Ex-U.S., we enjoyed strong double-digit growth for both the bimatoprost and brimonidine franchises in the quarter, and are pleased that per IMS data for Q2, that's the last period for which data is available, the LUMIGAN became the #1 selling glaucoma product in the world.

In Europe, we launched GANFORT unit dose in September into the preservative-free category in the first wave of countries, namely in Germany, the Netherlands and the U.K., adding to the launches of LUMIGAN unit dose earlier in the year. In the U.S., we're encouraged that 2014 LUMIGAN formulary coverage in Part D and in commercial plans will be broadly similar to the situation in 2013. And now that we have converted all of the prescriptions over to the improved LUMIGAN 0.01% product, that we can concentrate all our efforts onto growing the brand again.

Regarding the world ophthalmic market per IMS for Q2, IMS shows first half of the year growth of the market at a robust 12%, boosted by 28% growth in retinal therapeutics and Allergan growing end market at 11%. For glaucoma, IMS reports world market growth at only 3% for the first half, given the U.S. situation, with Allergan worldwide growth at a healthy 10%.

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