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Allergan Inc. Q1 2009 Earnings Call Transcript

May 1, 2009 6:01 PM ET by: SA Transcripts

Allergan Inc. (NYSE:AGN)

Q1 2009 Earnings Call

May 1, 2009; 11:00 am ET

Executives

David Pyott - Chairman & Chief Executive Officer

Jeff Edwards - Executive Vice President & Chief Financial Officer

Dr. Scott Whitcup - Executive Vice President, Research and Development

Jim Barlow - Senior Vice President & Corporate Controller

Jim Hindman - Senior Vice President, Treasury Risk & Investor Relations

Analysts

Marc Goodman - UBS

Steve Willoughby - Cleveland Research

Peter Bye - Jefferies & Company

Amit Hazan - Oppenheimer

David Buck - Buckingham Research

Greg Gilbert - Bank of America/Merrill Lynch

Gary Nachman - Leerink Swann

Ronny Gal - Bernstein

Larry Biegelsen - Wachovia

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Ken Cacciatore - Cowen and Co.

John Boris - Citi

Operator

Hello, and welcome to the Allergan first quarter 2009 earnings call. Following today's presentation, there will be a formal question-and-answer session. Today's conference call is scheduled to conclude at 9:00 am Pacific Time.

To ensure that we are able to accommodate questions from as many participants as possible, we ask that each of you limit to a maximum of two questions. (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.

Jim Hindman

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Thank you, Pat. 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 and Jim Barlow, Senior Vice President and Corporate Controller.

Before we move ahead, I would like to remind you that certain statements that we will make in this presentation are forward-looking statement. 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 forwardlooking 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 first quarter 2009 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 this 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 this information on our website at <u>www.allergan.com</u>.

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

David Pyott

Thank you, Jim. Good morning ladies and gentlemen. Overall sales in the first quarter decreased 6.3% in dollars, being affected by the strength of the US dollar versus other currencies around the world, dragging down sales by 590 basis points and inline with the full cost we've given at the beginning of this year, our foreign exchange impact being in the range of 4% to 8%.

On a local currency basis, sales decreased by 0.4% given the impact of the recession, particularly on our elective cash pay businesses. We were however pleased with our product sales at \$995 million where at the top end of the guidance we've provided for Q1, which we've been given as a range of \$960 million to \$1 billion. Furthermore, also based on feedback from many customers, it is clear that Botox has been the most resilient part of all of our cash pay businesses.

Regarding earnings, we generated non-GAAP diluted earnings per share of \$0.55, which was 3.8% over the comparable number in Q1 of 2008 and comfortably over the guidance provided at the start of the year, as we applied great attention to management of our costs and focused our spending on high return areas of expenditure.

Non-GAAP R&D expenditure, as a percentage of sales was only 16.3% and is expected to be higher over the course of the year as we startup new projects. We were also able to increase R&D efficiency, negotiate to lower contract prices from CROs and benefited from currency regarding overseas R&D expenditure.

Since the beginning of the year, our ability to forecast trends across the world has improved considerably. Nevertheless, many uncertainties remain, for which reason we have not amended any of our full year guidance regarding sales or earnings.



The year holds many promising catalysts for performance, as we have potential product approvals in the United States alone for Botox, for post-stroke, upper limb spasticity, Lumigan are up 0.01%, Posurdex, ACULAR X, Juvéderm, lidocaine, and shaped gel Style 410 Breast Implant. Additionally, regarding the treatment of chronic migraine, we're interacting with the FDA and hope to file shortly thereafter. Furthermore, we expect the approval of Lumigan in Japan.

Regarding Botox and the approval of Dysport for both cervical dystonia and glabellar lines, we commented yesterday that the FDA has requested that Allergan considers certain class labeling, that we assume is found in the Dysport package insert, including a REMS program and of course we have not yet seen the Dysport label.

We are pleased that the FDA has emphasized that the dosing units are different between the products and the clinical doses expressed in units are not interchangeable from one product to another. Commercially, we believe that education, about non-interchangeability of botulinum toxin products will cause physicians to carefully consider the adoption of this port, when they have the practical experience, our predictable outcomes with Botox, a highly established brand name.

With the completion of the FDA's safety review of Botox and clarity on what the FDA would like in updated labeling and inner REMS, we hope that we'll be able to obtain a timely action on our application for approval of post-stroke, upper limb spasticity in adults, which was granted priority review with a PDUFA date in Q2.

Commenting the performance of our individual businesses, I'll start with Botox. Where we were pleased with the resiliency of sales and believe that the drivers of growth are multi-factorial, high patient satisfaction with the products performance based on 20 years of use, the quality of the Botox brand and the price points relative to other higher priced aesthetic treatments.

Sales declined 5.8% in US dollars, but it touched a growth of 0.7% in local currency. Based on our analysis of worldwide competition, it would seem that the market in Q4 2008 declined at about 2% at constant currency and that we gained a little share in the top 10 global market. For the full year 2008, we estimate that Botox enjoyed 83% market share facing five other products. In Europe, we estimate that we're maintaining market share, even as Merck has entered markets around the region with Zemen and the competitive sets went from two to three players. In the United States and Canada, we have drawn out detailed plans to execute against the arrival of competition both in the therapeutic and aesthetic arenas.

Regarding future drivers of growth, we are pleased that Botox Vista, which is the name for Botox Cosmetic has been launched in Japan and Botox, will grow better lines in China. In Japan we also secured approval for Botox for juvenile cerebral palsy.

Moving onto eye care pharmaceuticals, sales declined in U.S. dollars by 3.8% versus Q1 of 2008, growing 2.3% in local currencies, this contrast with Allergan's end market growth reported by IMS Global for Q4 of 10% in the market growing at 6%. Most of the reason for this variance in growth rates lies in the U.S. business. Although, a year ago at the end of March 2008 inventories were at the lower end of our target range of wholesale inventory, they were still higher than the situation at the end of March, 2009.

In terms of end-market demand in Q1 of the United States, Verispan shows acquisition dollar growth at 14.3%, and an overall market growing at 9.3% with Allergan outpacing all the major competitors in the overall market as well as in the Ophthalmology Channel. In Q1, Allergan enjoyed a record value market share of 30.8% in the overall market and 35.2% in the Ophthalmology Channel.

Offsetting this strong U.S. pharmaceutical performance was the market for OTC artificial tears, which has slowed down considerably as it is subject to outer pocket spending decisions. The market in the first quarter as reported by IRI grew only 0.4% in dollars and Allergan's tier line declined 13% as we consciously moved resources and detailing efforts from REFRESH and our other OTC brand to RESTASIS, which offers a much greater potential in the short term.

Putting the two pieces of the business together, eye pharmaceuticals no OTC tears, together Allergan end market U.S. demand, as measured by Verispan and IRI grew almost 13% versus Q1 of 2008. Regarding RESTASIS performance, we are pleased that Verispan reports growth in acquisition dollars, 15.6% versus Q1 of 2008.

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