Company Name: Mylan NV
Company Ticker: MYL US
Date: 2015-08-06
Event Description: Q2 2015 Earnings Call

Market Cap: 27,232.11
Current PX: 55.40
YTD Change($): -.97
YTD Change(%): -1.721

Bloomberg Estimates - EPS
Current Quarter: 1.282
Current Year: 4.137
Bloomberg Estimates - Sales
Current Quarter: 2784.400
Current Year: 9737.200

Q2 2015 Earnings Call

Company Participants

- Kris King
- Heather M. Bresch
- Rajiv Malik
- John D. Sheehan

Other Participants

- Sumant S. Kulkarni
- Gregg Gilbert
- Ronny Gal
- Elliot Wilbur
- Umer Raffat
- Andrew J. Finkelstein
- Jami Rubin
- Marc Goodman
- Douglas D. Tsao
- Louise Chen
- Jason M. Gerberry
- Emil Chen

MANAGEMENT DISCUSSION SECTION

Operator

Good day, ladies and gentlemen. Thank you for standing by. And welcome to the Mylan Second Quarter 2015 Earnings Call. At this time, all lines are in a listen-only mode. Later, we will conduct a question-and-answer session and instructions will follow at that time. [Operator Instructions] As a reminder, this call is being recorded.

I'd now like to turn the call to our host, Ms. Kris King. Ma'am, you may begin.

Kris King

Thank you, Eric. Good morning, everyone. Welcome to Mylan's conference call discussing our second quarter 2015 earnings and our offers to acquire Perrigo Company. Joining me for today's call are: Mylan's Chief Executive Officer, Heather Bresch; President, Rajiv Malik; Executive Vice President and Chief Financial Officer, John Sheehan.

During today's call, we will be making forward-looking statements pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the proposed acquisition which I will refer to as the Perrigo proposal of Perrigo Company, which I will refer to as Perrigo by Mylan, Mylan's acquisition, which I will refer to as the EPD Transaction of Mylan and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business, which I will refer to as the EPD Business; the benefits and synergies of the Perrigo proposal or EPD Transaction; future opportunities for Mylan, Perrigo, or the combined company and products; and any other statements regarding Mylan's, Perrigo's, or the

EXHIBIT
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combined company's future operations, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competition, and other expectations and targets for future periods.

Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: uncertainties related to the Perrigo Proposal, and the consummation thereof; the ability to meet expectations regarding the accounting and tax treatments of a transaction relating to the Perrigo Proposal and the EPD Transaction; changes in relevant tax and other laws; the integration of Perrigo and the EPD Business being more difficult, time-consuming or costlier than expected, operating cost, consumer loss and business disruption being greater than expected following the Perrigo Proposal and the EPD Transaction; the impact of competition, situations where we manufacture, market and/or sell products, notwithstanding unresolved allegations of patent infringement; any regulatory, legal or other impediments to our ability to bring new products to market; and those set forth under forward-looking statements in today's earnings release; and the risk factors set forth in Mylan N.V.'s Form 10-Q for the period ended March 31, 2015, as well as our other filings with the SEC.

These risks, as well as other risks associated with Mylan, Perrigo, and the combined company are also more fully discussed in the Registration Statement on Form S-4 and includes an offer to exchange/prospectus that Mylan filed with the SEC on May 5, as amended on June 9 and July 16, 2015, of which has not yet been declared effective, and the definitive Proxy Statement on Schedule 14A that Mylan filed with the SEC on July 28, 2015, and began mailing to its shareholders on or about July 31, 2015, in connection with the Perrigo Proposal.

Except as required by applicable law, we undertake no obligation to update any statements made today, whether as a result of new information, future events or otherwise. Today's call should be listened to and considered in its entirety and understood to speak only as of today's date.

In addition, we will be referring to certain actual and projected financial metrics of Mylan on an adjusted basis, which are non-GAAP financial measures. These non-GAAP measures are presented in order to supplement your understanding and assessment of our financial performance.

Please refer to today's earnings release which is available on our website as they contain detailed reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measure.

I would also like to point out that Mylan's offer for Perrigo is governed by the Irish Takeover Rules. Under the Irish Takeover Rules, Mylan management is prohibited from discussing any material or new information or significant new opinion which has not been publicly announced. Any person interested in shares in Mylan or Perrigo is encouraged to consult Heather and her professional advisor.

Before I turn the call over to Heather, let me also remind you that the material in the call, with the exception of the participant questions, is the property of Mylan and cannot be recorded or rebroadcast without Mylan's expressed written permission. An archived copy of today's call will be available on our website and will remain available for a limited time.

With that, I'll now turn the call over to Heather.

Heather M. Bresch

Thanks, Kris, and good morning, everyone. Mylan had a great second quarter. Top-line sales totaled nearly $2.4 billion, a constant currency increase of 36% compared to the same period last year. This result represents double-digit growth in our legacy business, as well as enhanced double-digit growth with the addition of the EPD Business. I'll note as well that EpiPen continues to post strong results and maintains an 86% share in a multi-epinephrine market and has delivered double-digit growth year-to-date.

On the bottom line, our adjusted diluted EPS came in at $0.91 for the second quarter, up 32% compared to the same period last year and exceeding our expectations. Again, this result represents double-digit growth in our legacy business

as well as enhanced double-digit growth with the addition of the EPD Business.

Our exceptional performance this quarter continues to underscore the underlying strength and diversity of our base business and our relentless focus on execution, even in the face of ongoing regulatory delays, as well as external activity.

Given the strength and momentum in our business, we are raising our 2015 adjusted diluted EPS guidance range to $4.15 to $4.35, an increase of 19% or 23% on a constant currency basis compared to our performance in 2014.

Our guidance now excludes any contribution from generic Copaxone and includes potential generic competition on EpiPen in the second half of the year. In addition, we see the potential for opportunities on the horizon, and we'll provide any updates as appropriate.

I'd like to take this opportunity to say thank you, more than ever, to all of our employees around the world for staying focused on executing and delivering great performance.

With respect to the external activity, you saw last week that Teva announced an agreement to acquire Allergan's generic drug unit and its withdrawal of its unsolicited expression of interest to acquire Mylan. We very much believe that this is the right outcome for both companies and their shareholders. We believe the transaction further differentiates Mylan as the industry's only predominantly global generics player and will enhance our ability to gain additional share in markets around the world.

We believe our offer to acquire Perrigo represents the right next step for Mylan, because it further diversifies our business that creates a paradigm shift in how we'll do business, and establishes a unique platform with the size and scale that allows us to continue being a leading consolidator in our industry.

Together, Mylan and Perrigo will create a one-of-a-kind global healthcare company with complementary businesses, unmatched scale in our operations, one of the industry's broadest and most diversified portfolio, and immense reach across distribution channels around the world, allowing us to mean the most to our customers and consumers.

We very much look forward to our shareholder vote on August 28; and as a reminder, we intend to take our offer to acquire Perrigo directly to its shareholders. We are confident that they, too, see the compelling value in our offer and this combination will support the transaction.

In addition, as an update to yesterday's press release, we have now executed an amendment with all of our bridge credit facility lenders that gives us full discretion to lower the acceptance condition from 80% to greater than 50%, if we so choose.

With that, I'd like to turn the call over to Rajiv.

Rajiv Malik

Thank you, Heather. And good morning, everyone. As Heather mentioned, all of our regions and businesses contributed to the outstanding performance we delivered during the second quarter. With each of the regions, delivery is very impressive double-digit growth.

Our global generics segment generated third-party net sales of just over $2 billion and increased year-over-year, up 43% on constant-currency basis. In North America, sales totaled $937 million, up 47% year-over-year. Our legacy business grew by 22%. This impressive growth is attributed to continued strong performance of sales from new products at less stable pricing and higher volumes on existing products.

In Europe, sales totaled $571 million, a 62% increase as compared to the second quarter of 2014. This increase was largely attributed to contribution of our acquired EPD Business as our legacy business was essentially flat quarter-over-quarter, whereas we benefited from sales of new products or higher volumes on existing ones, primarily in Italy and France, further enhancing our market share.

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In our rest of the world region, sales totaled $547 million, a year-over-year increase of 51%. Sales from our legacy business grew 23% on a constant currency basis, driven by new product launches in Australia and Japan and higher volumes from our India operations, especially our anti-retroviral franchise.

As for our Specialty segment, revenues totaled $302 million, an increase of 5% compared to the last year's second quarter based on double-digit volume growth. We have made very good progress in integrating the EPD Business across the various regions. Overall, we have not only successfully arrested the decline of the business, but we also saw constant currency low-single-digit growth in revenues across the geographies, and the improvement in this business has come quicker than expected.

We expect this performance to remain stable this year on a pro forma year-over-year basis. Also, we continue to analyze on a country-by-country basis and explore how we can tap portfolio opportunities for additional value creations that build on our respective sales such as cross-leveraging channels that were not available to either organization on a stand-alone basis.

We look forward to executing on these value-creating opportunities to realize the full potential of this combined asset. We also continue to make progress executing against our key growth drivers and positioning Mylan for continued organic growth well into the future.

Starting with the respiratory, we remain on track to file our ANDA for generic Advair by this year end. In June, we launched the first and only bioequivalent alternative to GSK's Seretide under the brand name Sirdupla in UK. We only saw a couple of weeks' impact of this product in the second quarter. However, we were very pleased with this launch performance and the boost it gave our business in the UK. We also recently launched the product in Germany. It's worth noting that we leveraged our EPD sales force of this launch, another example of how we are creating value through the combination.

We continue to further build out our global respiratory pipeline. For instance, we announced an agreement with Pulmatrix for a clinical stage bronchodilator therapy being studied for COPD. It's the first small molecule formulation from the Pulmatrix, novel inhaled dry powder technology.

Regarding our Copaxone program, we were very pleased to see FDA's response to the final Teva CP, where they clearly laid out the general criteria for sameness of a generic Copaxone such as same fundamental chemical reaction scheme, same physical chemical properties and composition, same structural signature for polymerization and de-polymerization and the same response in a biological assay.

We are confident that we are fundamentally on the same page regarding the signs and criteria to demonstrate sameness with FDA. Furthermore, we have just recently received some additional clarifying questions from agency, which give us even more confidence that any residual concern of sameness are now behind us.

Turning to biologics, following our launch in India, we have now launched our trastuzumab products in several countries in Africa and are filing spending in additional markets across Asia, MENA and Latin America.

In addition, we have also begun filing marketing authorizations for insulin glargine in Africa, Asia, Latin America and MENA. The two global clinical trials for generic insulin glargine have made significant progress with recruitment for both Type 1 and Type 2 diabetes studies now complete. Our insulin glargine commercial manufacturing facility is now fully commissioned and we expect will be fully qualified by the end of this quarter.

We continue to progress the [indiscernible] (14:11). Our trastuzumab and [indiscernible] (14:15) Phase III clinical trials are progressing very well towards completion. We are continuing our Phase III study with adalimumab and we have also initiated a Phase I PK comparability study for our bevacizumab program.

With regards to our infectious disease growth driver, we launched our branded Sovaldi and generic MyHep, sofosbuvir product for treatment of hep C in India. Additionally, we are making regulatory submission with the multiple emerging markets. We are also developing other combination products for treatments of hep C.

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As for the latest statistics, more than 150 million people are affected with hep C in emerging markets and Mylan is committed to provide access to the hep C drugs to the patients across these markets in partnership with Gilead. Our ARV products now have approximately half of all people being treated for HIV in the developing world, not just in sub-Saharan Africa, but also in markets such as Brazil and Thailand. Just last month, the United Nations announced that World Health met the target for reaching 15 million people with ARV treatment by 2015, and that the guidelines will now call for reaching 30 million people in the coming years. Mylan is committed to doing our part to reach that goal, which means continued, reliable and sustainable growth in this franchise.

Looking ahead to the rest of the year, we are on track to close our acquisition of Famy Care by end of the third quarter, which will further enhance our presence in women's health care. In addition to the strength of this business in the U.S. and other developed markets, we see significant opportunities to leverage this business through the Mylan's platform in emerging markets to enhance success with the contraceptives for more women.

We are excited about momentum we have going into the second half of the year. For example, we launched our generic Nexium in the U.S. earlier this week and believe that we are only the second generic to launch to-date. We believe this product has the potential to be a great opportunity for us.

I would also like to mention that we are seeing fairly good improvement from FDA in terms of dates of approvals and the level of transparency in communications from the agency. I believe this bodes well for the additional approvals we expect and our overall optimism in the second half of the year.

In closing, I would like to also give my sincere thanks to our employees, who have demonstrated unwavering focus on our business and our mission every day.

With that, I'll turn the call over to John.

John D. Sheehan

Thanks, Rajiv. Good morning, everyone. As Rajiv mentioned, our total revenues for the second quarter of 2015 were $2.4 billion, an increase of 29% or 36% on a constant currency basis from the prior-year period. Revenues were unfavorably impacted by foreign currency exchange rates by approximately $127 million in the current quarter, primarily reflecting the strength of the U.S. dollar as compared to the euro, yen, rupee, and Australian dollar.

Additionally, third-party net sales were positively impacted by a full quarter of results from the acquired EPD Business of approximately $402 million, of which $250 million was from Europe and $110 million within our rest of world, with the remainder coming from EPD Canada. We will continue to provide EPD-specific quarterly revenue for 2015. However, by the beginning of 2016, the EPD and Mylan commercial businesses will be operating as one, and as such, separate revenue information will no longer be available.

For the six months ended June 30, 2015, total revenues were $4.2 billion, an increase of 26% on a constant currency basis from the prior-year period, which includes revenues from the EPD Business of approximately $550 million. Revenues for the first six months of 2015 were unfavorably impacted by current currency translation by approximately $221 million.

As a result of the impact of the strong U.S. dollar on the translation of our non-U.S. dollar functional currency operations into U.S. dollars, we now expect full-year foreign currency translation to negatively impact our reported U.S. dollar revenues by approximately $200 million versus the foreign exchange rates used for providing our 2015 guidance.

As such, without further weakening of the U.S. dollar relative to the principal currencies in which our businesses operate, we expect that our actual reported 2015 revenues will be at the lower end of our 2015 guidance range.

Adjusted gross margin for the second quarter and the first six months of 2015 was a very strong 54%, up approximately 400 basis points for the quarter and 325 basis points in the year-to-date period. Our strong margins are primarily the result of the positive contribution from the EPD Business, new product introductions and increased margins on existing

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