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Subject Company:

Meda AB

## **FORWARD-LOOKING STATEMENTS**

This communication contains forward-looking statements. Such forward-looking statements may include, without limitation, statements about the proposed acquisition of Meda AB (publ.) ( Meda ) by Mylan (the Meda Transaction ), Mylan s related public offer to the shareholders of Meda to acquire all of the outstanding shares of Meda (the Offer ), Mylan s acquisition (the EPD Transaction ) of Mylan Inc. and Abbott Laboratories non-U.S. developed markets specialty and branded generics business (the EPD Business ), the benefits and synergies of the EPD Transaction and the Meda Transaction, future opportunities for Mylan, Meda, or the combined company and products and any other statements regarding Mylan s, Meda s or the 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. These may often be identified by the use of words such as will , may , could , should , would , project , believe , anticipate , expect , plan , estimate , forecast , potential , intend , continue , these words or comparable words. 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 Meda Transaction, including as to the timing of the Meda Transaction, uncertainties as to whether Mylan will be able to complete the Meda Transaction, the possibility that competing offers will be made, the possibility that certain conditions to the completion of the Offer will not be satisfied, and the possibility that Mylan will be unable to obtain regulatory approvals for the Meda Transaction or be required, as a condition to obtaining regulatory approvals, to accept conditions that could reduce the anticipated benefits of the Meda Transaction; the ability to meet expectations regarding the accounting and tax treatments of the EPD Transaction and the Meda Transaction; changes in relevant tax and other laws, including but not limited to changes in the U.S. tax code and healthcare and pharmaceutical laws and regulations in the U.S. and abroad; the integration of the EPD Business and Meda being more difficult, time-consuming, or costly than expected; operating costs, customer loss, and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients, or suppliers) being greater than expected following the EPD Transaction and the Meda Transaction; the retention of certain key employees of the EPD Business and Meda being difficult; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with the EPD Transaction and the Meda Transaction within the expected time-frames or at all and to successfully integrate the EPD Business and Meda; expected or targeted future financial and operating performance and results; the capacity to bring new products to market, including but not limited to where Mylan uses its business judgment and decides to manufacture, market, and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an at-risk launch ); any regulatory, legal, or other impediments to Mylan s ability to bring new products to market; success of clinical trials and Mylan s ability to execute on new product opportunities; any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, the EpiPen® Auto-Injector to meet anticipated demand; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on financial condition, results of operations, and/or cash flows; the ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan, Meda or the

combined company; the inherent challenges, risks, and costs in identifying, acquiring, and integrating complementary or strategic acquisitions of other companies,

products or assets and in achieving anticipated synergies; uncertainties and matters beyond the control of management; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with accounting principles generally accepted in the United States ( U.S. GAAP ) and related standards or on an adjusted basis. For more detailed information on the risks and uncertainties associated with Mylan s business activities, see the risks described in Mylan s Annual Report on Form 10-K for the year ended December 31, 2015, as amended, its Quarterly Report on Form 10-Q for the three months ended March 31, 2016 and its other filings with the Securities and Exchange Commission ( SEC ). These risks and uncertainties also include those risks and uncertainties that are discussed in the offer document that has been filed with the Swedish Financial Supervisory Authority ( SFSA ) and will be published by Mylan upon approval by the SFSA (the Offer Document ), the Registration Statement on Form S-4 filed with the SEC on April 11, 2016 (as amended from time to time, the Registration Statement ) and the EU Prospectus that has been filed with the Netherlands Authority for the Financial Markets ( AFM ) and will be published by Mylan upon approval by the AFM (the EU Prospectus ). You can access Mylan s filings with the SEC through the SEC website at [www.sec.gov](http://www.sec.gov), and Mylan strongly encourages you to do so. Mylan undertakes no obligation to update any statements herein for revisions or changes after the date of this communication.

### **ADDITIONAL INFORMATION**

In connection with the Offer, the Offer Document has been filed with the SFSA and will be published by Mylan upon approval by the SFSA. In addition, Mylan has filed certain materials with the SEC, including, among other materials, the Registration Statement. The EU Prospectus has been filed with the AFM and will be published by Mylan upon approval by the AFM. This communication is not intended to be, and is not, a substitute for such documents or for any other document that Mylan may file with the SFSA, the SEC, the AFM or any other competent EU authority in connection with the Offer. This communication contains advertising materials (*reclame-uitingen*) in connection with the Offer as referred to in Section 5:20 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*). INVESTORS AND SECURITYHOLDERS OF MEDA ARE URGED TO READ ANY DOCUMENTS FILED WITH THE SFSA, THE SEC AND THE AFM OR ANY OTHER COMPETENT EU AUTHORITY CAREFULLY AND IN THEIR ENTIRETY BEFORE MAKING AN INVESTMENT DECISION BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, MEDA AND THE OFFER. Such documents are or upon publication will be available free of charge through the website maintained by the SEC at [www.sec.gov](http://www.sec.gov), on Mylan s website at [medatransaction.mylan.com](http://medatransaction.mylan.com) or, to the extent filed with the AFM, through the website maintained by the AFM at [www.afm.nl](http://www.afm.nl), or by directing a request to Mylan at +1 724-514-1813 or [investor.relations@mylan.com](mailto:investor.relations@mylan.com). Any materials filed by Mylan with the SFSA, the SEC, the AFM or any other competent EU authority that are required to be mailed to Meda shareholders will also be mailed to such shareholders.

### **FURTHER INFORMATION**

The distribution of this communication and any related Offer documentation in certain jurisdictions may be restricted or affected by the laws of such jurisdictions. Accordingly, copies of this communication are not being, and must not be, mailed or otherwise forwarded, distributed or sent in, into or from any such jurisdiction. Therefore, persons who receive this communication (including, without limitation, nominees, trustees and custodians) and are subject to the laws of any such jurisdiction will need to inform themselves about, and observe, any applicable restrictions or requirements. Any failure to do so may constitute a

violation of the securities laws of any such jurisdiction. To the fullest extent permitted by applicable law, Mylan disclaims any responsibility or liability for the violations of any such restrictions by any person.

The acceptance period for the Offer has not commenced.

### **NON-GAAP FINANCIAL MEASURES**

This communication contains non-GAAP financial measures. Non-GAAP financial measures should be considered only as a supplement to, and not as a substitute for or as a superior measure to, financial measures prepared in accordance with U.S. GAAP.

### **TRADEMARK DISCLAIMER**

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## **PARTICIPANTS**

### **Corporate Participants**

**Kris King** Vice President-Global Investor Relations, Mylan N.V.

**Heather M. Bresch** Chief Executive Officer & Executive Director, Mylan N.V.

**Rajiv Malik** President & Executive Director, Mylan N.V.

**Anthony Mauro** Chief Commercial Officer, Mylan N.V.

**Paul Campbell** Chief Accounting Officer, Mylan N.V.

**Colleen Ostrowski** Treasurer, Mylan N.V.

### **Other Participants**

**Sumant S. Kulkarni** Analyst, Bank of America Merrill Lynch

**Jami Rubin** Analyst, Goldman Sachs & Co.

**Elliot Wilbur** Analyst, Raymond James & Associates, Inc.

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## **MANAGEMENT DISCUSSION SECTION**

Operator: Good day, ladies and gentlemen, and welcome to the Mylan N.V. First Quarter 2016 Financial Results Conference Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer

session and instructions will be given at that time. [Operator Instructions] As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Kris King, Customer Relations. Please go ahead.

**Kris King, Vice President-Global Investor Relations**

Thank you, Ashley. Good morning, everyone. Welcome to Mylan's conference call discussing our first quarter 2016 earnings, 2016 guidance, and the proposed acquisition of Meda AB, which I will refer to as the Meda transaction. Joining me for today's call are Mylan's Chief Executive Officer, Heather Bresch; President, Rajiv Malik; Chief Commercial Officer, Tony Mauro; Paul Campbell, Chief Accounting Officer; and Colleen Ostrowski, Treasurer.

During today's call, we will be making forward-looking statements. Such forward-looking statements may include, without limitation, statements about the Meda transaction; Mylan's related public offer to the shareholders of Meda to acquire all of the outstanding shares of Meda, which I'll refer to as the offer; Mylan's acquisition, which I will refer to as the EPD transaction of Mylan Inc.; and Abbott Laboratories' non-U.S. developed market specialty and branded generics business, which I will refer to as the EPD business; the benefits and synergies of the Meda transaction and the EPD transaction; future opportunities for Mylan, Meda or the combined company and products; and any other statements regarding Mylan's, Meda's, or the 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 uncertainty, 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 Meda transaction and offer, and the consummation thereof; the ability to meet expectations regarding the accounting and tax treatments of the EPD transaction and the Meda transaction; changes in relevant tax and other laws; the integration of Meda and the EPD business being more difficult, time-consuming, or costly than expected; operating costs, customer loss, and business disruption being greater than expected following the Meda transaction and the EPD transaction; the impact of competition, on 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; any changes in or difficulties with our inventory of or our ability to manufacture and distribute the EpiPen Auto-Injector® to meet anticipated demand; those set forth under Forward-Looking Statements in today's earnings release; and the risk factors set forth in Mylan N.V.'s annual report on Form 10-K for the year ended December 31, 2015 as amended; and our filings with the SEC.

These risks and uncertainties also include those risks and uncertainties that are discussed in the offer document that has been filed with the Swedish Financial Supervisory Authority, and will be published by Mylan upon approval by the Swedish Financial Supervisory Authority; the Registration Statement on Form S-4 filed with the SEC on April 11, 2016 and as amended from time to time, and the EU prospectus that has been filed with the Netherlands Authority for the Financial Markets and will be published by Mylan upon approval by the Netherlands Authority for the Financial Markets. 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 and should not be considered a substitute for or superior to financial measures calculated in accordance with GAAP. Please refer to today's earnings release which will be available on our website as it contains detailed reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measure.

Let me also remind you that the information discussed in the call with the exception of the participant questions is the property of Mylan and cannot be recorded or rebroadcast without Mylan's express 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 turn the call over to Heather.

**Heather M. Bresch, Chief Executive Officer & Executive Director**

Thanks, Kris, and good morning, everyone. Mylan's results during the first quarter marked a great start to what we believe will be another year of double digit growth. However, before we walk through our results, I'd like to make a few comments regarding the macro environment surrounding our industry.

First, I strongly believe that the rebasing of our sector was not only necessary, but helped draw distinction and differentiation amongst our peers. For far too long, one brush has been used across our industry and business models when, in fact, the business models have been very diverse. The

investment community has taken a flawed approach of one size fits all when it comes to the generics industry. The echo chamber around too good to be true results, stock prices and multiples has finally been silenced enough to allow investors to refocus on fundamentals and investment thesis.

While not always popular, Mylan has always been consistent. We have been steadfast that a great company cannot be built quarter by quarter, and that well-run companies return great results for shareholders and other stakeholders.

We laid out a vision almost a decade ago that our growth would come from creating scale in manufacturing and expanding the breadth of our portfolio to better serve patients around the world. And every acquisition we've done has complemented this strategy.

Our results have demonstrated that our continued organic investment coupled with inorganic opportunities have delivered short-, middle- and long-term growth. We appreciate that when applying a broad brush, there is investor concern of little to no growth in the generics industry.

With that said, our strategy has resulted in Mylan delivering consistent double-digit earnings growth. Most importantly, it is on the back of our last decade of hard work to vertically integrate our products, build out our manufacturing capabilities, invest in one of the broadest portfolios of complex molecules, all while maximizing our geographic footprint and commercial excellence in all distribution channels, that we have managed to differentiate ourselves from the pack and position ourselves for continued growth well into the future as the true leader in our space today.

In other words, we have not built a company on any one product or one practice. Instead, we have focused on diversifying and building one of the industry's most efficient and effective engines, one that's just getting started.

The reality of healthcare is that access to medicine is needed now more than ever around the globe, from our aging population to living longer healthier lives, making access to fundamental pillar for future growth. This is precisely why Meda is the right next strategic addition to our platform. Geographically, we will gain a more balanced and expanded presence and we will become a leader in the global respiratory allergy market and achieve scale in many other therapeutic areas, including a billion-dollar OTC business.

With that, I'd now like to turn to our performance during the quarter. On the top line, we delivered total revenues of \$2.2 billion, a year-over-year increase of 19% on constant currency basis. That was fueled by double digit revenue growth in our Generics and Specialty segments, including positive growth in all of our regions. Total revenues were unfavorably impacted by foreign currency translation by approximately \$33 million compared to last year's first quarter. On the bottom line, we delivered adjusted net earnings of \$386 million or \$0.76 per adjusted diluted share, a year-over-year increase of 9%. This strong quarter was achieved despite delays in certain product approvals as we continue to leverage our unique global operating platform and diverse mix of assets to take advantage of opportunities in markets around the world. Given our strong first quarter performance and strong momentum, we remain committed to our 2016 guidance metrics, including our adjusted diluted EPS guidance range of \$4.85 to \$5.15.

Turning to Meda for a moment; many of you know that the company reported first quarter results this morning. They were very much in line with our modeled expectations for the business as its dynamics were well-known and understood by us. Notably, Meda reported strong performance from top products such as Dymista® and Betadine®, as well as nice turnaround performance in Italy and solid execution in emerging markets. We continue to believe that Meda is a scarce, high-quality asset and we remain fully committed to look to and look forward to completing the deal.



Further, there is no change whatsoever to any of our expectations for the combined business. As stated previously, we expect the deal to be immediately accretive to Mylan's adjusted earnings with accretion increasing significantly after the first full year as synergies are realized. All of our public and private filings with respect to Meda deal remain on track, and we expect to publish the offer document later this month.

In addition, we expect to obtain all relevant clearances prior to the end of the acceptance period which would keep us on track to close the transaction by the end of the third quarter. We also look forward to hosting our next Investor Day event after the close.

I'd like to now take the opportunity on behalf of Mylan's board and entire leadership team to thank all of our employees around the world for their outstanding teamwork and execution during the quarter and for their continued commitment to our cause. I also note that we continue to attract exceptional leaders from outside as well, and today we announced that Ken Parks will join our team as Chief Financial Officer effective June 6.

Ken's deep functional expertise, strong leadership ability, experience leading organizations through change including overseeing significant acquisitions and expansion into emerging markets, and his impressive track record operating in complex, global cultures and manufacturing environments will make him an outstanding addition not only to our very strong global finance team but to Mylan overall.

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

**Rajiv Malik, President & Executive Director**

Thank you, Heather, and good morning, everyone. As Heather indicated, our business continues to perform strongly across all areas reflecting the powerful global manufacturing, R&D and commercial infrastructure we have in place and the opportunities we are seeing to leverage our expansive product portfolio across our geographies and channels as one Mylan.

In our North America Generics business, sales totaled \$920 million, a year-over-year increase of 8%. Growth came primarily from sales of new products and to a lesser extent from incremental sales of established products while the pricing environment was consistent with our expectations and guidance to you.

In Europe, sales totaled \$588 million, a strong year-over-year constant currency increase of 47%. This result was mainly due to incremental sales from established products and, to a lesser extent, sales from new products.

In Rest of the World, sales totaled \$421 million, a year-over-year constant currency increase of 15% driven by incremental sales from established products, new product launches and volume growth in Japan and Australia. Increases were partially offset by lower pricing throughout the region and a decrease in sales volume from our operations in India on account of some delays in HIV tenders. Specialty segment revenues totaled \$248 million, a year-over-year increase of 17% that resulted from higher sales of EpiPen® and Perforomist Inhalation Solution®.

We were happy to see that in the most recent quarter, each of our commercial regions increased their market share in terms of volume as they continue to outpace market growth. This shows again how the vertically integrated diversified platform, broad product portfolio and commercial skill across our regions is truly differentiating Mylan from the competition.

We also continue to make good progress on leveraging the opportunities from established products business acquired from Abbott, as well as women's healthcare businesses acquired from Famy Care. And we are now preparing for the

expected completion of the proposed Meda acquisition in the third quarter.

I would like to note that similar to all of our past transactions, we will apply Mylan's distinct approach to our integration of Meda. We believe that this approach, which is built on a foundation of mutual respect for people, the markets we operate in, and the stakeholders we serve, is part of what makes Mylan so special and what has made our transactions so successful. By doing things this way, we'll once again quickly and efficiently integrate the Meda platform to our One Mylan approach.

With the addition of Meda to all of the other strategic assets we have put in place over the past decade, we believe we now have in place the essential components key to successfully delivering on our mission and strategy and our goal of continuing to create exceptional value for shareholders and stakeholders while we continue to look for opportunities to further enhance our business to certain geographies or product areas such as dermatology. The foundation we have in place is second to none and we are very excited to demonstrate what we can do with this exceptional platform.

Finally, we continue to execute on our strategic growth drivers and made good progress against many of these during the quarter. Let me highlight just a few of these.

Turning to our biosimilars portfolio which is one of the industry's most robust and diverse. With our Biocon partnership and Momenta collaboration announced in January, we have a combined portfolio of 15 biosimilar and insulin analog generic products in development with a current total brand market value of more than \$75 billion in worldwide sales, positioning us to be a potential global leader in the biosimilar space. We continue to operationalize our partnership with Momenta and have commenced scientific collaboration and kicked off the joint governance of these programs. These interactions have further reinforced the excellent cultural fit of this partnership.

We also continue to successfully execute on our various programs with Biocon. The pegfilgrastim product met its primary endpoint in global Phase 3 clinical study. For our insulin glargine product, the 24-week data from the type 1 diabetes clinical study is now available and we met the primary and secondary endpoints whereas the data from the type 2 diabetes clinical study will be available in the near future.

The results for the Heritage clinical study with trastuzumab product are now available and will be presented as a late-breaking abstract in an oral presentation session at ASCO 2016. We look forward to providing you with additional updates as these applications are filed.

In the respiratory space, most notably, we announced during the quarter that our ANDA for our generic Advair Diskus<sup>®</sup> has been accepted by FDA and FDA has provided a GDUFA goal date of March 28, 2017. While we note that there has been one more subsequent filer, our ongoing dialog with the FDA and the progress of our program gives us continued confidence that Mylan will be the first to bring to market an AB-rated substitutable generic form of Advair Diskus<sup>®</sup>. Finally, I also would like to thank our committed and talented global workforce for their significant contributions to our business and mission during the quarter. With that, I will turn the call over to Tony Mauro, our Chief Commercial Officer for some additional perspective on commercial landscape and pricing environment.

**Anthony Mauro, Chief Commercial Officer**

Thank you, Rajiv. As you heard, our commercial platform continued to deliver for us in each of our key regions demonstrated by the continued strength and resilience of the Mylan business around the world, as well as our ability to continue to direct. Because there's been much talk about the pricing environment throughout our industry across both the Generic and Specialty segments, especially here in the U.S., I would like to address this right up front.

As Heather noted, not all generic companies are created equally. For our part, we expect to continue to benefit from the scale and diversity of our business and portfolio, our reach across customer channels and our unmatched operating platform and supply chain infrastructure, which gives us greater scale and control of our cost of goods sold and our time to market. We have created this highly differentiated model through focused execution against our strategic plan over the last 10 years and investment in scale and diversification which will become even more important going forward.

Therefore, I'd like to make clear that consistent with the guidance we laid out for 2016, we continue to see nothing out of the ordinary to change our generic pricing assumptions of low to mid-single digit erosion for the full year. Our performance this quarter, both in the U.S. and globally, was right in line with these expectations. With regard to EpiPen®, we continue to maintain our strong leadership position in the marketplace through the first quarter. We are very pleased with the strong volume growth in this product and see continued growth throughout the year. We also see significant opportunities to continue to expand this market to tap into more than 20 million patients at risk.

Looking ahead, we believe Mylan continues to be uniquely positioned to compete within today's market environment. We have found both our global and domestic customer needs to be closely aligned with what Mylan offers in terms of product breadth and quality and our ability to consistently deliver service and reliability around the world. We also continue to believe in the benefits of our One Mylan approach and have created a unique commercial operating platform to cross sell our portfolio across therapeutic franchises and customer channels.

Thank you, and I will now turn the call back to Heather.

**Heather M. Bresch, Chief Executive Officer & Executive Director**

Thank you, Tony. I'd like to take you through a few additional financial highlights for the quarter before turning to Q&A. Adjusted gross margin for the first quarter of 2016 was 54%, up approximately 100 basis points from the prior-year quarter due to the positive incremental contribution from established products and new product introductions. We expect our full-year adjusted gross margin to be in line with our previously communicated guidance range.

R&D expense on an adjusted basis was approximately 8.6% of total revenues for the first quarter and an increase as a result of incremental expense from our investment in established products as well as continued investment in our respiratory, insulin and biologics program. At the same time, SG&A, also on an adjusted basis, was approximately 23% of total revenues for the quarter. The increase in SG&A from the prior-year period is due primarily to incremental expense from established products in this year's first quarter. We anticipate R&D and SG&A, each on an adjusted basis and as a percentage of total revenues for the full year of 2016, to be within the guidance metrics we communicated in February.

Turning to cash flow and liquidity, adjusted cash provided by operating activities totaled \$202 million for the first quarter. Capital spending was up slightly as compared to the prior year at \$52 million as we continue to invest in our businesses and growth drivers. As of the quarter's end, our debt to adjusted EBITDA leverage ratio during this year was 2.4 times. We have no amounts outstanding on our accounts receivables, securitization and revolving credit facility. And we have full access to the \$1.2 billion of cash on our balance sheet. We continue to have ample borrowing capacity and financial flexibility. And as a reminder, we have fully committed financing to fund the proposed acquisition of Meda.

Subsequent to March 31 of this year, the warrants associated with our cash convertible notes, which matured in September of 2015, were settled, resulting in the issuance of 17 million ordinary shares. The dilutive impact of the warrants is included in our diluted share count for the quarter ended March 31 and was assumed in our guidance.

With that, I'll now turn the call over to the operator to take your questions.

## QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Our first question comes from Sumant Kulkarni of Bank of America. Your line is open.

**<Q Sumant Kulkarni Bank of America Merrill Lynch>**: Good morning. Thanks for taking my questions. First one, actually both for Rajiv. So first, could you say how much of an opportunity still exists in expanding margins within the Mylan base business, given that you've done a notable job there after you acquired Merck KGaA?

And second, you covered dermatology in your remarks. What are some of the specific ways in which the company could become a stronger player in that therapeutic area?

**<A Rajiv Malik Mylan N.V.>**: So, let me start with the first one. I think we have not lost our focus after integrating Merck. And we have not lost our focus on continued ways and means to optimize the parts, leverage our assets in the best possible way and not lose our sight on that cross-margin and the cost of goods line. So we continue to see opportunity as we bring more and more complex products, as we bring more and more strategic product internally to vertically integrate. We see more opportunities.

Now, from on the dermatology, other than having many organic R&D-incubated opportunities which we've already seen coming to life, we continue to look out for enhancing and strengthening this portfolio in a strategic way. So, we're looking for a group of portfolio, product portfolio of families around dermatology to further strengthen this line of the business and are out there to look for more and more opportunities in this space.

**<Q Sumant Kulkarni Bank of America Merrill Lynch>**: Thanks.

Operator: Thank you. Our next question comes from Jami Rubin of Goldman Sachs. Your line is open.

**<Q Jami Rubin Goldman Sachs & Co.>**: Thank you. I have two questions. Heather, for you first on Meda, we all did see the numbers this morning and they did look pretty weak. You did mention that they were in line with your expectations. But I guess if you can just give us a little bit of comfort that we saw Perrigo lower their earnings expectation in part due to Omega. Omega's business is not that much different from Meda. So, why are you so confident that Meda to Mylan is not Omega to Perrigo? If you can give us a little bit more color around your thoughts as to why you can turn that business around.

And then, secondly, back on the U.S. pricing dynamics, why is the environment different from you than it is for some of the niche players such as companies focused mostly on dermatology or narcotics? It seems that that's where the pressure is coming from, but maybe you could comment on that further. Thanks.

**<A Heather Bresch Mylan N.V.>**: Sure Jami. Thank you. So, first let me address your Meda question. As we stated, their results were very much in line with our expectations. I think one of the disconnects is that the Street, or here in the United States, had not followed Meda's business all that closely and then certainly, post our announcement of acquiring them, I think there's been no following of the business. So I think there was just a real disconnect with consensus as to what Meda was expected to do.

As far as the businesses, I would differ that Meda and Omega don't look alike really at all. Meda, as we said when we announced the acquisition, is a very diverse company with no concentration in any one country or any one product portfolio. It's truly spread out over hundreds of products that allow us to truly build critical mass in some continued very important countries for us, especially throughout Europe, and then as we mentioned emerging markets, a presence that we had not been in. So, I would first start out with the businesses look totally different.

With that being said, I think we've been very clear that Omega was a great asset. But you can put a wrong driver in charge of that asset. So, I can't comment. I'm not running Perrigo or Omega. What I can tell you is that our track record of integrating very large, diverse European businesses started almost 10 years ago with our acquisition of Merck KGaA which I would hope that we would all sit back and say that we did a great job of not only integrating them, but continuing to deliver double-digit growth over the last 10 years. So, look, we are committed 1 billion percent to bringing the Meda asset in. As we've always said, it's not what the company's doing on a standalone basis. It's what we're going to do as a combined platform. And we believe the Mylan-Meda platform will continue to be one of the most diversified and differentiated ones in our industry.

As far as pricing, look, I agree there's pressure. There's pressure on companies that have had a very, very niche concentration on a portfolio and have, I think, in many cases executed practices that are not sustainable. And I think we've talked about that for a long time. And I think as we—as I wanted in my opening comments to really resonate, I hope, with the investment community to say to really step back and take a look at companies who have—are making most of the products they sell, integrated a true global supply chain, meaning we control our own destiny, versus companies that are doing nothing but in-license products for all of their products, or acquiring products and after they acquire them cutting all of the R&D, the people, everything associated with it.

So, what I really was trying to call out this morning is over the last decade of us investing in products, R&D, and people, manufacturing, CapEx, over the years, I won't say that we didn't take our fair share of criticism that we maybe were investing too much. Maybe we were investing too much capital in our manufacturing operations and Paragraph IVs and injectables and complex products. And I would stand here and hope that as we look back at the last 10 years of growth that we've achieved, and more importantly, the growth that we see going forward. We've put targets out there that continue to show a very robust growth platform. And we believe, as I said earlier, we're just getting started. The runway out there for us to add more products, more dosage forms, more therapeutic areas to truly leverage now the platform we have in place is just, again going to accelerate that growth trajectory. Thank you.

Operator: Thank you. Our next question comes from Elliot Wilbur of Raymond James. Your line is open.

**<Q Elliot Wilbur Raymond James & Associates, Inc.>**: Thanks. Good morning. Maybe just following up on your commentary around targets, Heather, and going back to full year guidance, you had talked about, I think, essentially 20% top line growth in the entire Generics segment. And then thinking about, based on what you guys put up today and what that implies for the remaining three quarters of the year, certainly implies a pretty significant acceleration in terms of year-over-year growth. Essentially a doubling of the rate in the first quarter. And I guess one of the key dynamics there, or the largest factor in terms of bridging revenue growth was new product launches. Maybe you could just talk a little bit about where you are versus original expectations on the new product cycle at the beginning of the year. And just remind us for the balance of the year, what are some of the key known new product drivers?

**<A Heather Bresch Mylan N.V.>**: Thank you for that question. I will tell you that we remain completely on track with the guidance we gave. As you remember, historically, if you look back over the last couple of years, the phasing of our quarters have been very similar. From Q4 to Q1, we then step up to Q2, Q3 and Q4. Q3 typically, obviously with the EpiPen® contribution, is seasonally our highest quarter. But look, we have a significant amount of new product launches, new business and volume growth. I mean, we continue to see volume growth as well as taking, as we've talked about, the price erosion that we had put in our guidance from the beginning.

So, from our perspective, it's not about any one particular product. Again, we've got many, many different launches across the globe, but it's mainly here in the United States as well. And as I said, from everything we see today, we are completely on track to all the guidance ranges we gave you for the year.

**<Q Elliot Wilbur Raymond James & Associates, Inc.>**: Can I ask a second question as well, Heather, just real quickly?

**<A Heather Bresch Mylan N.V.>**: Sure.

**<Q Elliot Wilbur Raymond James & Associates, Inc.>**: Earlier in the year, you had talked about potential competition to EpiPen® in the form of a BX-rated product. And I don't know if you had something specific in mind or if that was just general conservatism, but if there's anything new there in terms of your line of sight on potential competitive assets to EpiPen®. Thanks.

**<A Heather Bresch Mylan N.V.>**: Sure. And in the context of talking about a BX, it was in the context of Teva saying that they were going to have an AB rated. And I think that I certainly have maintained that I think the bar to get an AB-rated product is very, I believe very high given the regulatory guidelines with the FDA in a device drug product. So, and obviously, as we've said before in a life-saving device.

So, we believe that as they continue to talk about AB that if anything, we would be take the financial responsible thing and put a BX in there. I think even to their most recent commentary, they've really taken that off the table to, at the earliest, the end of the year, if not 2017.

So, we continue, as Tony mentioned in his commentary, continue to be very excited in EpiPen®. We'd continued to invest in that product and to continue to educate, build awareness. And you know I think if you just look at the amount of if you look at just our school program and the amount of EpiPen® that we've been able to distribute to the public school system, and the amounts of lives that have been saved due to it. I mean, so we believe the investment has been well worthwhile and that the community continues to resonate to the education and awareness. And as we've said, there's over 20 million lives at risk. So, we believe that our just growth in the continued market place gets significant runway.

Operator: Thank you. Our next question comes from Chris Schott of JPMorgan. Your line is open.

**<Q Dana Flanders JPMorgan Securities LLC>**: Hi. Thanks. This is Dana Flanders on for Chris. Can you just comment on the Treasury regulations that came out last month and how you see the proposals impacting the industry and Mylan more specifically as it relates to M&A? And then is there any impact to Mylan's longer-term tax rate with some of the proposed rules around earning stripping?

**<A Heather Bresch Mylan N.V.>**: Yeah, no. Thank you. We see no effect, obviously, on Mylan or our inversion from the Treasury rules that came out. I think we've also been vocal about that we don't think a Band-Aid fix to the tax code is the right thing for the industry from a global competitive perspective. So I would continue to hope that the next administration takes a much more holistic view at the tax code and makes the United States a competitive place to do business, not a place to handcuff you to stay here. So that would be our comment on inversion. And as far as we'll continue, nothing changes about the guidance that we've currently given on our tax rate or any of the other ranges that we've given. And going forward, if there's any impact, we'll be sure to communicate that.

Operator: Thank you. Our next question comes from Randall Stanicky of RBC Capital Markets. Your line is open.



**<Q Randall Stanicky RBC Capital Markets LLC>**: Great. Thanks. Heather, just a bigger-picture question for you. The U.S. generics sector remains fragmented. Obviously, you are one of the market leaders. As we see approvals come through over the next couple of years, I guess a question. Understanding that you are positioned differently and you guys see a stable outlook for profitability, do you think that the sector profitability could come under pressure? And then two, do you think that's going to drive consolidation amongst some of the middle-tier players? And do you guys plan to continue to participate in that consolidation? Thanks.

**<A Heather Bresch Mylan N.V.>**: Yeah. Thank you, Randall. We absolutely believe consolidation will continue, I think not only just from a U.S. perspective, but from a global perspective. I think as you step back and look at the dynamics of this industry today, I mean they are just significantly different than they were just a few years ago.

Everything from our customer base that continues to consolidate and have a global footprint, there needs to have a global partner that can truly marry up an effective and efficient supply chain, cost of goods, the breadth of portfolio while not losing sight of investing in the complex products like a generic Advair®, bringing it to the market. So, I believe that there will be a continued consolidation around the globe. And we absolutely plan to continue to participate.

What we've said is that given the platform, both operational and commercial platform that we've built today, that it's easy to now complement it with bolt-ons that allow us to continue to grow critical mass, just like we're doing with over-the-counter business. As we bring in the Meda and now have a billion-dollar franchise, we'll be able to continue to think about the best ways to continue to grow that channel throughout the globe.

So, yeah, I think there's going to be much more consolidation and I think that the global players with global scale, which is why we do really believe we've differentiated ourselves. And it took 10 years; it's not a flip of a switch. Companies may want to change their business models, but to change your business model, you've got to be willing to take the time and the investment needed to truly change your business model.

Operator: Thank you. Our next question comes from Ronny Gal of Bernstein. Your line is open.

**<Q Ronny Gal Sanford C. Bernstein & Co. LLC>**: Hi. Good morning and thank you for taking my question. I have two of them, first for Tony. Tony, when I can look at your progress through the year on the public demand, I see Nuvigil®, Kaletra®, Benicar®, Benicar HCT®, Copaxone® and Estrace® as potential launches during the year of material size. Anyone else you'd like to highlight just so we have the right launches in place? And second, for Rajiv. Rajiv, I think Biocon mentioned on their call, they're going to file insulin glargine soon as part of your partnership. Can you just confirm to us you have both the vial and the pen as product? Obviously, there's a different IP situation on both, so it's kind of important to tell if you got both.

**<A Tony Mauro Mylan N.V.>**: Yeah. Thanks, Ronny. As it relates to 2016 launches, I think we have a very robust launch plan phasing throughout 2016, and we look forward to those opportunities to bring new products to customers across all of our markets.

**<Q Ronny Gal Sanford C. Bernstein & Co. LLC>**: Any other ones you care to highlight as important launches?

**<A Tony Mauro Mylan N.V.>**: Not specifically.

**<A Heather Bresch Mylan N.V.>**: Ronny, I think as we've said, we are well beyond being about any one product or launch. I mean, we're launching hundreds of products around the globe. And so I think again, as you look at more of the channels we're operating in from hospital with our injectable business to the retail business, on to our specialty, Rx business, I mean it's truly a holistic One Mylan that's allowing us to manage and absorb the volatility within the marketplace.

**<A Rajiv Malik Mylan N.V.>**: And Ronny, on insulin, we remain on track to bring forth [indiscernible] file very soon both in Europe as well as the U.S. And also I would like to highlight that Japan approving insulin of [indiscernible] that is the same [indiscernible].

Operator: Thank you. Our next question comes from Umer Raffat of Evercore ISI. Your line is open.

**<Q Umer Raffat Evercore ISI>**: Hi. Thank you for taking my question. Maybe first one for Rajiv. Rajiv on your generic Advair® trial that's posted on ClinicalTrials.gov, it seemed like the enrollment was done only in 18-plus-year-old patients. Just wanted to understand, I mean FDA guidance seems to imply 12 plus, and I wasn't sure if that was just semantics on the ClinTrials website or if you have an additional bridging study beyond for the 12 to 18 year olds, number one.

And then a couple of follow-ups. One was just in general, on the reclassification of Brazilian operation into North America. Just wanted to understand that and then also the cash flow conversion this quarter. Thank you.

**<A Rajiv Malik Mylan N.V.>**: So, I will only I don't know what specifically you're talking about but our study is very much in line with the guidance issued by the FDA and there is no separate bridging study just from that point of view.

**<A Heather Bresch Mylan N.V.>**: Yeah, no, and Umer, as far as Brazil goes, If we're down to talking about things that represent 1% of our revenue, I think we're doing pretty good. So, there is no, obviously, significant impact whatsoever from the reclassing of the Brazil operation. And as far as cash flow, I think it's all expected. We had some timing issues around inventory build and some of the product launches, but certainly nothing out of the ordinary, whatsoever.

Operator: Thank you. Our next question comes from Douglas Tsao of Barclays. Your line is open.

**<Q Doug Tsao Barclays Capital, Inc.>**: Hi, good morning. Thanks for taking the questions. Just maybe Rajiv, as a starting point, just could you provide some perspective in terms of timing for the filings for glargine, pegfilgrastim and trastuzumab in the U.S. in particular?

**<A Rajiv Malik Mylan N.V.>**: I would say all, pegfilgrastim, trastuzumab and glargine are very much on track and we'll be filing in the next few months.

**<Q Doug Tsao Barclays Capital, Inc.>**: Okay. Great. Thank you very much.

Operator: Thank you. Our next question comes from Andrew Finkelstein of Susquehanna. Your line is open.

**<Q Andrew Finkelstein Susquehanna Financial Group LLLP>**: Hi, and thanks for taking the question. I was hoping that you could speak a little more specifically about the dynamics with generics in the U.S. As we look at the gross margin, there's obviously a lot of moving parts depending on the timing of launches. But is the price erosion you're seeing or product mix a bigger factor in the gross margin development, particularly as we look on a year-on-year basis? And then in this environment where the customer picture has changed, how do you feel about the visibility on results for the rest of the year given we are seeing an increase in and approvals out of FDA which could mean new competition on some of your existing products over the course of the year? How much does that affect your planning assumptions for what the base portfolio is going to provide?

**<A Heather Bresch Mylan N.V.>**: No. Thank you. Look, I think there's been significant confusion both with the investment community and Washington when it comes between generics and specialty products. I think that as we look at some of the hearings that have taken place, at some of the dynamics and some of the discussions have all been around specialty products or one-player products. So, when you step back and look at the generics portfolio, the generic industry today represents 88% of the volume of all drugs dispensed in the United States. We've saved over \$1.5 trillion over the last 10 years for the U.S. healthcare system and we today represent 28% of the pharmaceutical spend, which is only 10% of our healthcare spend.

So, when you really drill down to, generics have continued to be the backbone of this system. We have continued to have products that continue to face competition and that's why we said mid-single digits has been our price expectation. It's been that way for the last several years. It's been very stable and as we came into this year, we said we see that remaining the same, that stability around pricing, but not for everybody.

And this is, again, why I think we're trying to do the best we can to help everyone understand and distinguish between companies. Companies who are focused on very small niche areas, focused on practices that are not sustainable, practices that they now have to take out of their future guidance which is showing no growth for certain companies has no bearing on a Mylan and the platform that we've built with having hundreds of products here in the United States, continuing to launch many, many new products, both that are high barrier to entry and afford the opportunity to continue to have, whether it's higher gross margin or complement our current platform. Is why we believe it's the right inflection point and why I truly believe the rebasing of this entire sector was needed to allow, I think, this refocus and the visibility around truly individual business models.

I think the investment community did a pretty good job beginning to differentiate between brand pharmas, whose expertise was in what, from an R&D perspective, from a manufacturing perspective and I truly believe that when you apply that same lens to our industry, it's going to become much more clear about the companies who do have a sustainable, long-term growth future ahead of them, and we believe Mylan leads that space.

Far as our customers go, the consolidation and their needs completely marry up and enure to our benefit. Our global customers have global demands. They need to be able to have high-quality, effective and efficient supply chain, have products where they need it when they need it, that time to market has never been more critical. And we, again, have put a global supply chain to meet those demands. I think our customers are recognizing it. And I think that it's about looking at our whole basket of products. So, yes, the FDA is going to continue to approve products. Mylan's got one of the largest pipelines waiting for approval with the FDA. So, we're looking forward to them hitting that backlog and getting products to the market. And again, we believe we'll get our disproportionate benefit because of the breadth of our current basket of business that we do with our customers today.

Operator: Thank you. Our next question comes from Jason Gerberry of Leerink Partners. Your line is open.

**<Q Jason Gerberry Leerink Partners LLC>**: Hi. Good morning, and thanks for taking my questions. Two for me. Just first maybe for Rajiv. On Advair®, do you believe that you'd be entitled to six months of regulatory exclusivity if, in fact, you get an approval on your action date which is a little bit ahead of the competitor's action date?

And then I apologize, but on my second question, I might have missed this, but can you just explain the Rest of the World Generics line, the sequential weakness of about 26% Q-over-Q. I know that the 1Q tends to be a little softer than the 4Q. But that was a bit further down than we expected for the quarter. Thanks.

<A **Rajiv Malik Mylan N.V.**>: Okay. Let me on Ad<sup>®</sup>, I think we have a head start from filing an acceptance but we don't have a head start from the six-month exclusivity from because it's not a [indiscernible] certification. But we might have a market exclusivity just because of that head start and where we are with the fine.

The second one was both...

<A **Heather Bresch Mylan N.V.**>: The emerging, Rest of World.

<A **Rajiv Malik Mylan N.V.**>: The emerging markets. It's a timing issue. It's nothing but a timing issue. It's some delay in the launch of tenders where we already have the contracts, but there's a delay in the launch of some of the tenders in our HIV business in those emerging markets. So, it's nothing more than that. Our commercial business in India and other emerging markets are going pretty well. You saw our HIV business where we saw some delay in the launch of those tenders.

Operator: Thank you. Our next question comes from Marc Goodman of UBS. Your line is open.

<Q **Ami Fadia UBS Securities LLC**>: Hi. This is Ami Fadia on behalf of Marc. Two questions. Firstly on EpiPen<sup>®</sup>, where are we on inventory levels and the changes impact to the quarter? And secondly, could you give us some color on some of the key markets in Europe such as France, Italy, UK, et cetera? Thank you.

<A **Heather Bresch Mylan N.V.**>: Sure. As far as EpiPen<sup>®</sup> goes, there's no issue with inventory. We never did have any issue with inventory. I think there was, again, a bit of a disconnect and some of the models had gotten it wrong. And I think that most of those have been corrected, at least as far as we can see. But our EpiPen<sup>®</sup> inventory levels are very, very much in line with our normal business as they always have been.

As far as Europe goes, Rajiv, do you want to?

<A **Rajiv Malik Mylan N.V.**>: Yeah. On France, we saw some pretty strong growth from our existing products and the volume and the market share perspective. We saw very strong growth in the UK, whereas our Italy was pretty stable and in line with the market growth.

Operator: Thank you. Our final question comes from Tim Chiang of BTIG. Your line is open.

<Q **Tim Chiang BTIG LLC**>: Hi. Thanks. Heather, in the past, you've talked about vertical integration being a very important aspect to Mylan. How does vertical integration sort of play into this acquisition with Meda? I mean, would you be able to bring in some of the manufacturing that Meda has in-house?

<A **Heather Bresch Mylan N.V.**>: Yeah. No. Thank you. Very much so. I think that it, both from a vertical integration as well as just our manufacturing operating platform. So there's two aspects of that. Vertical integration means that we're producing our own API that goes into the finished dosage form and then manufacturing our finished dosage form, or we're acquiring API from a third party but still manufacturing our finished dosage form. And the multitude of finished dosage forms that we now are capable of span by the dozen, so from oral solid to injectables, to extended release, to topicals.

So we've continued to really invest and build out that capability. And so what we see, again as being this differentiator, controlling our own destiny through being able to manufacture, perhaps vertically integrate as well our global supply chain is what really gives that gives us that head start or that advantage from a cost of goods perspective and the efficiency around it.

So, just like we did with the Merck business, we were able to look at products that we could either consolidate that buying, we could bring alternate manufacturing in-house and be able to really leverage again our platform. Today, even more so than eight years ago because our manufacturing footprint has expanded dramatically, ten-fold since we did the Merck acquisition.

So, our ability to bring the Meda's line which they do very, very little manufacturing. Most of their products are in-license. Again, that's just another added benefit of Mylan and Meda joining forces to really be able to optimize the operational and commercial platform that we've put in place.

**Heather M. Bresch, Chief Executive Officer & Executive Director**

Thank you very much for joining us. We'll look forward to seeing you soon. Thank you.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This concludes today's program. You may all disconnect. Everyone have a wonderful day.