

Mylan N.V.  
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**Pursuant to Rule 425 under the Securities Act of 1933**

**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.

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## **PARTICIPANTS**

### **Corporate Participants**

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

**Colleen Ostrowski** Senior Vice President and Treasurer, Mylan N.V.

### **Other Participants**

**Sumant S. Kulkarni** Analyst, Merrill Lynch, Pierce, Fenner & Smith, Inc.

## **MANAGEMENT DISCUSSION SECTION**

**Sumant S. Kulkarni, Analyst, Merrill Lynch, Pierce, Fenner & Smith, Inc.**

Hi, everyone. Thanks for being here and for tuning into the webcast. I'm Sumant Kulkarni. I cover the specialty pharmaceutical space for BofA Merrill Lynch. I also want to introduce my teammate, Steve Chen. He's out there hanging in the audience. So, he's responsible for a lot of the work we put out. So, thanks to him. But as I said, very pleased to have Mylan here. Heather is going to make a few comments, and then we're going to keep this very interactive with a Q&A.

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

Thank you. Thank you, Sumant, and thank you for having us. Just a couple of opening comments. I think Mylan has really prided itself that over the last decade we set out a vision of really creating global scale and to be able to compete in a global market. And I think, if you look back from our acquisitions starting in 2007 with Matrix, which gave us the ability to vertically integrate and then Merck Generics taking us truly from being a domestic company into over 100

countries overnight.

And then, from there, really bolting on acquisitions that build up critical mass whether around a therapeutic category or a dosage form, such as Bioniche and Agila, for us around the injectables. And then, most recently, with our Abbott transaction that really built out the Rx channel for us in Europe. We had historically had a very strong retail generic marketplace but we did not on the Rx side.

So, as we thought about building truly global scale, an operating platform, a manufacturing platform that is capable of now making 80% of what we sell, really controlling our own destiny with a global supply chain. Building out critical mass in all of the channels here in the U.S. from Rx, Gx to the institutional marketplace, having hundreds of products launching 50, 60, 70 products per year has always really been the driver of the generic industry.

Mylan has been in the U.S. generic industry for over 50 years, and I personally have been here 25. And I would say a driver to the market has always been volume and new launches, and we see that today. And I think the strength of having the ability to control your global supply chain, be able to have a global business to leverage not only the breadth and width of our portfolio, but also across each of these channels and across the globe.

And so, with our most recent announcement of the Meda transaction, it's just another step in the fact that it really creates and completes that critical mass from a company perspective for us. It builds out further in Europe, as well as some of the emerging markets and has now created for us about a \$1 billion OTC franchise. So, we really believe Mylan is best positioned to not only continue to add bolt-on product assets that would allow us to maximize these different channels, but continuing to be able to, like I said, leverage this global operating platform that we put in place that we truly believe differentiate us from the pack. And if there's anything I can say about the last several months in the sectors, as painful as it's been, I think it gives a real opportunity to let the market refocus on truly the fundamentals of companies.

And I think there were some very flawed business models out there that took either advantage of very small niche areas or therapeutic categories and had very aggressive price hikes that not only got a lot of attention, but I think shined light on truly separating fundamentals from, quite honestly, a very unsustainable, a lot of hot air business that hopefully allows the market to step back and revisit companies like ourselves that have truly built out over the last decade, invested in products, invested in R&D. We have one of the most robust pipelines. We've invested in people. We've invested in our infrastructure. And we believe that that's now paying off dividends, and we continue to invest in the future.

We've got one of the largest biosimilar R&D pipelines. We're investing in bringing what we believe will be the first generic Advair® to the marketplace and have built a dedicated facility in Dublin, Ireland. So, that willingness to continue to invest and produce. And like I said, in the volumes that we do today, we believe this is truly what differentiates us from the separates us from the pack.

So, with that, thank you, and we can open it up to questions.

## QUESTION AND ANSWER SECTION

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: There's going to be a mic going around the room, so please feel free to raise your hand, and I'll get it to you. I'll kick it off here.

Generic pricing erosion has been a theme that's been on many investors' minds. It doesn't seem to have been all that different relative to what you were thinking or any potentially diversified large company has been. So, what really has separated you from your pricing erosion expectations relative to some of the other players you've seen in this space who have had much worse erosion than they expected?

**<A Heather Bresch Mylan N.V.>**: I think that there is a couple of factors compounding that. We certainly have seen niche players that had a very concentrated portfolio that, when a market or there is volatility or disruption and your ability to absorb that volatility is much, that bandwidth is much, much more narrow when you don't have any other levers to lean on. And so, again, I go back and look at our model here in the United States. We have 400 products across every therapeutic category and have critical mass around many, many different dosage forms. It allows you to absorb that volatility.

And then, not only do we have that many products. But as I said, we manufacture 80% of what we sell. So, our ability to be nimble to react to market opportunities, to react to customer disruption when other players. That ability truly is not allows you to manage through volatility, but it's certainly then puts a different perspective of how you're leveraged with the customers. As our customers continue to consolidate, they need more product. Their reliance and needing for certainty has gone to an all-time high.

So, like I said, when you have a very small subset niche product, you don't have much room for veering right or left very much as well as I think we've all seen that there has absolutely been some abuse to the pricing policies out there that again, I think, if your growth was totally predicated on 30%, 40%, 50% market growth for your whole line, that that's not going to be sustainable today or into the future, which has I think caused a rebasing not only of market valuation, but a rebasing of people's business models.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: And I know that you are diversified and no single product really should be asked about it, I guess in terms of numbers, but we do know that Advair® is a pretty important product for you from a generic point of view. How important is that product to you being able to accelerate the ability to achieve \$6 of EPS by 2017?

**<A Heather Bresch Mylan N.V.>**: What we said really the opportunity to accelerate that hitting \$6 was around the Meda acquisition. To your point, it's not really about any one product. I think that the diversity of our platform we've been able to show, and our track record hopefully speaks for itself that we've met or exceeded the guidance we've given out there.

Our midpoint this year is \$5. We have a range that probability weights products coming not coming. As I always say, all good things don't happen in this business at the same time, all bad things don't happen at the same time, although sometimes it can feel that way. But that ability to really absorb that volatility goes to the strength of your business.

So, for us, I wouldn't look as generic Advair® being that driver as much as I would just us being able to bring the Meda opportunity and really optimizing those assets that really pulled up the \$6 opportunity.



**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: Some investors who recently saw Meda's numbers were a little I guess apprehensive about them, but you mentioned on your call that they were in line with your thinking. So, how should Meda evolve as a business to be able to help you meet your goals of achieving that \$6?

**<A Heather Bresch Mylan N.V.>**: Sure. So, yeah, as I said on our earnings call, Meda did as we expected them to do. I know they were off from consensus. But really, there weren't many analysts following Meda pre our announcing acquiring them. And certainly, once we announced that, it really dropped off the radar. So, you were down to two or three analysts following that hadn't really taken into consideration the recent business moves that Meda had taken.

I think when you look at the complementary fit—the strategic fit with Meda to our business, again, Meda primarily in-license their products. So, our ability, just like we did with Merck and some with Abbott, us being able to bring a different cost basis to that portfolio in a much more effective and efficient way is an opportunity.

As we think about opening up, now bringing critical mass around that OTC channel for us especially in Europe, that dynamic is very different with the pharmacy in Europe than it is here in the U.S. That ability to have pull-through from Rx, Gx and OTC does make a difference, and we believe leveraging and truly having a one Mylan product portfolio through those channels we'll be able to do more with the products they had.

They really had not as invested as much as we think that obviously we'll be committed to do. Similar to the Abbott business, it was a declining business. We were able to say we believe we'll be able to make that a slightly positive business, which we did on a shorter period of time than we had forecasted. But the financial flexibility that that gave us—that allows us to continue to reinvest in ourselves. Meda is very similar to that. You look here in their U.S. business. They have a product, Dymista®, but their reach with their sales force was much more limited than ours is with our allergy respiratory sales force from being able to hit specialists as well as primary care.

So, it's really about being able to do more with more and us being able to focus and invest in the areas that we believe we'll be able to get more out of those products, as well as take them to other geographies. We had a much broader footprint than Meda, but—and Meda put us into some countries we weren't in. So, that ability to bring the Mylan portfolio now where Meda has infrastructure from a commercial perspective is really where we say that's kind of the last large company that Mylan really needs. From this point forward, it's really looking at products that continue to feed—assets that will allow us to continue to feed these distribution channels.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: So, Meda has a pretty large over-the-counter portfolio. Given what we've seen with some of the other OTC players in Europe, notably Perrigo's Omega, who do you compare in contrast to Omega—Meda's portfolio relative to that one?

**<A Heather Bresch Mylan N.V.>**: I would say a couple of things. The Omega business and Meda business are quite different in this way. The Omega business was much more concentrated on a handful of products and a couple of countries. The Meda portfolio is much more diversified across hundreds of products in many countries. So, just by their natural business model, there's a much more of a de-risk in the Meda model. And you know, I've said before, you can have great assets, but have the wrong driver, and I think Omega is the combination of having a very different business model but also not having the best driver to be able to integrate and maximize that asset.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: Coming back to your diversity. It appears to be an advantage. But from an investing point of view, for people who are looking for catalysts, it becomes very tough for us to point to one. What would you say other than quarterly earnings should people look for in terms of catalysts coming up for Mylan?



**<A Heather Bresch Mylan N.V.>**: I hope that, again, in the phase of the rebasing of the sector and really being forced to go back and look at fundamentals that we'll do our part, continuing to show the diversification, get the Meda transaction closed, to come back forward with an Investor Day that really showcases Mylan assets today. And I know, I get that all the time, it goes from, we would like, we like the fact that there is not one thing that can go wrong to derail the business, but we want to model three things.

So, I know I've said, as you step back and think about how do you think about these big portfolios and there's not one particular driver. I think about it that if you step back and said okay, who's got look at the breadth and width of a portfolio, not an individual product, but just that breadth and width, the investment in R&D. So, you're launching 50, 60, 70 products a year in any given country. If you look then not only investing, but everything from complex products to the commodity products that you've got that full offering.

On top of that, having the manufacturing operating platform that is allowing you to make what you're selling vertically integrate and have that global supply chain. And on the backs of all of that has business management continuity. Mylan management has been together, this team has been together a decade and some of us for a couple of decades that those relationships in growing with our customers. As they've consolidated on a global basis has really allowed us to, like I said, even level that playing field that the leverage around our customers putting a value on the certainty and the ability of that supply. So, as I think about, from a modeling perspective, not down from a molecule by molecule basis, but more stepping back and really looking at the fundamentals of the business model, because I think our business models are very different. And I think that, we're now at a point in time, where looking at those models and evaluating the types of things I just outlined really start separating who can manage and compete on a global basis, provide our customers what they need. It becomes you're down to we really believe ourselves and Teva, that looked very different than anybody else in the industry.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: It sounds like, after the Meda transaction, the company has all the assets in place to operate as well as you'd like. So, what would you short of buying other things which you don't need a large component of, what types of shareholder return are you contemplating and at what point in time could we expect them?

**<A Heather Bresch Mylan N.V.>**: Now, look, as we've said, we have tremendous financial flexibility and we're going to continue to not only execute on closing the Meda transaction. We certainly said a share buyback is something that's out there that we had approved before the Meda transaction, there is still an opportunity for us as well as further BD. I think from a BD perspective, as I said earlier, continuing to add products that fill these channels and allow us to maximize them is what it's about, and we look at things like derms and ophthalmics. There are still product lines and product concentrations that we don't have critical mass around that when added to the portfolio we have we believe that continue to just bring incremental value.

So, I think you can rest assured that the other there's a silver lining to what's happening in the market today, the rebasing and the revaluing of a lot of these companies is it's a buyer's market. And I think there are some assets out there that would be very complementary to the platform we have.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.>**: Sure. And this is a bit of a technical question on the Abbott shares or the Mylan shares that Abbott owns. How could or what part could Mylan play in minimizing the impact of potential sale?

**<A Heather Bresch Mylan N.V.>**: Look and Colleen can weigh in here, too. I think that Abbott has been very transparent in saying that there's no they've got a lot of sources and



uses of capital to pull upon. They're not desperate for cash. But with that being said, they're going to be smart about how they look at their portfolio. I think they were clear in this most recent announcement with St. Jude that they don't need that. And so, like I said, it's not so—I think it's about just being smart and not being desperate sellers of the stock. And I think we've seen them do that historically, and I see no reason why that would not be the case in the future.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Sure. And then, moving on to the branded side, it's a business that you contemplated selling at one point in time. Now, it happens to have EpiPen®, which is a \$1 billion franchise for you. What else could you do in that branded franchise to make that stronger?

**<A Heather Bresch Mylan N.V.:** So, yeah, look, our—that allergy respiratory niche, not only with our EpiPen® asset, but as we acquired Sandwich from Pfizer, first, that was the generic Advair® platform, but there's also other technologies that we continue to look upon broadening our respiratory allergy niche. We have Perforomist® on the market today. We have our deal—our proposed joint venture with Theravance on the next COPD product.

So, we think a niche around nebulization, as well as a niche around obviously the EpiPen Auto-Injector® and some of our—the technologies that we've acquired will continue to allow us to really build out that space as a leader. Certainly, Meda complements that. One of their largest franchises were around respiratory and allergy. So, now as a global, again, kind of diversifying that it's not concentrating in any one country, we really see ourselves positioned to become a global respiratory and allergy leader.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Sure. In terms of geographic regions of the world where you may not be or where you think there is profitable growth, what would you point to as priorities there?

**<A Heather Bresch Mylan N.V.:** So, the—we have, I would say, a foothold in Brazil that we acquired with our Agila transaction. That's given us the opportunity to think about how we want to grow in that area. Meda takes us to China and to Russia and some of the other emerging markets that we have not previously been in.

And so, I think that we've got enough of now a base to say do you end up partnering. I mean, the thing is one size doesn't fit all. For some countries, partnering locally, investing in manufacturing locally. How we look to build out, acquiring some products or taking some products, quite honestly. When you look at our HIV franchise with infectious disease, we've had a very successful emerging market business, that's really been to cater to the global tender markets.

But with that being said, we've got a real opportunity to bring some of the innovation that we've done with these product portfolios into some of these countries that we now have infrastructure through Meda. So, I would say that we'll continue to really now concentrate on where we've got a foothold, like I said, China and Russia specifically.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** And in the U.S., how much of a runway do you think we have for traditional growth in the small molecule side before biosimilars have to become a bigger portfolio for you?

**<A Heather Bresch Mylan N.V.:** We've said we've got one of the largest investments in the biosimilar portfolio. We got one of the broadest now pipelines. We've said, over the next several years, we'll invest almost \$2 billion in R&D, but we've also said that we'll figure that we'll end up monetizing that globally more so than before here in the U.S. I think that we're still in somewhat of uncharted territory about how the market develops here in the U.S. I believe that there is definitely flaws with the current legislation. However, I would separate that from an administration perspective. In prosecuting the science and the application.



We've continued to see good progress there with the FDA. When you get to the evergreening and the patenting, that's where a lot of questions lie. And as you guys I'm sure know, there's a lot of there are several court cases right now that could end up setting precedents for how that goes. I also will throw out there depending on what happens in the next with the next administration. There's been all kinds of threats of repealing ObamaCare, which would affect the biologics law.

But I would say, if you have if we have status quo and the courts ended up coming to a favorable decision around the patent and so forth, that by 2019, 2020, I think you'll start seeing a pretty robust biosimilar. I think we know the science is there. As they can't be interchangeable, all products aren't created equally. Some are obviously more complicated than others. But I do believe that necessity is the mother of invention. And I think we know, if you look at the top molecules of spend of our healthcare system, it is around the specialty products, the biologics products.

I know states, once we are able to show the interchangeability of biologics, I believe that substitutability because the reality is we're going to need access to affordable medicine, and the space is going to be more important than ever, just given the cost basis that our country already has invested in it.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Okay. And then, moving onto the Generic Drug User Fees Act, you also play a prominent role in GPhA. So, how has that changed in the recent past? Have the FDA really started approving things or is it just complete response letters?

**<A Heather Bresch Mylan N.V.:** So, I would say I'm very happy with the with products that are being filed that get a GDUFA goal date, and our generic Advair® would fall into that bucket. I think that FDA transformed themselves, reorganized themselves and that has certainly been more painful than I would have liked. But I would say we see real progress in, like I said, the products that were filed after that GDUFA goal date.

For the backlog, I'd say we are grinding our way through it. We are working with FDA constantly about how to prioritize. I can assure you we've got more product in the pipeline than almost anybody else. So, our wanting them to get through that backlog, but it's a churn and I think it's not going to happen as fast as we'd like. I think they will continue to work through that backlog as kind of the machine they set up here with GDUFA continues to run, I think, fairly well. They've been on on-time and on-point with the products and their response times and their responsiveness to the products we have filed under that.

So, like I said, I think it's going to be it's going to take longer than we would have liked, especially to address the backlog as well with the inspection fees. I mean, getting to a risk-based inspection that everybody who is selling product into the market has a clean a good GMP health check is going to take longer than we thought. So, I think both of if you think of the backlog and the inspection and how they reach, both the whole universe of that is going to take longer, but I think we're making progress. It's just slower than we like.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** How would you characterize Mylan's confidence in the potential to get a first-cycle approval on generic Advair®?

**<A Heather Bresch Mylan N.V.:** I we're very confident. I think, like I said, our even pre-submission dialog with FDA around the guidelines and how we were developing the product, the acceptance of our application, I mean, we feel very good that, from everything we can see today, that all that we're hitting all the timelines and all of the, kind of, next steps with the FDA along that first-cycle approval.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** On biosimilars, specifically on a product like a Humira®, there could be like nine participants in the marketplace. So,





assuming that Mylan has the commercial infrastructure already to play in such a marketplace, how do you see an ultra-competitive biosimilar marketplace playing out in the U.S.? Do you think something like that could happen? Or is it going to be limited to people that or companies that have actual infrastructure in the play and in place?

**<A Heather Bresch Mylan N.V.:** Yeah. Look, I think the bar is going to be much higher, just the investment. As I said, we have to spend billions of dollars to bring a portfolio to the marketplace, already sets a pretty high bar in place. I think that the way biosimilar market plays out is going to look different than small molecule. I think that it will be the line will be even much more blurred between brand and generics because I think we see some of the biopharm companies themselves positioning that they could do biosimilar applications as well as the brand. So, I think that it will be multiplayer market and competitive. I think there is certainly room for that, but I don't think it will ever look like the small molecule.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** You had spoken for a long time about consolidation in the generic space, but what do you feel about the potential for a large established product business that could be coming online here, if Pfizer decides to do what it wants to do?

**<A Heather Bresch Mylan N.V.:** Look, I think that we're going to continue to see capacity be taken out of the market at the larger player, the mid and the small. And I—as we've said, we kind of—we look at everything of what makes sense to complement a platform. These businesses all look different at any point in time.

We—at the time we did the Abbott established products, we had looked at all the other established products that were on the market at that time and believed that Abbott was the most complementary to us. So, I think we will continue to look at assets, and I think there is even opportunities to look at product families and countries versus just one entire business. And so, we'll stay open to that. But I think there's certainly a lot of products and assets out there that would be very complementary, especially in some of the emerging markets from some of these larger businesses.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** And then, staying on the theme of consolidation, do you see any potential for any kinds of non-traditional consolidation, namely manufacturers with distributors or some other thing like that?

**<A Heather Bresch Mylan N.V.:** Look, I think, if you look at our customers, they are already integrating vertically and horizontally. You look at it from managed care to retail pharmacy to globalization. So, what I would say is that, again, unique business models may get there in very different ways. But I think the reality is that you're going to have to be very globally competitive to compete. And whether you end up doing that traditionally or nontraditionally, I think you could make interesting partners. But I think that, like I said, you see a kind of rebalancing of the leverage between customers and the large players today. And I think—but we've said this will remain a competitive market no matter what. I think it's just perhaps a little bit healthier dynamic.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Sure. Mylan is now an inverted company for tax purposes. How do you see the new earnings stripping rules effecting the company and what could we see as an impact on the tax rate, if at all?

**<A Heather Bresch Mylan N.V.:** So, I guess, first, I'd say, we said all along we weren't going to invert just for tax, so to say. For us, it was the right strategic business that gave us the opportunity to invert. As we look at what the treasury did, even if it was on a retrospective basis, that wouldn't have affected our inversion because we truly did a we purchased assets that were 100% outside of the United States.

As far as earnings stripping, I think, from our perspective, the rules are still a bit gray, but the reality is it would be over the longer term and it would affect all companies. So, it's not just inverted companies that would be affected by the earnings stripping, it would be all companies that do earnings stripping as a part of having global operations.



**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Sure.

**<A Colleen Ostrowski Mylan N.V.:** And I think I would just add to that that it doesn't impact anything we already put in place post Abbott that allows us to enjoy the tax rate we have today.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** Right. Given the competitive dynamics in the EpiPen® space, when could we start seeing a tailwind on your branded product?

**<A Heather Bresch Mylan N.V.:** Well, look, I think you're already seeing a tailwind. I mean, we've seen we've continued to obviously take the market share from the Auvi-Q® recall. And I look, I've said before, I think EpiPen is a great product. But as we become larger and diversified, especially post the Meda closing, it'll be almost less than 5% of our sales. So, when you think about being an important product, but again not too heavily weighted, that the concern is if anything ever happens I've always said I think the bar to having an AB-rated product is very high. I continue to think that. I think and all the latest commentary would continue to support it's not in the foreseeable future.

So, we're going to continue to invest in EpiPen®. We're going to continue to invest in educating on anaphylaxis and reaching those at-risk patients. We still believe there are millions that need to be reached and need to be carrying their EpiPen®. So, look, I think you'll see opportunities for us to continue to have that price per pen increase, but it's because of that longevity. And us, again, I would say to everybody we take a balanced approach because we have huge portfolio that we're negotiating with these with our customers.

**<Q Sumant Kulkarni Merrill Lynch, Pierce, Fenner & Smith, Inc.:** With a few seconds left, I'm just going to squeeze in three quick ones. First, what's happening on your generic Copaxone? That's the first. Second, what would you need in the U.S. that you don't have already, which you might want to buy in terms of capabilities? And, third, how do you reconcile running a business versus being shareholder-friendly?

**<A Heather Bresch Mylan N.V.:** Okay. So, Copaxone is part of the backlog at FDA. I don't know what to tell you. I'm so tired of talking about Copaxone. The good news is I think we've met or exceeded all of the guidance we set out there in the last few years when we thought we should have had it. I mean, from our perspective, it could come any day, but don't hold your breath. As far as what was your second question?

**<A Colleen Ostrowski Mylan N.V.:** What we want in the U.S.

**<A Heather Bresch Mylan N.V.:** What we want in the U.S. So, look, as I've said, I look at the channel, the critical mass we have from our hospital business to our Gx business with retail to our Rx business. Our ability now to really just continue to feed these channels, like I said, just bring incremental value. We don't have critical mass around dermatology. I like that space. I still think there's great products and assets there. Ophthalmics, there is great assets available.

So, I mean, we're going to continue to look at things that we think just feed the infrastructure we have today. As far as shareholder, here is we have said that, yes, we're a stakeholder company and shareholder is the most important stakeholder that a well run company delivers value to shareholders. And I think, if you look at our track record over the last almost decade, we had a 28% CAGR between 2008 and 2015. We have our \$6 target out there. I think we've continued to deliver shareholder value and I think you can see for companies who I would say were only shareholder-friendly have perhaps incentivized the wrong behavior.

**Sumant S. Kulkarni, Analyst, Merrill Lynch, Pierce, Fenner & Smith, Inc.**

Thanks. We're out of time. Thank you again.

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

Thank you, thank you.