

# MYLAN N.V.

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SCHEDULE 14A  
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INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

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*On June 14, 2017, Mylan N.V. Chief Executive Officer Heather Bresch participated in the Goldman Sachs 38th Annual Global Healthcare Conference. Below is a corrected transcript of that discussion. Corrections in the text below are shown in {braces}.*

#### CORPORATE PARTICIPANTS

Heather M. Bresch  
Chief Executive Officer & Executive Director, Mylan NV

#### OTHER PARTICIPANTS

Jami Rubin  
Analyst, Goldman Sachs & Co. LLC

#### MANAGEMENT DISCUSSION SECTION

##### **Jami Rubin**

Good afternoon, everyone. I'm really, really happy and pleased to introduce Heather Bresch as our next speaker. As everyone knows, Heather is CEO of Mylan, and there's always a lot to talk about, but I think as a leader of the industry in particular, really, really good timing, and thank you very much for coming on.

##### **Heather Bresch**

Thank you.

##### **Jami Rubin**

I always enjoy our fireside chat sessions. So much to talk about, but I think one issue that's really important to address, it's kind of the white elephant in the room. We're just going to talk about it, get it out of the way, and I want you to address it. And that is it – let me set it up this way. We think that there is a ton of value in Mylan shares and you guys have...

##### **Heather Bresch**

We agree with you.

##### **Jami Rubin**

...but the market doesn't, that's where I'm getting at. So you've executed better than peers, you've had a more robust pipeline, you have a strong geographic footprint with superior balance sheet, but corporate governance issues continue to plague the stock, which now trades at a deeply depressed valuation. And, of course, there are lots of reasons for that, you look at your peer group, but this is a year where I think your performance should have been recognized, but it isn't, in large part because of, I think, these corporate governance issues and just recently the ISS letter addressing many issues including Robert's compensation, the \$100 million in the year that EpiPen kind of exploded, put pressure on the stock. So, here's my question, Heather. As CEO, firstly, is corporate governance important to you? Do you care about it? And more importantly, what are you going to do to remediate some of these issues and be responsive rather than just, oh, it's overblown? What specifically can you do to address them?

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**Heather Bresch**

Sure. No. Thank you. Of course, I care about governance, I care about Mylan, I care about our commitment to truly bring access to 7 billion people affordable medicine. We've got over a 55-year track record of doing that. So, of course, I care, and it's something that the board talks about, and those discussions, I promise you, take place.

As far as I think the recent headwinds, I guess the first thing I'd say is, I don't necessarily agree that the stock price and governance has that kind of correlation. I absolutely would say that our sector has had headwinds, and that there is sometimes this – I have stated it this way, that there is this brush, everybody with the same brush, and then kind of figure it out later. So I think that as our industry as a sector has gone through these headwinds, kind of everyone kind of lumped together, and I think – and I've said the onus is on us to differentiate ourselves, to talk about the diversification, the sustainability of our platform compared to some of our peers and why – and thank you for the shout-out on execution and performance, because I think that's a differentiator as well. I think that, as far as the ISS letter, I can tell you there's just a lot of misperceptions and misleading information out there. You brought up Robert's comp. This idea that it was \$100 million for 2016 is just not true, it's not based in facts. The reality is, he retired from an executive position after 15 years with the company, and moved to Chairman, and he did that back in May of last year, announced that in May of last year, {...} close to 90% of that number is for the 15 years that he served Mylan {or has been previously disclosed in proxy statements}. And when I look at, again, our track record performance, grew this company from a \$3 billion market cap to \$21 billion market cap. So I think to your point that performance, that track record, speaks for itself, and I think there's just a lot of misperception.

And so we, I can promise you, doing our part on education. I think, across the board, education on what the realities are of our governance and what's not true. I think that there is huge education in the generic industry. I've continued over these last 12 months when I realized the lack of appreciation of what the generic industry means to this healthcare system, from Washington across to consumers. There is just the isolation of the role that patients have played in their healthcare has just been minimal. And I think so – I would say, if there's a theme that I believe as a steward of this company and my most important role, it's education on all these fronts, from our shareholders to our patients to our legislature and regulators.

**Jami Rubin**

Is there any thought or any discussion internally about making some changes, even symbolic gestures that might address corporate governance? I think one other issue is, in addition to the Robert Coury compensation, which I think you did explain well, and, yes, I agree, it's been blown out of proportion, but I do think that when you look at how management is compensated at Mylan, is there some discussion about tying your compensation to total shareholder return versus hitting a certain EPS? I think there's skepticism again about that \$6 number because you'll get there come hell or high water because you'll get paid, but that doesn't mean the stock is going to work depending on how you get there. So, I mean, I think that that will go a long way in addressing some of the concerns.

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**Heather Bresch**

So, look, we were one of the first in this industry to tie our incentive comp to performance, for both long term and short term. So there is many factors that play into that, it's not just EPS. And what I would say, Jami, I hope people recognize it. If you look at the last decade or even the last five years of the CAGR that we've continued to deliver from our EPS growth while investing billions of dollars in R&D, so it's not as if, I know you can say we could have, but we haven't. We haven't sacrificed investing in from generic Advair to complex, to building a plant, a standalone facility for generic Advair. I mean, we have not short changed our investment, whether you look at biosimilars, we've got one of the largest portfolios in the industry.

So, what we could have done and what we have done, I believe, are two very different things. But our ability to continue to educate on some of these misperceptions are the fact that we're driven. The reality is I hope that what this also shows, not only our investments, but that long term, that we've continued to be a company that's delivered on the short term while investing in the long term, and that hasn't changed and it's not going to change.

I mean, like I said, we're right now from biosimilars to insulin, to the things that we're continuing to invest in. These aren't things that are for tomorrow. There are things to deliver over the next 10 years. When you look at the commercial platform, the infrastructure we've put together, again, that's to continue to deliver over the longer term. So, hopefully, our actions have spoke loudly that it is about long term, it was when we went global 10 years ago, and it is today as we're making investments in important products, in important therapeutic categories, and in new countries to continue to expand our presence.

**Jami Rubin**

But do you worry about your stock trading at a sub 6, 7 sort of multiple that you could be vulnerable to a takeout or is the stiching sort of poison pill that protects you from that? And by the way, investors would be really happy if you got rid of that. It may be a symbolic gesture, but that's one opportunity that doesn't exist for shareholders at Mylan that might at another company.

**Heather Bresch**

Look, I think that we've said we are open to everything, we're a public company, we'd be open to any conversation out there. I think that we said that Teva wasn't the right company and I think it's again, as you look, time has – I would hope that with time I said is that that was the right decision. So it's not about preventing or not allowing something to happen. I think if the right thing and that was the right opportunity, we absolutely would be open minded to it.

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**Jami Rubin**

All right. Let's talk about the business.

**Heather Bresch**

All right.

**Jami Rubin**

Clearly, it's been a tough couple of years for the industry. While Mylan has been able to skirt some of the headwinds afflicting many of your peers, you have faced some of your own headwinds, obviously EpiPen. How do you feel about the year sitting where you do right now, given that generic Advair got a CRL? I haven't seen the press release yet on Copaxone. How are you feeling about things? Just generally about where you're positioned is.

**Heather Bresch**

So, I'll talk about the macro and then we get them back on some of the product specific. Look, I feel good about where we are. If I look at the headwinds, you know I said this and when you think about EpiPen, we've said and I've been vocal about the fact that it was a window into a broken system. And I mean that sitting here today, and as it took EpiPen to be the catalyst for change that this country needs because I think that the burden we've put on patients walking up to the pharmacy counter is not sustainable. And I think that, while painful, I agree because of the lack of information, the fact is not mattering as much as the PR headlines can be frustrating, but I think that as a company, we are resilient and our fundamentals and our performance and our execution has allowed us to continue to navigate that.

And I said here today and I look at the conversation, the conversation is much different than it was nine months ago, people didn't even know there was a system. People thought the drug is manufactured and somehow it just shows up at the pharmacy counter and that there was nothing in between. And this wasn't about pointing fingers, and I continue to read some of the rhetoric around that. It was about exposing that there is a complicated system, it's a draconian system, and it doesn't work for healthcare today, healthcare benefit design that's putting the burden of thousands of dollars on patients.

So, let's look at the HELP Committee yesterday, a whole hearing and they're going to be two more on the entire supply chain. So you see that there is understanding that it is complicated. There is a system that's broken and needs fixed, and I can tell you we'll continue to play a role in trying to help what those right solutions are to make sure that patients are able to afford their medicines, get the benefit of the healthcare plans they're part of, and know what their product – the product is going to cost when they walk up to the counter.

As far as Mylan and our business, I've never been more optimistic. I mean, we've got a lot of great things in the pipeline. Yes, I can be frustrated on timing, but they're coming. I think that we've got a great pipeline. I look at the Mylan integration we talked about on Investor Day, that if I look now, say in Europe where we took Mylan legacy, we take the Abbott business and now Meda, and are really bringing that in-country, a lot of synergy and really that one Mylan approach from generics, branded generics OTC. We see that being a very winning strategy.

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We've continued to maintain leadership in France, grow in Italy, opportunities now where Meda had some strengths. You look at rest of world, we've got whole portfolio team dedicated to how do we maximize these assets. We haven't get these products into other territories. So, I've never been more optimistic about, I think, the assets we have today, but more importantly the infrastructure we have in place, that's going to allow us to bring in product portfolio opportunities. As you have said, there's a lot of weakness out there. So there's a lot of opportunity to pick up assets. We don't need the infrastructure. I can pick up whole product portfolios and put them in, whether it's in the United States or any other part of the world.

So, I've never been more upbeat about our business, more confident about where we're headed, and more excited about, honestly, the kind of products and therapies whether its biosimilars, insulins and really, again, working on making sure that we're making products affordable and accessible. I mean, the access is just as important. I think the recent Supreme Court ruling on biosimilars yesterday is all these are important steps forward.

**Jami Rubin**

So – but today as we sit here, generic Advair didn't get approved. I haven't heard anything on Copaxone. There has been a slowdown clearly in complex generic drug approval.

**Heather Bresch**

No question, there has been. I would tell you that we are working steadfastly to get these over the finish line. As far as Copaxone, on the 20 milligram, we very recently got an information request. We're responding to that real time. I certainly would hope, as we're here at the end of a quarter and coming into our earnings call, we'll be able to bring you visibility and clarity on what that is, but I can tell you, we're answering that.

**Jami Rubin**

So, you won't get it approved in June?

**Heather Bresch**

I don't – we could. We absolutely could. We got an information request. We're responding to that. And so that would be totally in the FDA's hands on this, but I can't speak for them, but it could get approved.

**Jami Rubin**

So that, like can you tell us to of the nature of the information?

**Heather Bresch**

No. What I can tell you is that, we feel confident we can answer everything. As we've said, we had a CRL previously, we answered that in full. We received this information request, we're confident to respond to that, like I said, very, very timely. And...

**Jami Rubin**

Does that require a meeting with the FDA?

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**Heather Bresch**

No, not necessarily, it's much more fluid in the sense that what they've asked for us getting to them, and then let us see where that takes it. It could lead to being able to be approved or it would require a discussion that is certainly not – it doesn't necessarily dictate one.

**Jami Rubin**

So, did the action date actually come and go? The target date that's...

**Heather Bresch**

So we have said that both the 20 and 40 were in June. And like I said, we recently got the information request on the 20.

**Jami Rubin**

Okay.

**Heather Bresch**

And we haven't gotten anything yet on the 40.

**Jami Rubin**

So, does that actually resolve before the 40 is approved?

**Heather Bresch**

There are separate applications, it won't necessarily – it doesn't necessarily mean that.

**Jami Rubin**

Okay. Most of your competitors have warned about continuing headwinds from the evolving buying consortium groups, specifically the impact of ClarusOne, which I don't think has even gone into effect yet, you're still in the process of negotiating, and they recently announced Express WBAD, et cetera, right?

So, it's just – what's interesting is that we've had some generic companies here at our conference, and it seems that because of Mylan's global diversification, that the company is somehow protected from those pressures. Can you better explain why that is, why you are less impacted? Because one of the companies who spoke either earlier today or yesterday said that the buying consortiums are negotiating on a product-by-product basis, therefore having a broad portfolio is no advantage. I never really heard that before, but why – or maybe things are changing for you, but the company's line has been, nothing has changed. We're sticking with our gut, we're sticking with our forecast. But it does seem that the headwinds are gathering steam and other companies have acknowledged that, but Mylan.

**Heather Bresch**

We have said, mid single-digit price erosion in the U.S. market, and so I can't speak to other competitors or their product portfolios. What I can say is that not only, I think, our globalization is one factor, that diversity, because as this consolidation happens, many of them are becoming global themselves. So, again, what we've said and what



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we've seen over the last couple of years, their need for more product, more supply, the reliability of that supply are all extremely important, and I think again Mylan has earned a track record of having a reliable supply, a global supply chain where we control a lot of our own destiny because of our internal integration, both vertical and horizontal, of our product line.

And then when you look at the U.S., our diversification, we have over 635 products in the United States across all therapeutic categories, dosage forms. So, our ability to absorb that, I think, speaks a lot to that. I mean, a lot of companies have more niche portfolios, are concentrated in one therapeutic category or one dosage form. We'd certainly expand. And then our pipeline. I think our investment in these products that are important and that bar to entry is higher, and so I think all of that creates more of, let's call it, a level playing field or ability to have a more win-win with our customers. So, with that being said, I said this all the time, this industry is competitive, it always has been.

The Generic Association released yesterday numbers on '16, 89% of the prescriptions filled in the United States, that's 3.9 billion scripts, are with generic products, and those costs, not savings, because I think people – because it doesn't go into your pockets, the savings number seems meaningless, but the cost of that was \$110 billion.

The last 11%, the 500 million scripts, on the brand side, cost \$330 billion. So you would have to believe that the 3.9 billion scripts for \$110 billion is a pretty good deal, and that that competitiveness is robust, it always has been and always will be. So, I'm not sitting here shying away from the competitiveness, what I'm saying is, because of our diversification and ability to absorb and have, be able to, if one area has got – has more volatility, we have another area that perhaps is able to offset that, and now being able to do that on a global basis, just gives more ability to absorb.

### **Jami Rubin**

Just in general though, how far can these consortiums groups go in terms of trying to extract savings from the manufacturers?

### **Heather Bresch**

Look, I think that's a question that is going to continue to maybe be asked from a competitive perspective. I mean, again, on the education front, you can have all the competition you want on the manufacturing side, but you need competition all the way through. So I think that there is a lot to be said for how much further, how much can this consolidation, because I think the robustness of that competition, if you only have it on one piece of the pie and it's not as robust as perhaps it needs to be on the other pieces, there – that's an inherent conflict. And I think that the more people understand the supply chain and perhaps the competitive or the lack of at any part of it can only help, because like I said, I think a lot of these things and decisions made in our country have happened, with not really appreciating how it affects perhaps the entire ecosystem.

### **Jami Rubin**

I think that if I remember, on the last earnings call, you predicted \$850 million in global new product sales this year. Yet, so far, you've missed out on some of the higher value

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approvals like Vytorin, Seroquel and Strattera. And we're still waiting on the others, Copaxone, which will hopefully be soon and generic Advair. How do you feel about that \$850 million projections? I think – I mean, if you could help us with the number of approvals, I think it's over 10, none of them are big needle movers, but there have been approvals this year, but help us to put that \$850 million into context. That seems like a stretch now.

**Heather Bresch**

Well, look we've had 20 approvals. And, look, I'm coming here at the end of the quarter, our earnings call will be coming up. I can promise you that if we need to update that or need to do anything, we will absolutely do that at that time. But – so like I said, I won't say anymore on that, except that, like I said, we've had 20 product approvals and absolutely still believe there is some important ones coming.

**Jami Rubin**

What is happening though with some of these, like the Vytorin, Seroquel, Strattera? What – like, why haven't you gotten approvals on those?

**Heather Bresch**

Look,...

**Jami Rubin**

I think one was tied to the...

**Heather Bresch**

Yeah.

**Jami Rubin**

...the manufacturing.

**Heather Bresch**

Right. So, look, they all have a different story. I think that, as I said in the beginning, there is no one more frustrated at some of the delays at the FDA. Again, as we're going through – as our sector is going through this cyclical storm that we're in, I think that if you look at FDA, they're going through the most transformation they've ever had since they've been an agency. So, inherent in that is a lot of change and unfortunate delay. I will say that we have been in constant communication, and I think that our ability to, like I said, work towards getting these over the finish line is definitely in the near term.

I would also say I'm very encouraged by Dr. Gottlieb. I've known him a long time. He has been at the agency two other times before. He's been in the trenches. He understands how theater works. He understands the importance of generics. I think he's commented on the need to really bring a focus to complex generics and be able to recognize first to market formation and their importance. So I think that certainly helps to have a leader come in that appreciates and understands, and more importantly understands the inner workings of the agency, will go a long way.

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**Jami Rubin**

I think during the conference call, the first quarter, Tony warned of a tough year-on-year comparison in the coming quarters. Can you clarify that? I think that's more related to that comparison.

**Heather Bresch**

Yeah. I think he was just pointing out that sometimes people, if – when you look at first-to-market opportunities and not even just necessarily in the quarter they happen but as you know that can stretch over a couple of quarters, that it's just important to be able to be able to kind of look at apples-to-apples. So I think we will continue, as quarters come, to be able to highlight that; whereas there is a year-over-year comparison issue, to make sure we do our part in calling out that – why that may exist or what we could have launched in the previous year that would have given kind of bumpiness versus when you look back over a year in totality.

**Jami Rubin**

I want to talk about some of the acquisitions you've made. Mylan's obviously been very acquisitive over the years, Abbott's EPD business, and remember when that was first announced, there was concern because revenues were in decline. You've turned that around. But there hasn't been as much visibility on the Meda acquisition or Renaissance, but particularly Meda because at the time that that business was acquired, I think there were issues with that book of business with some pressure. What can you tell us about Meda and Renaissance, and where you are in the transition, and are you able to generate value from those acquisitions?

**Heather Bresch**

Yeah. No. Absolutely. And I think that when we came out at Investor Day, we did break out Meda and Renaissance...

**Jami Rubin**

Yeah. Right.

**Heather Bresch**

...from our existing business, and we'll do that this year. So you'll continue to see the contribution from the acquisition from our legacy business. Look, we have said – and as we've done acquisitions, we've always said that it's not what they've done on a standalone basis, it's what we believe we can do together. And I think if you go back to after the Merck acquisition, from Bioniche to Agila to – we've continued to prove that the integration and how we integrate does allow us to get more out of these assets. I think, to your point, we showed it on Abbott. I can tell you we are at or exceeding anything we thought with Meda and Renaissance. And I think as we've said, it's not just about now bringing them into the fold. We really have stepped back last year and said, it's really about now integrating Mylan, because we had these three distinct platforms both from Abbott, Meda, and Mylan legacy. And our ability to – in countries really maximize that physician call point, the pharmacy call point. As you know, country by

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country is extremely different, and the ability to be able to have that pull through works very differently.

So, I'm really pleased, and I think we're in early days of seeing the benefit of that. I think we'll see it throughout 2017 and 2018, of us really being able to maximize these assets that we've brought from a Mylan portfolio. And then, most importantly, taking these assets and bringing them to other geographies, right? And we've spent a lot of time and have a team dedicated to just that, to looking at these products, how do we bring these into other countries that we didn't necessarily have a large presence in before.

**Jami Rubin**

So, will the benefits stay on the cost side or on the revenue side, and when should we start to see [indiscernible]?

**Heather Bresch**

I think it's on all aspects. I would say that probably the least area, I mean, it's not from a – it's not necessarily heavy on the cost reduction, from a taking out head count, it's much more – there is synergy in infrastructure. If we were running in a country three separate offices and three separate teams, being able to pull that together in one location, so there is inherent cost reduction. Yeah, there is revenue opportunity and there is bottom line opportunity because as we're able to leverage infrastructure and leverage country to country, whether it's marketing plan, the benefit that we'd now be able to – have been able to create are these global centers.

We have a global center in the U.S., we have one in Budapest, we have one in India, that's really allowing us not only kind of best practices and consistencies, but leverage a lot of work, great work that – whether it could have been in India launching hep C product or one of our biosimilars to – our HIV and being able to take that platform and bring other products now because we've got that infrastructure and relationships within the developing countries. So, like I said, I couldn't feel better about our ability to really – over these next couple of years, really maximize the assets that we pull together and while we're doing so, continue to look at product opportunities. I think there is a ton of opportunities out there right now. I think it's a buyer's market for assets.

**Jami Rubin**

On that question, obviously, the industry has been in turmoil, and we would expect that there would be continued consolidation. Understanding that Mylan would likely be a buyer and to take advantage of that, how do you value generic assets when the industry is evolving so rapidly? And I don't want to bring up a sorry subject, but I'm going to anyway, because I feel comfortable saying anything here, but Perrigo was on the brink of a free fall before you made a bid for that company. So, in...

**Heather Bresch**

Before or after, I think.

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**Jami Rubin**

No. After, after, right? But anyway, the point I'm making is that, how do you value these assets when the industry is evolving so quickly and you have to forecast how fast or how slow these assets are going to grow before you put a multiple on them. How do you do that?

**Heather Bresch**

So, look, I think you've got to be very grounded in why you're doing the acquisition. If you do an acquisition for acquisition's sake, and I think we've seen those companies that were just serial acquirers for the sake of acquiring, and if that strategy doesn't hold together and there you run into volatile times, like you are now, the house isn't very strong. I think that where Mylan and sometimes we weren't doing as many or people were like, why aren't you just doing it and wiping out R&D?

And we've said, we certainly pay attention around the financial parameters, but most importantly, with bringing it in-house, how do we do more with that together. And in the sense of Perrigo, it was around OTC and changing that leverage dynamic with our customers. And I'm still sitting here today, say back then that was – that, I think, would have been a good call. I think we've gone well past that and I think that our ability to bring in and grow the OTC, we've got a lot of opportunity in that space.

So I think it's about making sure you're grounded in the fundamentals about why you're acquiring something and then if you are, people are going to need medicine and people want – not only do they need medicine, they need access to it. So I think that as healthcare evolves and as we get closer to the consumer and closer to the patient, the opportunity for the low-cost alternative is going to even grow more, past the 89% that we have today. I think that reach into other therapeutic categories and dosage forms and everything else are still a great bit of opportunity. So, like I said, it's being grounded in the value and what you can do together, and I think that's quite honestly why we've been able to be successful in these integrations and why we're pretty stingy and make sure that it is the right fit and that it makes sense.

**Jami Rubin**

Can you tell us – in buying Meda, you increased your exposure to OTC – to the OTC business. Can you tell us more about your efforts to get bigger in that space?

**Heather Bresch**

Sure.

**Jami Rubin**

Are you talking about branded or national brand OTC or store brand OTC that competes with companies like Perrigo, can you describe it a little bit more?

**Heather Bresch**

Yeah. No. And we've said part of diversification is not – while we diversified geographically, we diversified from a product portfolio perspective. I think we will continue, and I'm interested in continuing to diversify from a reimbursement perspective.

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And so I think as you look at businesses like OTC that aren't subjected to the reimbursement model, again it's just more diversification that allows you to absorb where there is volatility in any other area of your business.

So I think we've got – we're looking at a whole host of strategies around OTC. You saw our Cold-EEZE deal earlier today, which was a national brand. I think there's opportunities for us with some of our prescription product as we look at being synergistic, at going over-the-counter. I think there are certain therapeutic categories that we have a larger presence in. So we're not in a – the good news is, because it's not related to a company and we're doing this by products and pulling in asset, we're able to really build this in a tailored fashion way that I think, again, will let us kind of maximize and not kind of have bringing along the whole infrastructure.

**Jami Rubin**

We don't have much time but I want to make sure we touch upon your biosimilar program, because I think you are far more advanced than most people appreciate. Tell us about where you are. I know you...

**Heather Bresch**

And – look, it's exciting. We have an AdCom coming up in July, I think middle of July. I think, again, we've been in constant discussions with the agencies, with the advocacy groups, with key opinion leaders. I think that the affordability and the access needed to these important products is just by necessity. And I always say necessity is going to make things happen. I had said that if you look back at Hatch-Waxman, when it came into being in 1984, it really took. We didn't even have 180 days till the mid-1990s. So it took almost a decade of litigation to get us to – to be – and able to really fully optimize that innovation competition.

I said the same about biosimilar. That law passed back in 2009, and so if you apply kind of that same framework to it and say it's going to take at least a decade to work our way through, so I'm excited about not only having the most robust portfolio, I'm also excited about as we're reaching here to 2019, 2020 and you see things like the Supreme Court ruling the other day, that the regulatory framework is really catching up to, I think, the need that this country has for these important products. I look at insulin, our ability to get a AB-rated product, I think we feel very good about. So I think that there is a lot coming over this next decade that's going to bring tremendous value, tremendous – something that this country is going to desperately need.

**Jami Rubin**

When do you expect to have [indiscernible] on the market?

**Heather Bresch**

I know – I think, again, we'll update if there is any updates to that. From what we said, I think that things like what happened in the Supreme Court yesterday can impact that, so we'll be – I promise that when we come at earnings call, if there is any updates to give on these products or timing around that because of dynamics changing in the market, we will do that.

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**Jami Rubin**

And can you just lastly update us on your CRL related to generic Advair? What are the steps? I know you had talked about on the last earnings call a meeting with the FDA...

**Heather Bresch**

Yeah.

**Jami Rubin**

Have you had that meeting yet?

**Heather Bresch**

We have not had the meeting yet, but we have certainly responded. We've started sending in our responses to these questions in some of the areas where we said we had a difference of opinion on, and all of that ahead of getting in there for absolutely a face-to-face meeting. And again, I hope, by the time our earnings call comes, that we'll be able to give a report out on that.

**Jami Rubin**

Is it a question as to whether or not you have to pursue a human factor study or is that...

**Heather Bresch**

Well, look, I think that we feel confident we can give the responses that's needed, and I think – and again I need to wait till these conversations happen about some of the areas that we feel that we disagree with on their categorization.

**Jami Rubin**

Well, now, presently, we've run out of time.

**Heather Bresch**

Thank you very much.

**Jami Rubin**

As always, it's been a pleasure.

**Heather Bresch**

Thank you. Thank you.

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## Forward-Looking Statements

This communication contains “forward-looking statements.” These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about the acquisition of Meda AB (publ.) (“Meda”) by Mylan (the “Meda Transaction”), 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 potential benefits and synergies of the EPD Transaction and the Meda Transaction, future opportunities for Mylan and products, and any other statements regarding Mylan’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,” “target,” and variations of 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: 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; actions and decisions of healthcare and pharmaceutical regulators; 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, the Meda Transaction, and the December 2016 announced restructuring program in certain locations, within the expected time-frames or at all and to successfully integrate the EPD Business and Meda; with respect to the Company agreeing to the terms of a \$465 million settlement with the U.S. Department of Justice and other government agencies related to the classification of the EpiPen<sup>®</sup> Auto-Injector and EpiPen Jr<sup>®</sup> Auto-Injector (collectively, “EpiPen<sup>®</sup> Auto-Injector”) for purposes of the Medicaid Drug Rebate Program, the inability or unwillingness on the part of any of the parties to finalize the settlement, any legal or regulatory challenges to the settlement, and any failure by third parties to comply with their contractual obligations; 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, including but not limited to generic Advair, to market; success of clinical trials and Mylan’s ability to execute on new product opportunities, including but not limited to generic Advair; any changes in or



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difficulties with our inventory of, and our ability to manufacture and distribute, the EpiPen<sup>®</sup> Auto-Injector to meet anticipated demand; the potential impact of any change in patient access to the EpiPen<sup>®</sup> Auto-Injector and the introduction of a generic version of the EpiPen<sup>®</sup> Auto-Injector; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, 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; 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 of America 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, 2016, as amended, and our other filings with the Securities and Exchange Commission (the "SEC"). 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 filing date of this communication.