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Mylan N.V. (MYL) CEO Heather Bresch on Q3 2019 Results - Earnings Call Transcript

Nov. 5, 2019 5:33 PM ET17 comments | 2 Likes

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Q3: 11-05-19 Earnings Summary

Press Release *10-Q* *Slides*

EPS of $1.17 beats by $0.03 | Revenue of $2.96B (3.47% Y/Y) misses by $-44.99M

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Mylan N.V. (NASDAQ:MYL) Q3 2019 Earnings Conference Call November 5, 2019 10:00 AM ET

Company Participants

Melissa Trombetta - Head, Global Investor Relations

Robert Coury - Chairman

Heather Bresch - CEO

Rajiv Malik - President

Tony Mauro - Chief Commercial Officer

Ken Parks - CFO

Conference Call Participants

Randall Stanicky - RBC Capital Markets

Chris Schott - JP Morgan

Elliot Wilbur - Raymond James

Umer Raffat - Evercore

David Risinger - Morgan Stanley

Greg Gilbert - SunTrust

Operator

Good morning, my name is Lisa, and I will be your conference operator today. At this time, I would like to welcome everyone to the Mylan Third Quarter 2019 Earnings Conference Call and Webcast. All participants have been placed on mute to prevent any background noise. After the speakers' remark, there will be a question-and-answer session. [Operator Instructions] Thank you.

I will now turn the call over to Melissa Trombetta, Head of Global Investor Relations. Please go ahead.

Melissa Trombetta

Thank you, Lisa. Good morning everyone. Welcome to Mylan's third quarter 2019 earnings conference call. Joining me for today's call are Mylan's Chairman, Robert Coury; Chief Executive Officer, Heather Bresch; President, Rajiv Malik; Chief Commercial Officer, Tony Mauro; and Chief Financial Officer, Ken Parks.

During today's call, we will be making forward-looking statements on a number of matters, including our financial guidance for 2019 and the proposed transaction pursuant to which Mylan will combine with Pfizer Inc.'s Upjohn Business in a Reverse Morris Trust transaction. These forward-looking statements are subject to risks and uncertainties that could cause further results or events to differ materially from today's projections.

Please refer to the earnings release we furnished to the SEC on Form 8-K earlier today, as well as our supplemental earnings slides, all of which are posted on our website at investor.mylan.com for a further explanation of those risks and uncertainties and the limits

applicable to forward-looking statements.

Mylan routinely posts information that may be important to investors on this website, and we use this website address as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure. 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. We will refer to these measures as adjusted and present them in order to supplement your understanding and assessment of our financial performance.

Non-GAAP measures should not be considered a substitute for or superior to financial measures calculated in accordance with GAAP. The most directly comparable GAAP measures, as well as reconciliations of the non-GAAP measures to those GAAP measures, are available in our third quarter earnings release and supplemental earnings slides, as well as on our website.

Please note that this call released to Mylan's third quarter 2019 earnings and we will be limited in what we can speak about during Q&A regarding the new company, and we will not be speaking about Upjohn Business. Let me also remind you of the information discussed during this call, except for the participant questions is a 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'd like to turn the call over to Robert.

Robert Coury

Thank you, Melissa. Good morning everyone with a special hello and welcome to all my own employees around the world and to the Upjohn employees who will be soon joining forces with us. I would like to provide you with a brief update regarding the proposed combination of Mylan and Pfizer's Upjohn Business, which we announced in July. But before I do, I would like to briefly remind all of our Mylan's stakeholders, some of our Board's rationale for this very powerful strategic and financial transaction.

The Mylan has a standalone company. This transaction represents an acceleration and combination of our own long stated goal of building a truly one of a kind global platform, positioned to serve and deliver high quality affordable medications to patients around the world. The transaction will be what I described as Mylan's final legacy transaction. The combination with Upjohn, not only achieves our original goal, but it does so well expanding the geographical reach and scale that Mylan start to create on its own.

In that context, it also allows Mylan to accelerate the expansion of its broad product portfolio in future pipeline, particularly in the Asia-Pacific region for example in countries like China. At the same time, we do expect Mylan's existing business to benefit greatly from the significant assets that Upjohn will bring to the new company. In particular, the new company will have the benefit of Upjohn's own high quality iconic brand portfolio. Its own highly talented workforce, needed bench strength and expertise, especially in the emerging growth markets and an enhanced commercial platform.

Overall, I am very impressed with the talented and committed to Upjohn team members, whom I've met since the announcement. And I know that the Pfizer and Mylan teams are continuing to work hard to transfer all the requisite commercial and other assets to a standalone Upjohn prior to the combination with Mylan, taking into consideration, these two expected transaction benefits, as we have listened to input from many of our shareholders and other stakeholders overtime.

And in light of Mylan's recent strategic review intended to find ways to unlock the unrealized value that we believe still exists in Mylan today. The Mylan Board of Directors decided to take this opportunity to create a new company, Newco. By combining Mylan with Upjohn's business, two highly complementary businesses establishing a truly unique new company profile with no direct pharmaceutical peer set.

Newco will represent more than just a new name. Once the transaction closes, Newco will have a new strategy, a new operating model and a further differentiated product portfolio as compared to Mylan today, as well as even a stronger balance sheet with new financial profile that will emphasize a renewed focus on capital returns to shareholders through anticipated dividends and softly purchases.

Newco will also be a Delaware company with a shareholder concentric governance model and then expand the new management team comprised of both Mylan and Upjohn executives to support the new operating model going forward.

With that said, one thing will never change at Newco, neither from the perspective of Mylan nor Upjohn, and that is our steadfast commitment to provide high quality medicines to patients around the world, while serving Newco's employees, our customers, the communities in which we operate, and Newco truly will create a new champion for global health.

We also envision that Newco will be placing much more emphasis and focus on total shareholder return and striving to earn multiple expansions from a market. We believe that once investors have had the opportunity to learn more about the newly created company and its unique profile, its differentiated platform and its ability to deliver sustainable and more predictable results overtime. Investors will eventually afford Newco a rerating in this market multiple relative to Mylan on a standalone basis.

This is obviously something that is not going to be automatic, but instead will have to be earned and earned overtime and I assure you Newco will be up for the task. The Mylan Board of Directors set the clear first example, when it signal to investors that is willingness on its own accord to return the Company back to the United States and organize the Company in Delaware. We continue to make good progress on the integration and other regulatory steps to be taken prior to closing.

We will also at the appropriate time continue to visit and speak with both the Mylan and Pfizer shareholders over the coming months, as well as sell-side analysts to communicate our commitment to the success of a new company and help them better understand and appreciate the value creation opportunity that can be derived for all stakeholders.

Since the announcement, I've been spending a considerable amount of time with both, Michael Goettler, the new company's incoming CEO; and Rajiv Malik, Newco's incoming President, both independently as well as together. To discuss Newco's anticipated key company initiatives, considerations and priorities, I'm very pleased to report that the Mylan Board is very encouraged with their progress and collaboration today.

We truly believe that Michael and Rajiv represent the right combination to deliver the real power of what both organizations are bringing to the table. In addition, I've spent time with other executives on both Mylan and Upjohn teams and can already see and feel the power of what those individuals will also be bringing into Newco.

I would like to thank our current CEO, Heather Bresch for not only her continued leadership here at Mylan but for also playing a key role and working very closely with Pfizer, Michael and Rajiv to help lead our integration planning efforts for Newco. I would also like to thank Ken Parks for his continued contribution and his efforts for this critical stage of transition. In terms of the new CFO search, things continue to progress well and we fully expect to have one announced before closing.

I am excited about Newco's new management team and other future senior executives of Newco who will be playing a significant role in optimizing total shareholder return by demonstrating their ability to execute flawlessly on Newco's new strategic plan, while consistently delivering on their financial objectives. This will be one of the most critical variables, if we are truly to earn the multiple experiences that I discussed above.

I would also like to note there since our announcement, I have been on the road with Michael and Rajiv and others as well, to meet with shareholders, in addition to sell-side analysts to not only discuss the transaction, but also what we believe to be a solid roadmap for Newco and its management team to focus on and to execute against.

And lastly and before I turn the call over to Heather, to discuss what today's calls really all about, which is Mylan's third quarter and year-to-date performance, I would like to comment on one question we received on the S-4 that was recently filed in connection with the transaction.

I would simply like to point out that the internal financial projections in the S-4 are not and should not be used as financial guidance for Newco. The financial guidance for the new company will only be delivered by Newco's management at or around the time of closing, which is still on track to occur in mid 2020.

What I can tell you is when Newco's management does provides initial financial guidance and targets to investors, I fully anticipate that you will be given a strong range of revenues, EBITDA, EBITDA margins, and shown significant free cash flow generation and provided other financial metrics that will be very important for shareholders.

My expectation is that the guidance they provide will also fully account for all the questions that have been swirling around and the new ones that even may come up, whether it's the VPP in China or Lyrica and the United States, or Lyrica in Japan, et cetera and on and on. The new companies management will fully incorporate their assessment of the potential risk, but even more importantly, the potential upside opportunities known at that time.

In closing, I can certainly tell you that everything I have learned on both sides of the equation. Since the announcement has only further confirmed my excitement, my competence, and not only the powerful rationale for this transaction, but the anticipated strength of a combination of these two highly complementary businesses, and the ability of the new companies that deliver real value to shareholders based on our new business model over the long and sustainable future ahead.

I will now turn the call over to Heather, but we'd like to emphasize what Melissa mentioned that we will be limited and what we can speak about on the Q&A regarding the new company and we will not be speaking about Upjohn's business. Thank you.

Heather Bresch

Thank you, Robert. Good morning everyone and thank you again for joining today's call. I would first like to reiterate Robert, the Board and management's continued enthusiasm for the progress we're making on the path for the successful close for the combination of Mylan and Pfizer's Upjohn business. As Robert highlighted, the combination not only makes good financial sense, but also will make a meaningful difference for the patients we serve.

Importantly, the deal also has the potential to create opportunity for Mylan and Upjohn colleagues around the world. For those Mylan employees joining us on today's call, thank you for all that you continue to contribute to bring our mission to life each day. I'd also like

to welcome any Upjohn colleagues who may be listening in. We look forward to continuing to collaborate with you as we work towards next steps and the successful combination of our two companies.

As we prepare for the closing of the Upjohn deal, we are still continuing to focus on the previously announced transformation of Mylan business. You'll recall from previous calls, we view this work as an opportunity to unlock latent value within the organization and instill additional focus on economically profitable performance. We have now begun the execution phase of our transformation.

Rajiv will share more detail in his remarks. However, at a high level, we have applied a highly disciplined financial lens to the assets we've integrated and built throughout the Company in order to streamline our portfolio, right size investments and improve the efficiency of our company's operating model.

Our approach across the board with business transformation has been very purposeful. Purposeful and how we rationalize operations and purposeful and how we invest. You'll see some of the levers we've been pulling reflected in this quarter's results. However, it's important to note that our meaningful transformation will be a multiyear process. So one quarter cannot be a proxy for the long-term profile of the Company.

At a minimum, it would be best to view our results on a year-to-date basis, where you will see that we are aligned with the ranges we provided in the beginning of the year. The strength of our performance highlights our holistic, intentional and focused approach to managing the overall health of the Company for today and the long-term. Today, steps we've taken to rationalize value consuming volume from our global portfolio of products are reflected in the top-line this quarter.

Notwithstanding, we grew every region year-over-year on a constant currency basis. And on a year to date basis, we achieved 3% growth in total net sales, with all segments contributing to the positive results on a constant currency basis. Adjusted gross margins were down slightly for the quarter; however, despite ongoing pricing headwinds and changes in the competitive environment this year. We have been able to maintain our target total company adjusted gross margins of over 53% year-to-date.

For the balance of 2019, we remain confident the Company's ability to execute and in fact have already achieved the milestones necessary to reach our expected full year results. Year-to-date, we've already launched 800 million and new products and remain on track to have more than a billion for the year including our launch of Ogivri, our biosimilar to Herceptin, which are expect to occurred within the coming weeks.

We also see adjusted free cash flow sequentially improving in Q4, resulting from the normal cadence of the business along with realized benefits from targeted working capital initiatives. The strong cash flow generation will help fund the remaining portion of the 1.1 billion of debt pay down we committed to at the beginning of the year.

As we close out the year, we will remain extremely focused on execution in order to deliver on our commitments. To that end, we are tightening our guidance within the ranges we provided at the beginning of the year including $11.5 billion to $12 billion in total revenues and 422 for 440 in adjusted EPS, while maintaining our expected adjusted free cash flow range of $1.9 billion to $2.3 billion.

With that, I'll turn the call over to Rajiv and Ken for additional detail on the quarter before opening the line for Q&A.

Rajiv Malik

Thank you, Heather. I would like to echo my excitement about the proposed combination between Mylan and Pfizer's Upjohn business. As we continue to plan for integrating the Company, I look forward to working with Michael and other members of Upjohn management team to ensure our shared success. At the same time, I can assure you that we as Mylan today, have a steadfast dedication to our standalone execution and are highly committed to finishing the year strong.

I'm proud of all of our employees who work tirelessly across the world to increase access to the medicine each and every day. I would like to take a moment to thank them for their continued commitment and hard work. I also would like to welcome any Upjohn employees who are on this call. Let me start by providing an overview of our business results by region.

Starting with North America, we had high single-digits net sales growth of 8% in comparison due to previous year. The increase was primarily influenced by the strong execution and performance of several key products.

Starting with Fulphila, we have been able to accelerate the expansion of manufacturing capacity and are optimistic to operationalize within the very near term. With the entire backfill growth to market going at a high single-digit and only 23% of the total Neulasta market converted to biosimilars, the underlying demand is there and we're confident that we will play a meaningful role as a continued expansion of this market.

Next, the launch of our novel once daily LAMA, Yupelri has met our initial expectations and is now gaining further momentum. Yupelri today has 83% market share of nebulized LAMA market. We see this as a short-and long-term opportunity in a critical therapeutic disease state.

Moving onto generic Copaxone, we have strong demand with current market share exceeding 35% as we continue to meet patient needs on this important product. We continue to see uptick on growth as the new prescriptions are now greater than 40% market share.

We also are happy that Wixela is steadily gaining market share and that's now cost 30% despite a very aggressive share attention strategy taken by the bank. We remain optimistic that it will continue to steadily grow and remain durable for the product as we look ahead to 2020 and beyond.

And last but not the least, we continue on our journey to expand access to our biosimilars stress road map, Ogivri. We have secured regulatory approvals in more than 75 countries globally and are on track to launch in U.S. in coming weeks. We expect to be the first company to bring core strength of the product the 120 milligrams and 150 milligrams to the market.

Moving to Europe, net sales were up 6% on a constant currency basis in line with our expectations. We are making good progress across daily markets and being prudent where we invest to optimize market returns. Influvac, Creon, DYMISTA performed above

expectations, and are continuing to go year-over-year. We were especially pleased with Germany's growth for key products including Hulio, our biosimilar to Humira and Influvac.

In the rest of the world segments, net sales were up 4% on a constant currency basis. This increase was primarily driven by the new product sales in Australia and emerging markets and higher volumes of existing products including growth in our global key brands such as Dona and Elidel as well as our biosimilar.

I would like to share a few highlights related to our pipeline. For bevacizumab, a biosimilar to Avastin in collaboration with Biocon, the top-line clinical results for our Phase 3 study, a non-small cell lung cancer have met the necessary endpoint criteria. Mylan is on track to submit the U.S. BLA by the end of this year. The EU submission will follow in Q1 of 2020. Additionally, we have initiated a Phase 3 clinical trial for insulin aspart. Our U.S. regulatory application was accepted for review at the end of October.

Our FDA submission is on track to be submitted mid next year, and we are projecting to launch the product in the second half of 2021. For insulin glargine in collaboration with Biocon, we have received more than 40 regulatory approvals and recently launched in Australia. For the U.S. market, Mylan received a complete response letter in August 2019. The CRL confirm that the scientific matters of the review were closed and found acceptable.

Biocon and Malaysia are addressing the Malaysia facility concerns and are committed to resolve these in a timely manner. We are working closely with FDA and remain optimistic for a first quarter approval prior to the transition date to a biology. Regarding Hulio, our biosimilar to Humira, with our partner FKB, we remain on track for a 2020 launch in USA. We now have regulatory approvals in nearly 30 countries.

For our biosimilar to EYLEA [indiscernible] being developed in collaboration with Momenta, under Mylan lead, our pivotal global Phase 3 clinical trial is underway and we continue to target U.S. submission for quarter one of 2021.

Regarding our partnership with Revance for a biosimilar to BOTOX, the FDA meeting has earlier this year showed the biosimilar pathway to be viable. We extended our decision timeline with Revance to the first part of 2020. In the meantime, Revance will be working

to provide some additional deliverables related to the program.

Our partner Mapi recently announced the enrollment of the first patient in its Phase 3 study for Glatiramer Acetate once a month depot. This is a key clinical study for our U.S. submission. We are excited to have this phase underway and continue to be encouraged by the scientific success of this program.

Now I would like to further build up on Heather's comment on our business transformation program. We have completed a holistic review of our business plan and developed an integrated transformation plan for Mylan's standalone business. We have already begun the implementation of this plan which will continue into 2020 prior to and concurrent with Upjohn integration.

The business transformation program includes; rationalization of products not earning their cost of capital, refocusing commercial resources to promote further growth of our most responsive product, while improving margins of unresponsive product, and further centralizing and rightsizing our commercial and operating infrastructure.

Let me walk you through some examples, our first area of focus was on product rationalization. For example, in U.S., the customer consolidation and market dynamics have continued to put pressure on prices of some of our oldest commodity products, and as a result, product margins have been driven below fully loaded economic cause. To date, we have decided to rationalize more than 350 SKU across all solid doses.

Throughout this process, the FDA shortlist has been top of our mind along with the patient and customer specific needs. While the rationalization does not impact us from the bottom line, it does have an impact on our top line results. Another area of review was on refocusing our commercial resources.

A comprehensive assessment of the sales responsiveness of commercial investment has been conducted across all major markets, and at the general product level to determine where we should direct our future commercial spending. This work has highlighted the opportunity to further optimize for SG&A expenses in the near-term, while evaluating potential revenue growth in future years. We'll continue to assess the return on our commercial investments going forward.

Regarding capital allocation for the future, we comprehensively renovated our R&D pipeline and rationalized investments taking into consideration that evolving industry landscape regarding commoditized products while focusing on our stated objective of moving up the value chain with our scientific platform.

Lastly, we are focusing on centralizing and price sizing our commercial and operating infrastructure by creating shared centers of excellence and consolidating our production capacity. As an outcome of this exercise, we will be eliminating the standard costs across the organization.

As you can see, we have a lot of exciting initiatives underway and remain focused on the performance in 2019, while looking ahead to our next journey in 2020 and beyond.

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

Ken Parks

Thanks, Rajiv, and good morning everyone. I'll take the few minutes to provide a quick overview of our financial results for the third quarter. Total revenues of $2.96 billion were 3% higher than the prior year. Excluding the negative impact of foreign exchange, constant currency total revenues grew 6% with all segments growing year-over-year.

The growth was primarily driven by new product sales of approximately $247 million with approximately two-thirds of that number, and our North America segment primarily driven by Wixela and Yupelri sales. The remaining amount was split evenly between Europe and the rest of world. This growth combined with higher volumes from existing products was partially offset by the impact of the lower global pricing.

In the third quarter, our adjusted gross margins were approximately 53%, compared to 54% in the prior quarter and approximately 55% in the same period last year. The declines for both comparisons are primarily the results of higher sales of the authorized generic version of EpiPen, which carries a lower than company average margin, as well as changes in the competitive environment on certain products.

In addition, there were certain inventory write-offs, the largest of which is dated Wixela product resulting from the later than expected approval and launch date for that product. These inventory adjustments are not expected to recur in the fourth quarter.

Moving to segment profitability, excluding approximately $58 million in 2019 and $98 million in 2018, relating to the Morgantown restructuring and remediation program, North America adjusted segment profitability grew 1% quarter-over-quarter, which reflects contributions from new product sales, partially offset by impacts from lower pricing and volumes on existing products due to changes in the competitive environment including the loss of exclusivity onto Tadalafil along with higher investments in selling and marketing.

Europe segment profitability expanded 5% driven by benefits from new product sales including Hulio, our biosimilar to Humira, higher volumes on existing products and lower restructuring costs. These increases were partially offset by the expected higher selling and marketing investments and lower pricing. Rest of the world was down 12% versus the prior year mostly driven by lower gross profit on ARV sales resulting from higher API costs, expected higher investments in selling and marketing and lower pricing, which was partially offset my contributions from new product sales.

Both Europe and rest of world reflect unfavorable impacts from foreign currency translation. Adjusted R&D was down 10%, compared to 2018 for the third quarter due to reprioritization of global programs. For 2019 full year, we continue to expect to invest between 4.5% and 5.5% of total revenues to fund the long-term health of our business. During the quarter, adjusted SG&A increased 6% compared to the third quarter of 2018, reflecting the expected incremental investments in selling and marketing partially offset by benefits from existing restructuring activities, along with business transformation initiatives.

In addition, the prior year included the favorable impact of reversing certain performance based incentive approvals. As previously indicated, we'll continue to make our investments as efficiently as possible monitoring and managing such costs to support top-line expectations and growth opportunities. For the quarter, we reported adjusted net earnings of $604 million and adjusted EPS of $1.17.

The year-over-year decline is primarily driven by unfavorable impacts from foreign exchange, and the increased SG&A that was previously discussed. Adjusted free cash flow for the quarter was favorable to our expectations at $542 million year-over-year adjusted free cash flow was slightly lower by $156 million as a result of the expected increase in operating net working capital required to support the new product launches in the year.

In 2018, North America revenues were essentially flat from Q2 to Q3 requiring little change in working capital. In 2019, North America revenues grew 6% sequentially from Q2 to Q3 generating trade AR build in Q3 of the current year that will result in incremental Q4 cash collections and cash inflow. We're ahead of our year-to-date expectations for adjusted free cash flow and remain on track to deliver between $1.9 billion and $2.3 billion of adjusted free cash flow for the year, including ongoing working capital velocity improvement initiatives.

During Q3 2019, we repaid the remaining $100 million of our outstanding term loan and reduced our credit agreement debt to adjusted EBITDA leverage ratio to 3.8 times. On a year-to-date basis, we repaid approximately $650 million of debt and expect to repay additional depth in Q4 to reach our target of $1.1 billion of debt repayment for the year. We remain fully committed to our deleveraging strategy and our investment grade credit rating.

Finally, as you heard Heather mentioned earlier, we've narrowed our full year 2019 guidance range. We now expect total revenues in the range of $11.5 billion to $12 billion. We narrowed our revenue outlook to the lower end of our previous guidance range for two primary reasons. Currency movement is expected to generate approximately $250 million of headwinds versus our budgeted expectations along with slightly lower expectations for new product revenues.

While our Launch of Wixela has been very successful, full year sales are anticipated to be a bit short of original expectations as a result of the aggressive share retention actions by the brand that Rajiv mentioned. In addition, the approval of generic Restasis continues to

be delayed. Despite these headwinds, we remain on track to deliver adjusted EPS at the midpoint of our original ratings due to proactive cost management through the year and are narrowing our adjusted EPS outlook to $4.20 to $4.40.

Based upon year-to-date strong cash flow generation as a head of our initial expectations, we're maintaining our outlook for adjusted free cash flow in the range of $1.9 billion to $2.3 billion for the full year 2019.

With that will now open the call for questions.

Question-and-Answer Session

Operator

[Operator Instructions] Your first question comes from the line of Randall Stanicky of RBC Capital Markets.

Randall Stanicky

Just two quick ones. One, just going back to the comment on, not viewing the S-4 projections as guidance with Newco guidance coming at closing, should we still be doing the initial Newco guidance when the deal was announced as appropriate targets?

And then the follow-up for Rob, the bigger picture one on business development, now that you can become a bigger -- have a bigger brand footprint and given the fragmentation of the smaller cap specialty brands space and there's a huge opportunity to therapeutically consolidate that space. Is that something you guys are looking at? And can you start to looking at, pursuing that now? Thanks.

Robert Coury

Thank you, Randall. Let me start with the last question. I think you're spot on. I've read some of your prior notes and have been following you very closely. I think you're really onto something there. I think what we're most mostly excited about in terms of the future outside and you're exactly correct, we are definitely -- Mylan was already moving up the value chain.

But with the size that we are now, our investment in partnering especially in the potential to look at future capital allocation and what areas of concentration, the answer is, yes, I do see further alignment to participate in that. Because our portfolio that we're going to be bringing, especially to the Asia-Pacific region is going to present huge potential upside. And I think as a time of the closing, I fully expect that we're going to outline as we talk about future capital allocation and touch on some of these points.

In terms of the numbers we gave in July, we absolutely and I understand, I wasn't on Pfizer's call. But look, we stand by what we gave in July for 2020. I'm simply just reminding people to level set them on a going forward basis. Obviously, we have -- I think, very clear vision about what we're faced with. And nothing I see today that has been brought up, not even any new issues that were raised by some who are now getting a better understanding business. Does anything to remotely change my absolute excitement about what we created with the two combinations? And I'm very much anxious and looking forward to be able to show you that once we can get closer to close.

Operator

Your next question comes from Chris Schott with JP Morgan.

Chris Schott

First one here, can you just comment on the China opportunity for the pro forma company, in light of the temporary dynamics that's being enrolled out is obviously a lot of focus on that market by the street. So maybe just talk a little bit about, what is China look like for the pro forma Company overtime? And just another comment on the pro forma guidance, does it fully anticipate some of these tender dynamics?

Second really quick one, can you talk earlier this year about this step up in SG&A investment in the portfolio? Does the Upjohn deal change either the priorities for that investment or the size of those investments as you think about the much broader business that you'll be running over time? Thanks very much.

Robert Coury

So thank you, Chris. And I'll just start with your second question, because it really applies to my commentary on the S-4. When you bring it to organizations together, what was in the S-4 or 2 internal companies projections, internal independently company projections. One of the things that you can't see, that's actually well underway to your exact question is. Those projections do not take into consideration for example, the regulatory overlay, what products we may have to divest. Product rationalization between the two organizations and then where do you now put your emphasis when you bring the two organizations together.

So your question is well founded, and I want you to know that work is underway. And I do believe between now and closing, we'll have that all sorted out and be able to lay that out for you in terms of, how we see whether it's SG&A, or other costs allocation for the business model and a going forward basis.

In terms of China, there is nothing really happening in the China, to be very honest with you that we've not -- I can't say that we didn't anticipate. Now, there's always nuances, I'm not going to say that we're Nostradamus and we can predict everything, especially in China, but there's nothing really there other than there could be a tweak and some of the new rules that they're putting out that that may cause some changes.

But I would say in large part overall, there is an anticipation on our side, not for just what's happening in China today, but there's an anticipation for a continuation as that healthcare system over there changes. And what, the reason why we continue to be extraordinarily bullish, is because we now got a true commercial infrastructure over there that is well situated in suited, especially with the massive product portfolio, which that we've bringing. And by the way, this is a product portfolio that's very much needed over there.

So, we think that all the stars are aligned to move our massive product portfolio that has already been identified to move into the China pipeline. And also to Randall's question, some of the opportunities we see that we can also, as we go up the value chain, to bring and leverage now the strong commercial infrastructures that the Pfizer Upjohn division now brings us.

Operator

The next question comes from a line of Elliot Wilbur with Raymond James.

Elliot Wilbur

Couple questions, I guess, most appropriate for Rajiv. First, Rajiv, could you clarify your earlier commentary around the portfolio rationalization process? I wasn't clear to me if that was more of a retrospective comment or perspective. I think you said 350 SKUs and talk about the negative revenue impact. I'm assuming that was largely on that historical not a going forward basis but maybe just clarify that please?

And then just a follow-up on insulin glargine, should we be expecting to hear nothing from FDA until March '18? I believe meaning that there would not be a tentative approval, only a final approval issued on that. I'm not sure what is going to happen on that product. And obviously, March 20 is sort of a key date with respect to hitting the FDA deadline?

Rajiv Malik

Regarding the portfolio rationalization, what I had given you was just an example in USA, that what we are undertaking that that if the products are not -- if the products have been commoditized to an extent that they're not earning their cost of a capital, more you sell them, it doesn't make any business rational. So, yes, if when you rationalize those products, these are --there can be some top line impact, but there's no significant bottom line impact. And we have extended this not just to USA, but we have evaluated our global portfolio from that point of view.

Now why do we see that this not a onetime exercise, because this is a new discipline we have created. It will be on an ongoing basis. But you would not see a bolus like this, but what I just said, 350 SKU because once you clean it up on our going forward basis, there will be some products here and there will be not bolus like that.

Regarding insulin, we absolutely expect to hear from them. I think before March, we believe that this concern about Malaysia facility which we are in the process of addressing will be behind us, in the early first quarter. And yes, the final approval is on the date of the March 20th or something around that that's a date. And we are very confident that it will be -- we'll get our final approval before the transition date to biology.

Operator

Next question comes from the line of Umer Raffat with Evercore.

Umer Raffat

Robert, you mentioned you're comfortable with the numbers previously communicated for 2020, but 2020 still influx because of things like Lyrica, Japan, which will still be part of 2020, but not pro forma or 2021, if I may. So I guess if we were to focus on true pro forma number for the combined Newco and I realize a lot of work is going on. A lot of the street debate is aggregating around number closer to 18 billion than not. I'm curious to what extent you're willing to comment or able to comment on that?

Secondly, I'm curious the magnitude of divestitures that might potentially be required because I think that's one of the things that perhaps isn't baked into a lot of the street numbers where they've just put the two together and trying to model out China. So, I'm curious, any early feedback on that?

And finally, one for Ken as if I may. Ken, I've looked at the purchase accounting amortization numbers and the share magnitude of it always confuses me a bit. So I was going to ask you, in simple words, what exactly is that? And do you expect it to stay 1.5 billion for the foreseeable future?

Robert Coury

Why don't you go first Ken?

Ken Parks

Sure. So, over the 1.5 billion is truly as you know when you go to purchase accounting of a certain amount, this, but in goodwill, any other certain amount that's attributed to customer portfolios, products, valuations of assets, and that goes into this amortization bucket that gets amortized over various lives depending on the estimated remaining live with the appropriate asset.

The short answer to your 1.5 billion question is and this is on a mile and standalone basis, obviously, there will be other work done, once the Newco transaction occurs, but that that's billion prior should take down slowly overtime, because each year some of the amortization or some of the intangible falls off. So I would expect for the near-term, it may take down slightly, but it will continue for a period of time, because many of these underlying assets have long lives. Especially things like customer assets and products.

Robert Coury

I think on the divestitures, at least what I'm being told now Umer. I don't see it as a real significant number, but I don't want to jump out in front of the regulators because they can actually go in one direction or the other, whether it's our products or even their product that they would require to be divested. So I prefer not to jump out front, but I think we said this before and I feel very comfortable. I don't see it as significance, but there obviously is going to be some and my understanding that those discussions are progressing quite well.

In terms of, I mean look Umer, I think that's, I really can't comment more on the numbers that we put out that, -- as we were trying to say with the assumption if we looking forward, by the time we anticipate the clothes, I think it was July 2020. Here's kind of sort of what we saw the organization looking like that range that we've given you, that is what it is. Since then and since we've been out trying to discuss with investors and we're not giving any guidance, I actually been following a lot what you have been trying to rationalize.

I actually think you're doing a pretty damn good job forgive me, but I really think you're doing a great job and trying to also find that light level set. I cannot wait until we can get closer to close get some of this work done and really clear up for investors just where is, that starting point. And I've made it abundantly clear that starting point from everything I can see and know today without giving any guidance. I am extremely confident that the street will be very pleased about wherever that starting initial guidance is.

And the strong EBITDA that's going to come with it because remember, what you're going to see is the rationalization of the portfolio, rationalization of costs based on what we can see out in the future and then the synergies coming in. So that's why we feel very confident that will give you a very strong range of revenue, without me telling you exactly

where that starting points going to be. And then an even a stronger range of EBITDA due to the synergies that we intend on bringing in and the cost rationalization that we can see, as we adjust for the various healthcare market, the markets around the world.

Operator

Your next question comes to my mind is David Risinger with Morgan Stanley.

David Risinger

So I have a follow-up question for Rajiv. Could you just provide a little bit more clarity so the 360 SKU rationalization. What is that timing? What inning are we in now? Or are we in the first inning? And then for the 360 that you've identified, is that going to be done in a year or two years? Just wanted to understand that in terms of that constraint on the global revenue line?

And then Ken a quick question, you mentioned inventory adjustments in the third quarter. Could you quantify the negative impact on COGS and gross profits in the third quarter?

Rajiv Malik

David, that 350 was a U.S. specific number and as, as you go along, the business transformation in USA, as long as, as well as mortgage down remediation, which was more driven -- resolving the complexity issue of the site could not have come like a better time. So both of these are facts, if any of those commoditized products were adding to the complexity, so it was very natural for us to take that block and rationalize it right up front. So, I would say for the U.S., almost 80%, 90% of rationalization is already been done, and it's behind us as we go along rest of the world and the European rationalization will be I think the second phase.

Ken Parks

And David on your question around the inventory adjustments and the COGS impact. In the quarter, approximately 30 to 40 basis points on the gross margin, rate, and as we called out, the biggest chunk of that was this, David, Wixela inventory. That was, as we were preparing for commercialization and launch, we built inventory to be sure we could

launch on a timely basis and the launch was delayed. I think it's important just to reiterate again, that we do not want an explanation for the third quarter, we have no reason to believe that will require in the four.

Operator

Your next question comes from the line of Greg Gilbert with SunTrust.

Greg Gilbert

Rajiv, can you give us your thoughts on the environment that you'll be launching into for the biosimilar Herceptin in terms of your supply situation? And what launch trajectory you're expecting?

And then for Robert, going back to you setting the bar in 2020, and then providing outlook from there, You've had some experience, you in the board and might have had some experience setting long-term guidance for the standalone company in the past that seemed to create concerns and controversy around your ability to hit it, whether this step would be required et cetera, et cetera. So my question to you is. How will you and the board approach the concept of long-term guidance when the deal closes and perhaps what was learned from the last time?

Robert Coury

I have to tell you, that's a great question. But Rajiv, why don't you go first and then let me respond.

Rajiv Malik

Let me go ahead with Herceptin, and Tony and Kenneth, please feel free to add. First of all as for as the capacity that's not a constraint, capacity for Herceptin is the only constraint, and we have ample capacity to still -- so it's adequate market. Second, I know why we are second, Amgen has been there yet, but we will be the first one to bring in. Hopefully, we are expecting to be the first one to bring in the bold strength, and we will be launching it for a couple of weeks. Yes, there are already, four more approvals out here. We see that.

But again in this one, I would say, the two differences if I have to compare. One is part B and the incentives are very well aligned. Also, in this case of, if we have to compare with the Neulasta biosimilar, we see a slower ramp because it will be more. If it will not, it will be lesser of a switch but more prescribed to the newer patient. So you can see a little bit slower ramp on that as compare to that, but we see that shift-wise, ultimately leading to the decent conversion of this road to the biosimilars. Tony, you want to add something?

Tony Mauro

No, I just might add that our 15 sales reps who are going to be selling this oncology, these very viral products to the marketplace and trained and ready to go. And I think as Rajiv articulated, we're well positioned for success with this launch in the coming weeks.

Robert Coury

So, Greg, let me hit what I consider to be a very powerful and potent question, quite frankly. And I think a very fair question. Let me start with the frustration that we, the board, and has had in the past in deal just with the point that you have outlined. And let me tell you why I do not see the same things on a going forward basis. It comes in two parts. The first is in the past, what was -- what management was trying to predict was predominantly, in my opinion, a North American story, a North America story.

I don't know what more to say, the U.S. generics business we had a very high class issue. We have some really rare, powerful large opportunities in the pipeline to launch. And when we planned, when we invested in those original programs, I don't think anybody could have anticipated the structural changes that have been put into -- that have come into play in the U.S. market in the North America region, that you had two things happen.

And there was a tiny issue of when we would get the approvals from the FDA and then you have the structural changes that actually were occurring and it was almost like one after the other. So, the frustration that the board and I'm certain that a lot of shareholders had, was the predictability of such, a powerful pipeline was very large opportunities And if you don't -- these things don't line up, well, it causes a tremendous amount of oscillation, variability, uncertainty, unpredictability.

And then if you put on top of that, the fact that investors have told us time and time again, that if we're not as transparent about all these things that I'm now explained to you, and it seemed like that we were, coming forward after the fact, to try to explain these things. And one of the things I learned and speaking with investors and also sell-side analysts, is how we can do a much better job, if on the inside we can envision and see all of this potential risk, then why not come to investors and sell-side analysts as quickly in advance as we can and to lay out what we potentially could proceed.

So that people don't get frustrated that the Company is not being as open as transparent, not provided the right type of disclosures for analyst or investor the right to model, and not wait to the actual events occur. So I'm taking my time articulating all this because if we're not aware of ourselves and if we're not aware of what went wrong in the past, there's it's going to be we're just kidding ourselves about correcting all this as we move forward in the future.

Now as we move forward in the future, one of the other reasons why I'm helping level set everybody, and I do look, I think Homer is done a great job in his quest to really dig in deep, and really try to understand, and I think, what I can assure you, what we're doing is identifying all those potential risks that we could see in front, we don't see anything that we have not that really has surprised us. But what we haven't had a chance was to talk about all the other opportunities.

And so one of the things I think would be helpful is that once these LOEs of the Upjohn portfolio is out of the way, which we're fully incorporated, we're fully anticipating the final LOE that will go out of the way. You're going to find even a broader and more diversified portfolio that actually has a lot less oscillation to it. And that way we're to get investors comfortable going forward is, let me give you an example.

If we decide to report the business on three regions, let's just say, developed markets, emerging markets and Asia Pacific markets. And if there's one particular market very large, like China and Asia Pacific will carve that out. But I think doing what we promised both all you analysts and investors, we're going to sit with each and every one of you and we're going to walk you through and do a SWAT analysis around each particular region, each particular country.

And as we talk about the strengths, the weaknesses, the opportunities and threats, rather than you relying on us solely to being the only ones giving the, telling you what we anticipate. I think once we go through that exercise, and have our discussion about our views about how we're looking at the business going forward, your views, how we should look at the business going forward.

There's going to be discussions about how we report on our business, uncertain there's going to be three buckets. Metrics that we absolutely cannot give you, metrics, we absolutely are very easy to give you, and the middle bucket, those metrics that I think can provide some great dialogue, and really come to a compromise but make sure that the starting point. Everybody is on the exact same page.

I don't think I want you investors going forward as you analysts to rely solely on management, if we do a good enough job, giving you all the information that we have upfront, being even more transparent than maybe what we have them and allowing you all to reach your own judgment. So I do feel that going forward to summarize, I think it's going to be a combination of a less volatile business with not as much oscillation to it, the way we're going to level set and demonstrate this new diversified global platform that we have. I think we can get people comfortable with that.

And then look, we're trying to bring in a different kind of a management team who really is focused on execution. When I think about where we're taking the Company and we're going to definitely need this 2, 3 year transition period, I'll be honest with you, we're moving the Company to something quite different in terms of a business model. And when it comes to execution, which does require a different mindset, a different managerial mindset, I think we were well on our way with the beginning of the transformation work that was done. That was going to take time.

And -- but I do believe that this transaction has only forced us to accelerate the strategies that we were doing on our own anyway. And I think that Michael and others, I do believe represents more of a future of where we're moving the Company, because they are much more driven through surely, executing our numbers and delivering our numbers. Well be just very humbly honest with you, up until this point, my land from 15 years ago, we built it spend our entire time building a true, one of a kind, global platform that is second to none,

spend our entire time building a true, one of a kind, global platform that is second to none.

There is not another peer set that matches what we have built. And that's why we're so excited about Randall Stanicky, what he's going around this concentration of therapeutic categories, because we really have a global platform to leverage the return on our future investments. And so I think, look, all this is culminating together, and I hope, I apologize for the long-winded answer. But I really thought that was a pretty powerful and potent question that's on everyone's mind. And I hope I was able to answer that.

Operator

Your final question comes from the line of Jason Gerberry with Bank of America.

Unidentified Analyst

This is [Sean] for Jason. Two questions here, please. So first is, your partner Biocon is guiding to $1 billion in biosimilar sales by financial year 2022. How does that impact your thinking about some of the opportunities that you have in front of you? And then the second question is more around 2014 standalone Mylan. It seems like you have the tailwinds of a better biosimilar Advair in International Pharma, but not major U.S. ANDA launches. So, are those some of the major pushes and pulls or are we missing anything?

Rajiv Malik

Let me give you the first part, from the Q2 to Q4, we've been very confident and we can go geography-by-geography. There are very gratifying drivers of this Q3 to Q4 ramp whether it's Yupelri in USA, continued market -- Ogivri launch, or Fulphila and Wixela for performance. Europe is being driven by products like Creon, DYMISTA, Brufen and Herceptin, we see that momentum behind these products.

And the rest of world whether it's our ARV portfolio, Amitiza, Sebivo and [indiscernible]. So, we have mapped this very carefully and we've been very confident about that. Now about Biocon spend, I cannot -- it's not for us meant on Biocon billion dollar plan. We have shared with you very clearly the portfolio the weather its glargine, aspart, Avastin biosimilar launch of Herceptin. We have our own business case and we remain very confident behind that.

Ken Parks

And I'll add the comment on 2020 is that. Look as we get closer to the normal time that we'll speak here about 2020, we'll look at the -- in my term, lay of the land, how close are we to the transaction. Does it make sense to provide Mylan standalone outlook? Or does it make sense to look at the new company together? The reality is, at this point in time, we typically wouldn't start talking about the next year yet. And as we move closer to those dates, we will keep you obviously fully appraise of the Mylan numbers as well as the push and pulls in those.

Operator

This does conclude today's Mylan third quarter 2019 earnings call and webcast. Please disconnect your line at this time and have a wonderful day.