PERRIGO Co plc
Form 425
August 10, 2015
Filed by Mylan N.V.
Pursuant to Rule 425 under the Securities Act of 1933
and deemed filed pursuant to Rules 14a-6 and 14d-2(b) of the Securities Exchange Act of 1934

Subject Company:
Perrigo Company plc
Commission File No. 001-36353

FORWARD-LOOKING STATEMENTS

This communication contains "forward-looking statements." Such forward-looking statements may include, without limitation, statements about the proposed acquisition of Perrigo Company plc ("Perrigo") by Mylan N.V. ("Mylan") (the "Perrigo Proposal"), Mylan's acquisition (the "EPD Transaction") of Mylan Inc. and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business (the "EPD Business"), the benefits and synergies of the Perrigo Proposal or EPD Transaction, future opportunities for Mylan, Perrigo, or the combined company and products, and any other statements regarding Mylan's, Perrigo's, or the combined company's future operations, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competition, and other expectations and targets for future periods. These may often be identified by the use of words such as "will," "may," "could," "should," "would," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "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: uncertainties related to the Perrigo Proposal, including as to the timing of the offer and compulsory acquisition, whether Perrigo will cooperate with Mylan and whether Mylan will be able to consummate the offer and compulsory acquisition, whether Mylan shareholders will provide the requisite approvals for the Perrigo Proposal, the possibility that competing offers will be made, the possibility that the conditions to the consummation of the offer will not be satisfied, and the possibility that Mylan will be unable to obtain regulatory approvals for the offer and compulsory acquisition or be required, as a condition to obtaining regulatory approvals, to accept conditions that could reduce the anticipated benefits of the offer and compulsory acquisition; the ability to meet expectations regarding the accounting and tax treatments of a transaction relating to the Perrigo Proposal and the EPD Transaction; changes in relevant tax and other laws, including but not limited to changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; the integration of Perrigo and the EPD Business 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 Perrigo Proposal and the EPD Transaction; the retention of certain key employees of Perrigo and the EPD Business being difficult; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with the Perrigo Proposal and the EPD Transaction within the expected time-frames or at all and to successfully integrate Perrigo and the EPD Business; 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 our ability to bring new products to market; success of clinical trials and our ability to execute on new product opportunities; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on financial condition, results of operations, and/or cash flows; the ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the

businesses of Mylan, Perrigo, or the combined company; the inherent challenges, risks, and costs in identifying, acquiring, and integrating complementary or strategic acquisitions of other companies, products, or assets and in achieving anticipated synergies; uncertainties and matters beyond the control of management; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with accounting principles generally accepted in the United States of America ("GAAP") and related standards or on an adjusted basis. For more detailed information on the risks and uncertainties associated with Mylan's business activities, see the risks described in Mylan's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015 and our other filings with the Securities and Exchange Commission ("SEC"). These risks, as well as other risks associated with Mylan, Perrigo, and the combined company are also more fully discussed in the Registration Statement on Form S-4 (that includes an offer to exchange/prospectus) that Mylan filed with the SEC on May 5, 2015 (which Registration Statement was amended on June 19, 2015, July 16, 2015, and August 6, 2015 and has not yet been declared effective, the "Registration Statement") and the definitive proxy statement on Schedule 14A that Mylan filed with the SEC on July 28, 2015 (the "Proxy Statement") in connection with the Perrigo Proposal. You can access Mylan's filings with the SEC through the SEC website at www.sec.gov, and Mylan strongly encourages you to do so. Except as required by applicable law, Mylan undertakes no obligation to update any statements herein for revisions or changes after the date of this communication.

RESPONSIBILITY STATEMENT

The directors of Mylan accept responsibility for the information contained in this communication. To the best of the knowledge and belief of the directors (who have taken all reasonable care to ensure that such is the case) the information contained in this communication is in accordance with the facts and does not omit anything likely to affect the import of such information.

DEALING DISCLOSURE REQUIREMENTS

Under the provisions of Rule 8.3 of the Irish Takeover Panel Act, 1997, Takeover Rules 2013 (the "Irish Takeover Rules"), if any person is, or becomes, 'interested' (directly or indirectly) in, 1% or more of any class of 'relevant securities' of Perrigo or Mylan, all 'dealings' in any 'relevant securities' of Perrigo or Mylan (including by means of an option in respect of, or a derivative referenced to, any such 'relevant securities') must be publicly disclosed by not later than 3:30 pm (New York time) on the 'business' day following the date of the relevant transaction. This requirement will continue until the date on which the 'offer period' ends. If two or more persons co-operate on the basis of any agreement, either express or tacit, either oral or written, to acquire an 'interest' in 'relevant securities' of Perrigo or Mylan, they will be deemed to be a single person for the purpose of Rule 8.3 of the Irish Takeover Rules.

Under the provisions of Rule 8.1 of the Irish Takeover Rules, all 'dealings' in 'relevant securities' of Perrigo by Mylan or 'relevant securities' of Mylan by Perrigo, or by any party acting in concert with either of them, must also be disclosed by no later than 12 noon (New York time) on the 'business' day following the date of the relevant transaction.

A disclosure table, giving details of the companies in whose 'relevant securities' 'dealings' should be disclosed, can be found on the Irish Takeover Panel's website at www.irishtakeoverpanel.ie.

Interests in securities arise, in summary, when a person has long economic exposure, whether conditional or absolute, to changes in the price of securities. In particular, a person will be treated as having an 'interest' by virtue of the ownership or control of securities, or by virtue of any option in respect of, or derivative referenced to, securities.

Terms in quotation marks are defined in the Irish Takeover Rules, which can also be found on the Irish Takeover Panel's website. If you are in any doubt as to whether or not you are required to disclose a dealing under Rule 8, please consult the Irish Takeover Panel's website at www.irishtakeoverpanel.ie or contact the Irish Takeover Panel on telephone number +353 1 678 9020 or fax number +353 1 678 9289.

Goldman Sachs, which is authorized by the Prudential Regulation Authority and regulated by the Financial Conduct Authority and the Prudential Regulation Authority in the United Kingdom, is acting for Mylan and no one else in connection with the Perrigo Proposal and will not be responsible to anyone other than Mylan for providing the protections afforded to clients of Goldman Sachs, or for giving advice in connection with the Perrigo Proposal or any matter referred to herein.

Goldman Sachs does not accept any responsibility whatsoever for the contents of this communication or for any statement made or purported to be made by them or on their behalf in connection with the offer. Goldman Sachs accordingly disclaims all and any liability whether arising in tort, contract or otherwise which it might otherwise have in respect of this communication or any such statement.

ADDITIONAL INFORMATION

In connection with the Perrigo Proposal, Mylan has filed certain materials with the SEC (and anticipates filing further materials), including, among other materials, the Registration Statement and the Proxy Statement. In connection with the Perrigo Proposal, Mylan currently intends to file with the SEC a Tender Offer Statement on Schedule TO and certain other materials. This communication is not intended to be, and is not, a substitute for such filings or for any other document that Mylan may file with the SEC in connection with the Perrigo Proposal. INVESTORS AND SECURITYHOLDERS OF MYLAN AND PERRIGO ARE URGED TO READ THE DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY (IF AND WHEN THEY BECOME AVAILABLE) BEFORE MAKING AN INVESTMENT DECISION BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, PERRIGO AND THE PERRIGO PROPOSAL. Such documents will be available free of charge through the website maintained by the SEC at www.sec.gov or by directing a request to Mylan at 724-514-1813 or investor.relations@mylan.com. Any materials filed by Mylan with the SEC that are required to be mailed to shareholders of Perrigo and/or Mylan will also be mailed to such shareholders. Mylan first began mailing the Proxy Statement to its shareholders on or about July 31, 2015. This communication has been prepared in accordance with U.S. securities law, Irish law, and the Irish Takeover Rules.

A copy of this communication will be available free of charge at the following website: perrigotransaction.mylan.com. Such website is neither endorsed, nor sponsored, nor affiliated with Perrigo or any of its affiliates. PERRIGO® is a registered trademark of L. Perrigo Company.

PARTICIPANTS IN SOLICITATION

This communication is not a solicitation of a proxy from any investor or shareholder. However, Mylan and certain of its directors, executive officers, and other members of its management and employees may be deemed to be participants in the solicitation of proxies in connection with the Perrigo Proposal under the rules of the SEC. Information regarding Mylan's directors and executive officers may be found in Mylan Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed with the SEC on March 2, 2015, amended on April 30, 2015, and updated by Mylan's Current Report on Form 8-K filed on June 11, 2015, as well as in the Registration Statement and the Proxy Statement. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the interests of these participants, which may, in some cases, be different than those of Mylan's shareholders generally, will also be included in the materials that Mylan intends to file with the SEC when they become available.

NON-SOLICITATION

This communication is not intended to, and does not, constitute or form part of (1) any offer or invitation to purchase or otherwise acquire, subscribe for, tender, exchange, sell or otherwise dispose of any securities, (2) the solicitation of an offer or invitation to purchase or otherwise acquire, subscribe for, sell, or otherwise dispose of any securities, or (3) the solicitation of any vote or approval in any jurisdiction pursuant to this communication or otherwise, nor will there

be any acquisition or disposition of the securities referred to in this communication in any jurisdiction in contravention of applicable law or regulation. No offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

FURTHER INFORMATION

The distribution of this communication in certain jurisdictions may be restricted or affected by the laws of such jurisdictions. Accordingly, copies of this communication are not being, and must not be, mailed or otherwise forwarded, distributed or sent in, into, or from any such jurisdiction. Therefore, persons who receive this communication (including, without limitation, nominees, trustees and custodians) and are subject to the laws of any such jurisdiction will need to inform themselves about, and observe, any applicable restrictions or requirements. Any failure to do so may constitute a violation of the securities laws of any such jurisdiction. To the fullest extent permitted by applicable law, Mylan disclaims any responsibility or liability for the violations of any such restrictions by any person.

TRADEMARK DISCLAIMER

All trademarks, trade names, product names, graphics and logos of Mylan or any of its affiliates contained herein are trademarks, registered trademarks or trade dress of Mylan or such affiliate in the United States and/or other countries. All other trademarks, trade names, product names and logos contained herein are the property of their respective owners. The use or display of other parties' trademarks, trade names, product names or logos is not intended to imply, and should not be construed to imply, a relationship with, or endorsement or sponsorship of Mylan by such other party.

NON-GAAP FINANCIAL MEASURES

This communication includes the presentation and discussion of certain financial information that differs from what is reported under GAAP. These non-GAAP financial measures, including, but not limited to, adjusted diluted EPS, adjusted cash provided by operating activities, adjusted gross profit, adjusted gross margins, adjusted earnings from operations, adjusted net earnings attributable to Mylan, constant currency total revenue, constant currency third party net sales, EBITDA, adjusted EBITDA, debt to adjusted EBITDA leverage, and adjusted free cash flow, are presented in order to supplement investors' and other readers' understanding and assessment of Mylan's financial performance. Management uses these measures internally for forecasting, budgeting and measuring its operating performance. In addition, primarily due to acquisitions, Mylan believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared only in accordance with GAAP. In addition, Mylan believes that including EBITDA and supplemental adjustments applied in presenting adjusted EBITDA pursuant to our debt agreements is appropriate to provide additional information to investors to demonstrate Mylan's ability to comply with financial debt covenants (which are calculated using a measure similar to adjusted EBITDA) and assess Mylan's ability to incur additional indebtedness. We also report sales performance using the non-GAAP financial measure of "constant currency" total revenues and third party net sales. This measure provides information on the change in net sales assuming that foreign currency exchange rates had not changed between the prior and current period. The comparisons presented as constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. We routinely evaluate our third party net sales performance at constant currency so that sales results can be viewed without the impact of foreign currency exchange rates, thereby facilitating a period-to-period comparison of our operational activities, and believe that this presentation also provides useful information to investors for the same reason. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliations of the non-GAAP measures to their most directly comparable GAAP measures, and investors and other readers should consider non-GAAP measures only as supplements to, not as substitutes for or as superior measures to, the measures of financial performance prepared in accordance with GAAP.

NO PROFIT FORECAST / ASSET VALUATIONS

To the extent that any Mylan quarterly results and/or the calendar year 2015 guidance contained or summarized in this communication constitute a profit forecast for the purposes of Rule 28 of the Irish Takeover Rules, such results and/or

guidance will (unless the Irish Takeover Panel consents otherwise) be reported on in accordance with that rule at the appropriate time. Except as described in the previous sentence, no statement in this communication is intended to constitute a profit forecast for any period nor should any statements be interpreted to mean that earnings or earnings per share will necessarily be greater or lesser than those for the relevant preceding financial periods for Mylan or Perrigo as appropriate. No statement in this communication constitutes an asset valuation.

On August 6, 2015, Mylan hosted a conference call and live webcast in conjunction with the release of its financial results for the quarter ended June 30, 2015. Below is a transcript of the presentation.

PARTICIPANTS

Corporate Participants

Kris King Vice President-Global Investor Relations	Rajiv Malik President & Executive Director
Heather M. Bresch Chief Executive Officer & Executive Director	John D. Sheehan Executive VP, Chief Financial Officer

Other Participants

Sumant S. Kulkarni Bank of America Merrill Lynch	Jami Rubin Goldman Sachs & Co.
Gregg Gilbert Deutsche Bank Securities, Inc.	Marc Goodman UBS Securities LLC
Ronny Gal Sanford C. Bernstein & Co. LLC	Douglas D. Tsao Barclays Capital, Inc.
Elliot Wilbur Raymond James & Associates, Inc.	Louise Chen Guggenheim Securities LLC
Umer Raffat Evercore ISI	Jason M. Gerberry Leerink Partners LLC
Andrew J. Finkelstein Susquehanna Financial Group LLLP	Emil Chen Morgan Stanley & Co. LLC

MANAGEMENT DISCUSSION SECTION

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

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

Kris King
Vice President-Global Investor Relations

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

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

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

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

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

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

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

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

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

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

Heather M. Bresch
Chief Executive Officer & Executive Director

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

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

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

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

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

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

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

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

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

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

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

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

Rajiv Malik
President & Executive Director

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

Our global generics segment generated third-party net sales of just over $2 billion an increase year-over-year of 43% on a constant-currency basis. In North America, sales totaled $937 million, up 27% year-over-year. Our legacy business grew by 22%. This impressive growth was attributed to continued strong performance of sales from new products as well as stable pricing and higher volumes on existing products.

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

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

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

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

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

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

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

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

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

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

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

We continue to progress with our partnership with Biocon our Trastuzumab and pegfligrastim Phase III clinical trials are progressing very well towards completion. We are continuing our Phase III study with Adalimumab and we have also initiated a Phase I PK comparability study for our bevacizumab program.

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

As per the latest statistics, more than 150 million people are affected with hep C in emerging markets and Mylan is committed to provide access to the hep C drugs to the patients across these markets in partnership with Gilead.

Our ARV products now have approximately half of all people being treated for HIV in the developing world, not just in sub-Saharan Africa, but also in markets such as Brazil and Thailand. Just last month, the United Nations announced that World Health met the target for reaching 15 million people with ARV treatment by 2015, and that the guidelines will now call for reaching 30 million people in the coming years. Mylan is committed to doing our part to reach that goal, which means continued, reliable and sustainable growth in this franchise.

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

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

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

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

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

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer

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

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

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

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

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

Adjusted gross margin for the second quarter and the first six months of 2015 was a very strong 54%, up approximately 400 basis points for the quarter and 325 basis points in the year-to-date period. Our strong margins are primarily the result of the positive contribution from the EPD Business, new product introductions and increased margins on existing products in North America. We expect the strong margins we saw in the first half of 2015 to continue and we now expect our full-year gross margins to be in the upper half of our 2015 guidance range.

R&D expense on an adjusted basis was $168 million, an increase of 21% over the prior-year quarter as a result of continued investment in our respiratory, insulin and biologics growth programs, as well as the impact of the EPD Business. However, as a result of the strong increase in quarter-over-quarter revenue, R&D as a percent of sales fell from 8% to 7%.

For the six month period, adjusted R&D expense was $320 million or approximately 8% of total revenues. As we continue to invest in our key growth drivers during 2015, we expect adjusted R&D spending as a percentage of total revenues to be within our guidance range for the full-year.

At the same time, SG&A also on an adjusted basis, was $506 million, or approximately 21% of total revenues for the quarter, which includes the impact of the EPD Business along with investments in our infrastructure to support the growth of the company. For the six month period, adjusted SG&A was approximately $914 million or 22% of total revenues.

For the full-year, as a result of the strength of the expected revenues in the second half of 2015, we expect adjusted SG&A as a percentage of total revenues to be closer to the midpoint of our 2015 guidance range.

We continue to realize tax benefits from the EPD Transaction and inversion that was completed earlier this year. And as a result, we reported a second quarter adjusted tax rate of 18%, which includes the cumulative effect of reducing in the second quarter our annual effective tax rate to 19% from the 20% we reported in Q1. We are continuing to identify opportunities to reduce our overall adjusted effective tax rate and it is possible that in the second half of 2015, we will be able to further reduce this tax rate.

Our second quarter adjusted net earnings was $474 million or $0.91 per share, a 32% increase from our Q2 2014 adjusted diluted EPS of $0.69 per share. This adjusted diluted EPS growth exceeded our expectations from the beginning of the quarter and was achieved in spite of delays in new product approvals and a negative $0.02 per share impact from the foreign currency translation that we encountered during the quarter.

Furthermore, foreign currency translation had a negative $0.05 per share impact on adjusted diluted EPS quarter-over-quarter from the prior-year. For the six month period, adjusted net earnings were $783 million or $1.62 per share.

Turning to our cash flow and liquidity metrics, adjusted cash provided by operating activities was $490 million, a decrease of approximately $69 million from the prior-year period, which is the result of the timing of customer remittances due to changes in contract terms in new agreements entered into in the current year. We expect the impact of this change to be mitigated in the third quarter. Year-to-date, capital spending was $122 million as we continue to invest in our business and growth drivers.

At the end of the quarter, our debt-to-adjusted-EBITDA leverage ratio was approximately 2.2:1. We continue to have ample borrowing capacity including our recently announced 2015 term loan, $1 billion of which we utilized to redeem the 2020 senior notes in July and we expect the remaining amount will be utilized for the redemption of the cash convertible notes, which mature in September.

We remain fully confident to even – fully committed to our investment grade credit ratings, including after the successful completion of the offer to acquire Perrigo and including in the event that we decide to reduce the acceptance level of the tender offer to greater than 50%.

With regards to the full year adjusted diluted EPS, as Heather indicated, we are raising our full-year guidance range to $4.15 to $4.35 per share, even after considering the impact of potential generic EpiPen® competition sometime in the second half of 2015 and including the removal of a Copaxone® launch. The midpoint of this revised guidance range of $4.25 per share, represents a 23% constant currency growth in adjusted diluted EPS, reflecting the ongoing strength of our global business.

We're also forecasting that our full-year adjusted EBITDA will be in the upper half of our $2.9 to $3.3 billion guidance range. For the third quarter of 2015, we currently anticipate adjusted diluted EPS in the range of $1.39 to $1.45 per share, which would be a 22% increase over the prior-year quarter. This guidance range assumes no generic competition for EpiPen® in Q3 and will be achieved without the launch of generic Copaxone®.

That concludes my remarks. I'll now turn the call back over to Eric for questions.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And our first question comes from Sumant Kulkarni from Bank of America Merrill Lynch. Please go ahead.

Sumant S. Kulkarni
Bank of America Merrill Lynch
Q
Good morning. Thanks for taking my questions. I have a quick couple. Would you comment on your alternatives just in case the Perrigo transaction does not go through? And on your lower threshold, would you find an impact in your credit rating there, just in case that comes to fruition from a lower threshold point of view? And second on Copaxone®, …. pushing out of the product out of 2015 based on a specific target action date receipt? Thanks.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Hi, there. Good morning and thank you. So, as far as alternatives to Perrigo, I think that we have continued, ever since closing our Abbott transaction, to say that it was going to be the first of a series. Obviously, we believe Perrigo is the right next transaction for Mylan based on the strategic initiatives that we laid out. But as we said before, we like Perrigo, but we don't have to have Perrigo.

There's lots of assets available out there that we believe very much would complement our platform that we would be able to leverage the infrastructure, both commercial and operational excellence that we have in place today. So, we've been actively looking at many targets out there. And as I said in my opening remarks, we believe that there's many different ways to get to the scale and size needed for us to continue to be a leading consolidator in this industry.

As far as Copaxone®, and then I'll let John take your other question on investment grade, look, we just did what we believe to be the financial responsible thing to do, given where we are in the year, given the momentum of our business, of our core business; and as we said, the ability to show not only a strong quarter raised our guidance that we don't need to keep uncertainty in there. So, as you get more into the year, the more we can take uncertainty out of the numbers. We thought that was the prudent thing to do.

I can assure you from getting the product approved, we are continuing to work as diligently as we ever had to get it approved. We think it's great. As we've said before, Momenta getting the first product approval, showing that it's possible to have generic Copaxone®. We believe – as, I think, Rajiv laid out in his remark, we feel very confident that we've met the expectations of the agency, and we look forward to that approval. So, our bullishness on the product really has nothing to do with us just wanting to remove any uncertainty that we can from our numbers.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
And lastly, Sumant, with respect to your question in investment grade credit rating, as I indicated in my remarks, we are fully committed to our investment grade credit rating. And we do believe that should we decide to reduce the acceptance level of our tender offer to a level greater than 50%, that we would maintain our investment grade credit rating during the period in which we didn't have full control of the Perrigo business.

Operator: Our next question comes from Gregg Gilbert of Deutsche Bank. Please go ahead.

Gregg Gilbert
Deutsche Bank Securities, Inc.
Q

Okay. Thanks. Can you hear me okay?

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Yeah.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
Yeah.

Gregg Gilbert
Deutsche Bank Securities, Inc.
Q
So, a couple for you, John. First, can you discuss those new customer agreements that led to the new payment terms? Is that for all major customers in the U.S. or the big buyer groups, and were there price concessions involved? And in exchange, you get any enhanced visibility, or is it the classic case of the big buyers to sort of get what they want?

Secondly, can you comment on trade inventory levels at the end of the quarter versus the last quarter or the end of the year, whatever you can provide? And then, lastly, for Heather, I appreciate your comments about there being other targets out there. I was going to ask if the Perrigo vote fails or if something else comes along for Perrigo and pays a bigger price, how quickly can you mobilize your financial resources and move on other transactions? Thanks.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Maybe I'll start and then I'll let John come back on some of the technical aspects. Look, I think, Gregg, you know us pretty well, I think we've shown our ability to move pretty quickly. So, I think you should expect nothing less than that. But, we will continue to be pursuing a lot of different pathways and be able to strike very swiftly and quickly, just like we did Abbott and then on to Perrigo. So, there's nothing changed on that front, or certainly nothing changed about our personality or appetite for acquisitions.

And I'll just, maybe more comment on the customer on the macro level, and then I'll let John speak to the agreements. But, Gregg, what we have said and what we continue to see is with the consolidation of our customers, especially from a global perspective, our ability to have proven to be that global reliable supply chain continues to prove itself and continues to put us in a position that not only are we able to secure and maintain over a longer period of time our business, but are able to really, like I said, drive and benefit from the stability of our supply.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
So, I think, Gregg, first of all, we did during the quarter complete an agreement that – or agreements with customers, and in particular one customer which had the impact of extending customer payment terms.

The business benefits coming out of that agreement, for us, far exceeded the cost of capital associated with the extended payment terms, and therefore it was absolutely the right business decision for us to take, and we did so with our eyes wide open. I would absolutely not characterize it as exactly how you said it, but as a big bully or something like that. So, it was a win-win, from our perspective, to conclude this agreement with customers. I think you also asked about the trade inventory levels and I can assure you that we have been operating normal business, and there are no unusual inventory levels at our customers.

Operator: Our next question comes from Ronny Gal from Bernstein. Please go ahead.

Ronny Gal
Sanford C. Bernstein & Co. LLC
Q
Good morning, guys, and thank you for taking my question. Can you just give us a feel how you're modeling Nexium® contribution? Is this kind of like a month or three months or until the end of the year trajectory? When are you assuming additional players come in, just so we can understand the contribution here to the model?

And second, can you discuss, are there any complexities associated with reducing the share of Perrigo, in case, there are some Perrigo shareholders listening, when you reduce their acceptance rate from 80% to 50%, if the result is in that range, 50% to 80%, how is that adds complexity or not to your ability to close the deal versus the result will be above 80%?

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Okay. So, Ronny, I'll start with Nexium®. Ronny, I would hope that especially demonstrating this quarter not raising our guidance under – showing that underscoring the strength of our core business, not relying on any one product or any one territory. So Nexium®, obviously, great product. And right now, there don't seem to be any other final approvals and there was no one else really tied to the August 3 date, because we were the only generic company that hadn't settled.

So, I won't speak or have a crystal ball on anybody else's approvals coming, but I can tell you that, as always, we're managing a whole basket of risks and opportunities around the globe. And so, we wouldn't be speaking to modeling of any one particular opportunity, except that it just continues to show the strength in our core business, as well as our ability to continue to receive approvals.

As far as the complexity, really, the way that the Irish Takeover Rules work and as we stated back on our – when we got the 2.5, giving us the ability to go directly to Perrigo's shareholders, we put in there that we had optionality to go down to the 50 plus 1%, and really the other – I would not say there is any operational complexity, there is a time period of perhaps one to two months of taking over the board.

And then, so once that happens, you've got full operational control of the company. So, it really allows you to be running the company with 50 plus 1% of the vote in a very short period of time. So anything that there would be, it would be a very small temporary amount of time that we weren't in control.

Operator: Our next question comes from Elliot Wilbur of Raymond James. Please go ahead.

Elliot Wilbur
Raymond James & Associates, Inc.
Q
Thanks. Good morning. Just a quick question, I guess relative to sort of external expectations around the Perrigo deal. Obviously, when you first announced it, there was a very strong initial embrace of the industry logic that you guys had outlined around the transaction, and obviously you've been out and about meeting with a lot of investors since that time.

And I'm just wondering, if things like confidence has sort of waned in the transactions just sort of judging by Mylan's stock price. I'm just kind of wondering sort of based on your read of the investment community, do you think it's a function on the fact that people were overly fixated on the type of transaction, maybe not paying enough attention to the standalone merits of the Mylan/Perrigo combination, or do you think it's just a function more of unique considerations around the transaction that have sort of led to now a rather pronounced slippage, I guess, in terms of Mylan's equity value versus at the time when the transaction was first announced? Thanks.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Yeah. Thanks, Elliot. Look, I think we started in the right place, which was people's reaction in April, and that's instinctive both – I think instinctive, but the fact that it was strategic and compelling and the right natural fit. I think everybody got right off the bat. I think a lot of shares traded that day and settled out with us at that $68 range, and we felt that was the right range, and we continue to maintain that.

What then subsequently happened, I absolutely believe Wall Street became very fixated on a near-term what they perceived to be an opportunity. And so we needed to get that behind us, so people could focus back again on the industrial logic of Perrigo.

And I think now that that has happened, sure, our stock – we've taken a little bit of a traumatic hit. There was trauma in the marketplace given Teva's actions, and I would say they're kind of disingenuous about maintaining that they were coming with a real offer and surprising the market by doing the Allergan deal.

And as I've said, I think that was the right deal for those companies, and this is a short-term, temporary bump in our stock. I think we know our value. We know what we've created for shareholders. We know what we'll continue to create both in the near, medium, and long term. And I think our results today just underscores the strength of our business, both in the – here and now, and then obviously, as we've demonstrated, by raising our guidance for the year.

And due to the Irish Takeover Rules, we can't say – give any forecast beyond that. But I can tell you, the strength and momentum in our business is strong, and I think our stock price will quickly come back to reflect that. And as you know, the tender to the Perrigo shareholders won't be until the September-October timeframe, and we think, by then, all of this noise will have worked itself out.

And I think that we still feel, as we're talking to shareholders, that they're back focusing on the Perrigo deal, realizing the industrial logic of it and we believe the Perrigo shareholders think that we have a very fair and compelling offer on the table. So, we're excited about the next steps and think that we'll see once we get to our vote and then move, hopefully, to the tender offer.

Operator: Our next question comes from Umer Raffat from Evercore ISI. Please go ahead.

Umer Raffat
Evercore ISI
Q
Hi, guys. Thanks for taking my question. Heather, would you consider buying back stock if it stays at current levels and do you have the flexibility to do that, while Perrigo is ongoing? And then, John, what's the year-on-year organic growth rate on revenues adjusted for FX and what drove the $500 million move in accounts receivable? Thank you.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Hi, Umer. Thank you. Yes, we absolutely have the flexibility to buy back our stock. And I would say, it's a great buy right now. So, it's a great inflection point for people to get back in, in this moment of, as the chaos that settles itself out, and like I said, I think as we've returned to the levels that we expect to be given, given our results and our performance. But I will tell you, we're committed to investment grade. So, while we have a ton of flexibility and optionality, we obviously stay very committed to our investment grade.

Umer Raffat
Evercore ISI
Q
Got it.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
And, Umer, with respect to accounts receivable, the increase year-over-year in the accounts receivable is the combination of the acquisition of the EPD Business, that's the majority of it, plus the change in customer payment terms that I referred to during my remarks.

And as it relates to organic growth in the business, our business actually grew organically ex-FX, without FX, by – at the top line by 36% year-over-year and with the EPD acquisition representing 22% of that. So, our Mylan legacy business, as I believe Rajiv had in his remarks, grew double-digit.

Operator: Our next question comes from Andrew Finkelstein from Susquehanna. Please go ahead.

Andrew J. Finkelstein
Susquehanna Financial Group LLLP
Q
Thanks very much. I was hoping you could talk a bit more about the outlook with EpiPen®, in particular, while you still anticipate the possibility of a generic in 4Q in the guidance. Was that part of the contribution to the increase in the range of guidance for the year?

And then as you look into formulary coverage and pricing for next year, as some of the exclusion lists come out and where your contracting has been, if there is no generic, where would you expect share and net pricing trends to come out for next year?

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Thanks, Andrew. So, look, our outlook for EpiPen® remains unchanged. I think we stay very positive on EpiPen®. It's been a great product. We continue to see growth, obviously, as I said double-digits so far this year. And it is not due to our raising the guidance. As we noted, we've continued to maintain EpiPen® generic coming in the second half of the year. So, if anything, it's an opportunity.

And with that being said, I've maintained that I think there's a very high bar to get AB-rated approval. And so, look, we're already on a multi-epinephrine market, to your point. We're competing and we're very proactively competing for market share with our payers and formularies. And we'll continue to do so.

And if an AB-rated does not come out, my thought would be next year will look very similar to this year, as far as the competitiveness of us maintaining, one our market share and our positions with formularies. So, EpiPen® continues to do great. And like I said, but we've done a financially responsible thing as factoring it in. And so, we'll just have to see how the year plays out.

Operator: Our next question comes from Jami Rubin of Goldman Sachs. Please go ahead.

Jami Rubin
Goldman Sachs & Co.
Q
Thank you. Just a couple of questions. Heather, what do you mean in your press release in your prepared remarks by saying that you expect potential opportunities on the horizon. I mean, don't most companies expect potential opportunities on the horizon? Can you just clarify that a bit more? And then maybe, Rajiv, if you could talk about the upcoming IPR decision related to Copaxone® 40. What we should anticipate? How you expect the legal roadmap to look like there? Thanks very much.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Sure. Well, Jami, and I think, as I alluded to you earlier, obviously, as you know, we're under Irish Takeover Rules which prohibit really quantifying much from a forecast perspective. But I think given what we were trying to indicate is, given the strength and momentum in our business for the first half of the year, we see just a lot of opportunities in the second half of the year. And as we've said, we'll certainly update that as appropriate. But it was really just to signal, one, the strength of our business, and two, the opportunities we continue to see over the near and medium-term.

Jami Rubin
Goldman Sachs & Co.
Q

So, that’s not related to a specific M&A opportunity?

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Not related to anything specific, it's just opportunities, in general.

Rajiv Malik
President & Executive Director
A
And Jami, on Copaxone® IPR, I think based on the legal arguments we see, and how it's going, we have been very confident on this IPR litigation or on IPR case and we are looking forward to the decision around end of August.

Operator: Our next question comes from Marc Goodman of UBS. Please go ahead.

Marc Goodman
UBS Securities LLC
Q
Good morning. So, Rajiv, you had talked about Copaxone®. I just want to make sure I understand. You said that you got feedback from the FDA and in those comments, there were not any concerns around the sameness of your products. So, there obviously were some other issues. Can you tell us what they were, whether just minor, procedural things that you quickly gave responses to and you feel really comfortable that the FDA has now gotten everything that they need? Were the things that they asked, were they surprising? I'm just trying to understand. I mean, I think we can understand why you would take it out of this year's numbers to be conservative, but it doesn't seem to make sense that you would be taking it out completely, given the commentary there.

And then second, Heather, maybe you can just talk about some of the key markets in Europe and the performance there, France and Italy. You mentioned the volumes and stuff. How is the pricing environment, what's going on with market shares? And mention the UK as well. Thank you.

Rajiv Malik
President & Executive Director
A
On Copaxone®. Let me say, Copaxone® has a – we all knew it's a complex product and if everything is not black and white, then there's a little bit of gray. So, the citizen petition response and Momenta's approval gave us a lot of confidence that, fundamentally, we are on the same page. The last bit of questions, the clarifying questions are around fine-tuning – I will not call exactly the fine-tuning, but there are some different methodologies which we have used, and we are trying to give them more information about some of the abstracts where they want to see more clarity. We just received that question. We're in the process of turning it around in the next couple of days. And then we will be working very closely with the FDA to take it to the next logical stage.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Yes. And, Marc, as far as Europe is concerned, look, I think we continue to be very optimistic. Our organic business was flat. However, we're still showing growth organically for Europe as far as the year is concerned. And our EPD Business was flat year-over-year for the EPD which, as you know, is a positive. They had budgeted and spoke about single-digit decline in that business, and we've been able to almost really accelerate the flattening of that business versus a decline in that business.

So, I think it, again, underscores it was the right transaction, given our portfolio and the complementary nature of the commercial infrastructure, as well as the products. I think the integration is going great. And as I look at France, we continue to regain market share in France. We've gained significant momentum in Italy.

As Rajiv spoke about earlier, we've launched the Seretide® in UK. And while we only had a couple of weeks under our belt for this quarter, we think that's going to be a great product and then look forward to that coming in Germany. So, look, I think there's a lot of momentum coming in Europe, and the business is doing great.

Operator: Our next question comes from Douglas Tsao from Barclays. Please go ahead.

Douglas D. Tsao
Barclays Capital, Inc.
Q
Hi. Good morning. Thanks for the question. So, first, Rajiv, maybe if you could provide a little bit more detail on the status of the Advair® program. I mean, I think you indicated you'd be able to file the ANDA by the end of the year. And just maybe when you would be able to – or showing your plan to – if you plan to show the Phase III clinical trial results from that program. And then, John, if you could provide just an update on the pricing environment in just the base generics business right now? Thank you.

Rajiv Malik
President & Executive Director
A
Doug, on generic Advair®, there are a number of studies which are currently underway. There are several PK, pharmacokinetic studies which are underway. We are expecting within the next few weeks or a couple of weeks, in fact, of the clinical endpoint data. We have a device robustness study which is coming around.

So, everything is aligned and progressing very well. Our commercial and manufacturing installation is not only installed, but now undergoing their qualification. So, we remain very confident about filing this ANDA towards the end of this year.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
And, Doug, with respect to the pricing environment, the way I would characterize it is extremely stable. For the year-over-year, the pricing environment, the price globally is really equal to zero, with the positive pricing in the North America mid-single-digit price declines in Europe which our volume more than offsets, and low-single-digit price in the rest of world. So, we're very pleased with the development of pricing around the globe.

Operator: Our next question comes from Louise Chen of Guggenheim Securities. Please go ahead.

Louise Chen
Guggenheim Securities LLC
Q
Hi. Thanks for taking my questions. First question I had was just on Mylan as a stand-alone. Curious what your strategic priorities are for this year and beyond this year. Maybe if you could refresh us on that one. And then secondly, you had mentioned that you don't have to have Perrigo. So, if it's not Perrigo, what other areas are you interested in? Is it still generics? Is it brand, U.S., O-U.S.? Any color would be greatly appreciated. Thank you.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
Sure. So, Louise, I would say our priorities right now is getting the Perrigo deal done. But as I said that if that does not happen, we obviously are actively looking at a lot of assets, and I think you should just expect there's obviously things for sale all over the globe. Starting with here in the United States, we see assets that would increase dosage form or therapeutic categories.

We see interesting bolt-on opportunities that will continue to enhance the infrastructure we have in place. We see assets in Europe that could, again, given now our commercial infrastructure with Abbott EPD and our legacy business that would complement that. We continue to see other OTC opportunities that would allow us to continue to be able to fill out that Ox channel.

So, I would say that, like I said, we've been very clear about our priorities. But with that being said, we believe there's a lot of – some priorities and the dosage form and the channels which we want to reach critical mass, mean the most to our customers and to the consumers, and we believe there's a lot of different assets that can get us there. It's just that the Perrigo kind of accelerates that for us and as well as for them. They talk about their base plus plus plus business. We get them to base plus overnight. So, we think that that synergy and complementary nature is why again it's the right next company for Mylan.

Operator: Our next question comes from Jason Gerberry from Leerink Partners. Please go ahead.

Jason M. Gerberry
Leerink Partners LLC
Q
Hi. Good morning. Thanks for taking my question. First question for Rajiv, just on the Advair® competitive landscape, any visibility in the other companies that were recruiting patients to run these equivalent studies? You guys are the most open and visible about your development updates. So, I'm just curious if you have any intelligence in terms of any other companies that might be on a similar timeline with you guys?

And then second question for Heather, just as you think about the evolution of the generics industry with the Teva/Allergan combination, just kind of curious how you think that competitively impacts your business, if you think there's any risk to that deal closing. I know you guys raised some anti-trust issues with the Teva/Mylan combination and given Allergan's book of businesses, pretty comparable in size, just kind of curious how you think about that issue? Thanks.

Rajiv Malik
President & Executive Director
A
So, Jason, I believe that our intelligence is not going to be far more than what you have. We have heard Sandoz-Oriel, some time back, we have heard Actavis having a program. We have also heard about 505(b)(2) between the Teva or some other programs. But, we are not actively or heard and seen that recruitment in the clinical, so we can't see anything more than that, but we believe that we are significantly ahead of others and we continue to maintain that momentum.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
And Jason, as far as the generic landscape goes, what's interesting is the FTC issues we've raised that obviously, there was the normal overlap consideration that the FTC should be looking at. But additionally, we said there is much more macro issues that they needed to take into consideration.

And in fact, I actually used the example that if you look at the four top players in our industry, three of them are predominantly in the brand. That leaves only Mylan as the true global generic company. And therefore, if one of the other three consolidated, which has now happened, you take Teva and Actavis, that we thought they brought to the marketplace would be much less significant than it's taking the only generic advocate out of the industry would be.

So, as I mentioned in my opening remarks, not only do I see it as different, I see it as a huge opportunity for Mylan. I mean, if we look historically at these large consolidations that have taken place, we've been able to disproportionately gain market share as others lose it as they divest and sell off assets. So, we see it as a great opportunity to build up our markets around the world.

Operator: Our next question comes from David Risinger from Morgan Stanley. Please go ahead.

Emil Chen
Morgan Stanley & Co. LLC
Q
Hi. This is actually Emil Chen on for Dave Risinger. Thanks for taking our question. John, earlier you mentioned that the pricing environment globally is relatively stable and apologies that I missed it, but can you just comment again specifically on the U.S. generic pricing environment? And then secondly, on EpiPen®, what are the prospects for any potential future price increases? Thank you.

John D. Sheehan
Executive VP, Chief Financial & Accounting Officer
A
So, I indicated that in my remarks that with the overall global environment for pricing being stable, that the North American pricing environment was positive.

Heather M. Bresch
Chief Executive Officer & Executive Director
A
And as far as EpiPen® goes, look as I've said, we are being very proactive and competitive in the multi-epinephrine marketplace; and therefore as we said here today, we continue to take – look at EpiPen® in a holistic manner and take opportunities as you would for a brand. So, you should foresee that just continuing as we continue to maximize the EpiPen® franchise.

Emil Chen
Morgan Stanley & Co. LLC
Q
Great. Thank you.

Operator: This concludes our Q&A session. I will now turn it back to Kris King for closing remarks.
[Closing.]