

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 5, 2018

MYLAN N.V.

(Exact name of registrant as specified in its charter)

The Netherlands (State or Other Jurisdiction of Incorporation)	333-199861 (Commission File Number)	98-1189497 (I.R.S. Employer Identification No.)
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**Building 4, Trident Place, Mosquito Way, Hatfield,
Hertfordshire**

(Address of Principal Executive Offices)

AL10 9UL

(Zip Code)

Registrant's telephone number, including area code: **+44 (0) 1707-853-000**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2018, Mylan N.V. (“Mylan” or the “Company”) issued a press release reporting the Company's financial results for the period ended September 30, 2018. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

As previously announced, Mylan will host a conference call and live webcast today at 5:00 p.m. ET to review the Company's financial results for the third quarter ended September 30, 2018.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
<u>99.1</u>	Press release announcing the Company’s financial results for the third quarter of 2018, dated November 5, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MYLAN N.V.

Date: November 5, 2018

By: /s/ Kenneth S. Parks
Kenneth S. Parks
Chief Financial Officer

FOR IMMEDIATE RELEASE

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Mylan Reports Third Quarter 2018 Results and Reaffirms 2018 Guidance

HERTFORDSHIRE, ENGLAND AND PITTSBURGH - Nov 5, 2018 - Mylan N.V. (NASDAQ: MYL) today announced its financial results for the quarter and nine months ended September 30, 2018.

Third Quarter 2018 Financial Highlights

- U.S. GAAP diluted earnings per ordinary share ("U.S. GAAP EPS") of \$0.34, up 113% over the prior year period.
- Total revenues of \$2.86 billion, down 4% compared to the prior year period and adjusted diluted earnings per ordinary share ("adjusted EPS") of \$1.25, up 14% over the prior year period.
- Revenue Highlights:
 - Rest of World segment net sales of \$773.7 million, up 4%, up 11% on a constant currency basis.
 - Europe segment net sales of \$1.04 billion, flat, up 2% on a constant currency basis.
 - North America segment net sales of \$1.01 billion, down 14%, down 13% on a constant currency basis, primarily due to the combined impact of the implementation of new accounting standards, lower volumes including EpiPen® Auto-Injector sales, the divestiture of certain contract manufacturing assets, the loss of exclusivity of a product and actions associated with the restructuring and remediation program at the Morgantown manufacturing facility.
- U.S. GAAP net cash provided by operating activities for the nine months ended September 30, 2018 of \$1.71 billion, up 9% compared to \$1.57 billion in the prior year period.
- Adjusted free cash flow for the nine months ended September 30, 2018 of \$2.02 billion, up 6% compared to \$1.91 billion in the prior year period.
- Mylan is not providing forward looking guidance for U.S. GAAP reported financial measures or a quantitative reconciliation of forward-looking non-GAAP financial measures. Please see "Non-GAAP Financial Measures" for additional information.

Mylan CEO Heather Bresch said: "Mylan's third quarter performance was in line with our expectations and we delivered solid year-over-year growth. Our confidence in the company's bright future extends well beyond any single factor or particular quarter, including the current, short-term macro market turbulence our industry is experiencing. Year-to-date, we have launched nearly 475 new products across our segments, including a record number of complex generics and biosimilars for Mylan. These medicines represent many different therapeutic categories, channels and dosage forms.

We remain committed to our full-year 2018 guidance, and this confirmation is not dependent on any single product approval or launch. As we look ahead, we're very optimistic about our long-term growth prospects as we have secured almost all regulatory approvals necessary for our key 2019 product drivers around the world."

Mylan President Rajiv Malik continued: "This record year of scientific accomplishments represents a significant milestone in the company's nearly 60-year history. Our recent successes demonstrate the strength of our scientific platform and our ability to manage and execute on new products, including complex generics and biologics. These milestones are the culmination of years-long scientific investments and reinforce our dedication to enhance access

to patients. The Mylan teams managing the science and working closely with our partners have consistently delivered remarkable results, and we look forward to continuing this momentum as we close out 2018.”

Mylan CFO Ken Parks added: “Mylan continues to generate strong cash flow with more than \$2.0 billion of adjusted free cash flow for the first nine months of 2018, up 6% from the prior year and a healthy 119% of adjusted net earnings of \$1.7 billion. We remain confident in our full year adjusted free cash flow outlook. As anticipated, our capital deployment priority is focused on deleveraging in the second half of 2018, and we expect this to continue into 2019. We intend to repay at least \$1.2 billion of debt maturing through year end 2019 and remain fully committed to maintaining our investment grade credit rating.”

Financial Summary

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
<i>(Unaudited; in millions, except per share amounts and %s)</i>	2018	2017	Percent Change	2018	2017	Percent Change
Total Revenues ⁽¹⁾	\$ 2,862.4	\$ 2,987.1	(4)%	\$ 8,355.2	\$ 8,668.8	(4)%
North America Net Sales	1,012.3	1,172.2	(14)%	2,998.4	3,666.7	(18)%
Europe Net Sales	1,041.3	1,040.8	—%	3,070.3	2,887.1	6%
Rest of World Net Sales	773.7	743.3	4%	2,164.5	2,016.4	7%
Other Revenues	35.1	30.8	14%	122.0	98.6	24%
US GAAP Gross Profit	\$ 1,039.2	\$ 1,178.1	(12)%	\$ 2,986.0	\$ 3,488.5	(14)%
US GAAP Gross Margin	36.3%	39.4%		35.7%	40.2%	
Adjusted Gross Profit ⁽²⁾	\$ 1,584.7	\$ 1,572.6	1%	\$ 4,500.2	\$ 4,621.8	(3)%
Adjusted Gross Margin ⁽²⁾	55.4%	52.6%		53.9%	53.3%	
US GAAP Net Earnings	\$ 176.7	\$ 88.3	100%	\$ 301.3	\$ 451.7	(33)%
US GAAP EPS	\$ 0.34	\$ 0.16	113%	\$ 0.58	\$ 0.84	(31)%
Adjusted Net Earnings ⁽²⁾	\$ 648.0	\$ 589.7	10%	\$ 1,695.1	\$ 1,679.5	1%
Adjusted EPS ⁽²⁾	\$ 1.25	\$ 1.10	14%	\$ 3.28	\$ 3.13	5%
EBITDA ⁽²⁾	\$ 841.6	\$ 776.9	8%	\$ 2,188.1	\$ 2,339.2	(6)%
Adjusted EBITDA ⁽²⁾	\$ 935.9	\$ 923.8	1%	\$ 2,616.4	\$ 2,667.2	(2)%

⁽¹⁾ Amounts exclude intersegment revenue that eliminates on a consolidated basis.

⁽²⁾ Non-GAAP financial measures. Please see "Non-GAAP Financial Measures" for additional information.

The U.S. Food and Drug Administration (“FDA”) completed an inspection at Mylan’s plant in Morgantown, West Virginia earlier this year and made observations through a Form 483. The Company has submitted a comprehensive response to the FDA and committed to a robust improvement plan. During the second quarter of 2018, the Company commenced a restructuring and remediation program aimed at reducing complexity at the Morgantown manufacturing facility. The program includes the discontinuation and transfer to other manufacturing sites of a number of products, a reduction of the workforce and extensive remediation activities. These actions have led to a temporary disruption in supply of certain products.

Once the remediation and restructuring activities in Morgantown are completed, the Company anticipates improved costs, efficiencies and profitability from the operations at the plant. The value and profitability related to the rationalized products is not proportionate to the reduced volumes of those products as the Company expects that manufacturing costs related to transferred products will be reduced and many of the discontinued products have lower than average gross margins. In addition, as it relates to North America, no significant new product revenue is forecasted from the Morgantown facility in 2019, and only eight of our top 50 gross margin generating products and only one out of the top 10 are currently manufactured in Morgantown.

The Company has incurred expenses amounting to approximately \$97.7 million and \$184.2 million for the three and nine months ended September 30, 2018, respectively, for incremental manufacturing variances, site remediation and restructuring charges. Mylan remains committed to maintaining the highest quality manufacturing standards at its facilities around the world and to continuous improvement in a time of evolving industry dynamics and regulatory expectations.

On August 31, 2018, the Company completed an agreement with certain subsidiaries of Novartis AG ("Novartis") to purchase the worldwide rights to their global cystic fibrosis products consisting of the TOBI Podhaler® and TOBI® solution. Tobramycin is the standard of care for treatment of pseudomonas aeruginosa, a leading driver of infection in cystic fibrosis. These products further strengthen our existing presence in cystic fibrosis, especially with our Creon Franchise in Europe, Australia, Japan and Canada. The asset acquisition allows us to further extend our respiratory franchise into rare/orphan disease indications and broaden our portfolio into dry powdered inhalers and nebulized products. Tobid Podhaler™ is manufactured using a proprietary Pulmosphere technology for which we have acquired exclusive rights for use, hence we expect a high barrier for generic entry.

Third Quarter 2018 Financial Results

Total revenues were \$2.86 billion, compared to \$2.99 billion for the comparable prior year period, representing a decrease of \$124.7 million, or 4%. Total revenues include both net sales and other revenues from third parties. **Net sales** for the current quarter were \$2.83 billion, compared to \$2.96 billion for the comparable prior year period, representing a decrease of \$129.0 million, or 4%. **Other revenues** for the current quarter were \$35.1 million, compared to \$30.8 million for the comparable prior year period, an increase of \$4.3 million.

The decrease in total revenues included lower net sales in the North America segment of 14%. This decrease was partially offset by increased net sales in the Rest of World segment of 4%. Net sales in the Europe segment were essentially flat. The overall decrease in total revenues was primarily driven by a decrease in net sales from existing products. Net sales from existing products, partially offset by new product launches, decreased on a constant currency basis by approximately \$14.6 million primarily as a result of lower volumes, and to a lesser extent, pricing. Net sales were also negatively impacted by approximately \$39.8 million due to the adoption of new accounting standards. Mylan's total revenues were unfavorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in India, Australia and the European Union. The unfavorable impact of foreign currency translation on current quarter total revenues was approximately \$75.0 million, resulting in a decrease in constant currency total revenues of approximately \$49.7 million, or 2%.

- Net sales in the **North America** segment totaled \$1.01 billion in the current quarter, a decrease of \$159.9 million or 14% when compared to the prior year period. This decrease was due primarily to lower volumes on existing products, including the EpiPen® Auto-Injector, partially offset by new product sales including the recent launch of Fulphila™, a biosimilar to Neulasta® (pegfilgrastim). The decline in volumes was primarily driven by the timing of purchases of our products by customers, the divestiture of certain contract manufacturing assets, the loss of exclusivity of a product, and actions associated with the restructuring and remediation program at the Morgantown manufacturing facility. In addition, net sales were negatively impacted by approximately \$50.4 million related to the implementation of new accounting standards. Pricing slightly decreased when compared to the prior year period. The impact of foreign currency translation on current period net sales was insignificant within North America.
- Net sales in the **Europe** segment totaled \$1.04 billion in the current quarter, an increase of \$0.5 million, when compared to the prior year period. This increase was primarily the result of new product sales and higher volumes on existing products. These were partially offset by lower pricing and the unfavorable impact of foreign currency translation which was approximately \$17.2 million, or 2%. Constant currency net sales increased by approximately \$17.7 million, or 2% when compared to the prior year period.
- Net sales in the **Rest of World** segment totaled \$773.7 million in the current quarter, an increase of \$30.4 million, or 4% when compared to the prior year period. This increase was primarily the result of new product sales, partially offset by the unfavorable impact of foreign currency translation and lower pricing. The increase in net sales as a result of new products was primarily due to new product sales from the Company's anti-retroviral therapy franchise combined with new product sales in Australia and China. Also, volumes were essentially flat as an increase in sales of key brands in China was offset by decreases in other markets. Overall, net sales from Rest of World were unfavorably impacted by the effect of foreign currency translation by approximately \$55.0 million, or 7% during the three months ended September 30, 2018. Constant currency net sales increased by approximately \$85.4 million, or 11%.

U.S. GAAP gross profit was \$1.04 billion and \$1.18 billion for the third quarter of 2018 and 2017, respectively. **U.S. GAAP gross margins** were 36% and 39% in the third quarter of 2018 and 2017, respectively. U.S. GAAP gross margins were negatively impacted by approximately 230 basis points related to the incremental amortization

from product acquisitions and in-process research and development (“IPR&D”) impairment charges. Gross margins were also negatively affected by approximately 340 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current quarter principally as a result of the activities at the Company’s Morgantown facility. In addition, gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America. The unfavorable impact of these items was partially offset by the impact from new product sales and the impact of incremental sales of certain key global brands. **Adjusted gross profit** was \$1.58 billion and adjusted gross margins were 55% for the third quarter of 2018 compared to adjusted gross profit of \$1.57 billion and adjusted gross margins of 53% in the prior year period. Adjusted gross margins were favorably impacted by new product sales and the impact of incremental sales of certain global key brands.

R&D expense for the three months ended September 30, 2018 was \$144.1 million, compared to \$182.3 million for the comparable prior year period, a decrease of \$38.2 million. This decrease was primarily due to lower expenditures related to the Company’s respiratory programs, lower expenses due to the reprioritization of global programs, and to higher payments in the prior year period related to licensing arrangements for products in development.

SG&A expense for the three months ended September 30, 2018 was \$577.3 million, compared to \$664.1 million for the comparable prior year period, a decrease of \$86.8 million. The decrease is due to ongoing integration activities and reduced share-based compensation expense primarily due to the Company’s determination that it was no longer probable that the minimum performance condition would be met and the reversal of all of the remaining cumulative expense related to the Company’s One-Time Special Performance-Based Five-Year Realizable Value Incentive Program (the “2014 Program”) that resulted in the Company recognizing a net reduction in share-based compensation expense of approximately \$27.1 million during the three months ended September 30, 2018. In addition, the Company experienced lower restructuring and acquisition-related expenses in the current quarter when compared to the prior year period.

During the third quarter of 2018, the Company recorded a net gain of \$20.4 million **in Litigation settlements and other contingencies, net** compared to a net charge of \$15.2 million in the comparable prior year period. During the three months ended September 30, 2018, the Company recorded a gain of approximately \$19.3 million for a fair value adjustment related to the contingent consideration for the acquisition of the exclusive worldwide rights to develop, manufacture and commercialize a generic equivalent to GlaxoSmithKline’s Advair® Diskus and Seretide® Diskus incorporating Pfizer Inc.’s proprietary dry powder inhaler delivery platform (the “respiratory delivery platform”). The fair value adjustment was the result of changes to assumptions relating to the timing of product launch along with other competitive and market factors. The net charge in the prior year period consists primarily of an increase to a litigation accrual for an anti-trust related matter.

U.S. GAAP net earnings increased by \$88.4 million to \$176.7 million for the three months ended September 30, 2018, compared to \$88.3 million for the prior year period and **U.S. GAAP EPS** increased from \$0.16 in the prior year period to \$0.34 in the current quarter. The Company recognized a **U.S. GAAP income tax provision** of \$15.5 million, compared to a U.S. GAAP income tax provision of \$91.3 million for the comparable prior year period. **Adjusted net earnings** increased to \$648.0 million compared to \$589.7 million for the prior year period. **Adjusted EPS** increased to \$1.25 from \$1.10 in the prior year period.

EBITDA was \$841.6 million for the current quarter and \$776.9 million for the comparable prior year period. After adjusting for certain items as further detailed in the reconciliation below, **adjusted EBITDA** was \$935.9 million for the current quarter and \$923.8 million for the comparable prior year period.

Nine Months Ended September 30, 2018 Financial Results

Total Revenues for the nine months ended September 30, 2018 were \$8.36 billion, compared to \$8.67 billion for the comparable prior year period, representing a decrease of \$313.6 million, or 4%. Total revenues include both net sales and other revenues from third parties. **Net sales** for the nine months ended September 30, 2018 were \$8.23 billion, compared to \$8.57 billion for the comparable prior year period, representing a decrease of \$337.0 million, or 4%. **Other revenues** for the nine months ended September 30, 2018 were \$122.0 million, compared to \$98.6 million for the comparable prior year period. The increase in other revenues was primarily the result of consideration received from a license of intellectual property during the current year period.

The decrease in total revenues included lower net sales in the North America segment of 18%. This decrease was partially offset by increased net sales in the Europe segment of 6%, and in the Rest of World segment of 7%. The overall decrease in total revenues was primarily driven by a decrease in net sales from existing products. Net sales from existing products, partially offset by new product sales, decreased on a constant currency basis by approximately \$426.5 million primarily as a result of lower volumes, and to a lesser extent, pricing. Net sales were also negatively impacted by approximately \$64.4 million due to the adoption of new accounting standards. Mylan's total revenues were favorably impacted by the effect of foreign currency translation, primarily reflecting changes in the U.S. Dollar as compared to the currencies of Mylan's subsidiaries in the European Union, the United Kingdom and Japan. The favorable impact of foreign currency translation on current year total revenues was approximately \$156.4 million. On a constant currency basis, the decline in total revenues for the nine months ended September 30, 2018 was approximately \$470.0 million, or 5%.

- Net sales from **North America** segment totaled \$3.00 billion during the nine months ended September 30, 2018, a decrease of \$668.3 million or 18% when compared to the prior year period. This decrease was due primarily to lower volumes on existing products, including the EpiPen® Auto-Injector, partially offset by new product sales. The decline in volumes was primarily driven by the timing of purchases of our products by customers, the divestiture of certain contract manufacturing assets, the loss of exclusivity of certain products, and actions associated with the restructuring and remediation program at the Morgantown manufacturing facility. In addition, net sales were negatively impacted by \$99.1 million related to the implementation of new accounting standards. Pricing also declined when compared to the prior year. The impact of foreign currency translation on current period net sales was insignificant within North America.
- Net sales from **Europe** segment totaled \$3.07 billion during the nine months ended September 30, 2018, an increase of \$183.2 million or 6% when compared to the prior year period. This increase was primarily the result of the favorable impact of foreign currency translation, new product sales, and to a lesser extent, higher volumes of existing products. The favorable impact of foreign currency translation was approximately \$184.0 million or 6%. Partially offsetting these items was lower pricing on existing products. Constant currency net sales were essentially flat compared to the prior year period.
- Net sales from **Rest of World** segment totaled \$2.16 billion during the nine months ended September 30, 2018, an increase of \$148.1 million or 7% when compared to the prior year period. This increase was primarily the result of new product sales, and to a lesser extent, higher volumes of existing products including higher sales of key brands in China. The increase in net sales as a result of new products was primarily due to new product sales from the Company's anti-retroviral therapy franchise combined with new product sales in Australia, Japan and China. This increase was partially offset by lower pricing on existing products and the unfavorable impact of foreign currency translation. Overall, net sales from Rest of World were unfavorably impacted by the effect of foreign currency translation of approximately \$33.4 million, or 2%. Constant currency net sales increased by approximately \$181.5 million or 9% when compared to the prior year period.

U.S. GAAP gross profit was \$2.99 billion and \$3.49 billion for the nine months ended September 30, 2018 and 2017, respectively. **U.S. GAAP gross margins** were 36% and 40% for the nine months ended September 30, 2018 and 2017, respectively. U.S. GAAP gross margins were negatively impacted by approximately 260 basis points related to the incremental amortization from product acquisitions and IPR&D impairment charges. Gross margins were also negatively affected by approximately 220 basis points as a result of incremental manufacturing expenses, site remediation expenses and incremental restructuring charges incurred during the current period principally as a result of the activities at the Company's Morgantown facility. In addition, gross margins were negatively impacted in the current quarter as a result of lower gross profit from the sales of existing products in North America. The unfavorable impact of these items was partially offset by the favorable impact from new product sales. **Adjusted gross profit** was \$4.50 billion and adjusted gross margins were 54% for the nine months ended September 30, 2018 compared to adjusted gross profit of \$4.62 billion and adjusted gross margins of 53% in the prior year period.

R&D expense for the nine months ended September 30, 2018 was \$555.7 million, compared to \$580.9 million for the comparable prior year period, a decrease of \$25.2 million. This decrease was primarily due to lower expenditures related to the Company's respiratory programs, and lower expenses due to the reprioritization of global programs. Partially offsetting this decrease were slightly higher payments in the current year related to licensing arrangements for products in development which totaled approximately \$100.5 million during the nine months ended September 30, 2018, compared to approximately \$89.9 million in the prior year period.

SG&A expense for the nine months ended September 30, 2018 was \$1.81 billion, compared to \$1.92 billion for the comparable prior year period, a decrease of \$107.3 million. The decrease is primarily due to ongoing integration activities, lower acquisition-related costs of approximately \$41.8 million, and reduced share-based compensation expense primarily due to the reversal of all of the remaining cumulative expense related to the 2014 Program that resulted in the Company recognizing a net reduction in share-based compensation expense of approximately \$50.6 million during the nine months ended September 30, 2018. These decreases were partially offset by an increase in bad debt expense of approximately \$23.0 million primarily related to a special business interruption event for one customer.

During the nine months ended September 30, 2018, the Company recorded a net gain of \$50.6 million in **Litigation settlements and other contingencies, net** compared to a net gain of \$25.8 million in the comparable prior year period. During the nine months ended September 30, 2018, the Company recognized a net gain of \$49.3 million for fair value adjustments related to the respiratory delivery platform contingent consideration. The fair value adjustments were the net result of changes to assumptions relating to the timing of product launch along with other competitive and market factors. In addition, the Company recognized a gain of approximately \$14.7 million related to a favorable litigation settlement, which was partially offset by litigation related charges of approximately \$13.3 million, primarily related to an anti-trust matter and a patent infringement matter. During the nine months ended September 30, 2017, the Company recorded a gain of approximately \$88.1 million for fair value adjustments related to the contingent consideration for the respiratory delivery platform. Offsetting this gain were accruals of approximately \$52.5 million primarily related to the modafinil and EpiPen® Auto-Injector litigation matters and an accrual increase related to an anti-trust related matter. In addition, a fair value loss of \$9.9 million related to the contingent consideration related to the acquisition of certain female healthcare businesses from Famy Care Limited was recognized during the prior year period.

U.S. GAAP net earnings decreased by \$150.4 million to \$301.3 million for the nine months ended September 30, 2018, compared to \$451.7 million for the prior year period and **U.S. GAAP EPS** decreased from \$0.84 in the prior year period to \$0.58 for the nine months ended September 30, 2018. The Company recognized a **U.S. GAAP income tax benefit** of \$79.9 million, compared to an income tax provision of \$124.2 million for the comparable prior year period. **Adjusted net earnings** increased to \$1.70 billion compared to \$1.68 billion for the prior year period. **Adjusted EPS** increased to \$3.28 from \$3.13 in the prior year period.

EBITDA was \$2.19 billion for the nine months ended September 30, 2018, and \$2.34 billion for the comparable prior year period. After adjusting for certain items as further detailed in the reconciliation below, **adjusted EBITDA** was \$2.62 billion for the nine months ended September 30, 2018 and \$2.67 billion for the comparable prior year period.

Cash Flow

U.S. GAAP net cash provided by operating activities was \$1.71 billion for the nine months ended September 30, 2018 compared to \$1.57 billion for the prior year period. Capital expenditures were approximately \$137.4 million for the nine months ended September 30, 2018 compared to approximately \$156.4 million for the comparable prior year. **Adjusted net cash provided by operating activities** was \$2.16 billion for the nine months ended September 30, 2018 compared to \$2.06 billion for the prior year period. **Adjusted free cash flow**, defined as adjusted net cash provided by operating activities less capital expenditures, was \$2.02 billion for the nine months ended September 30, 2018, compared to \$1.91 billion in the prior year period.

Conference Call and Earnings Materials

Mylan N.V. will host a conference call and live webcast, today at 5:00 p.m. ET, to review the Company's financial results for the third quarter ended September 30, 2018. The briefing can be accessed live by calling 800.514.4861 or 678.809.2405 for international callers (ID#: 9798175) or at the following address on the company's website: investor.mylan.com. The "Q3 2018 Earnings Call" presentation, which will be referenced during the call can be found at investor.mylan.com. A replay of the webcast will also be available on the website.

Non-GAAP Financial Measures

This press release includes the presentation and discussion of certain financial information that differs from what is reported under accounting principles generally accepted in the United States ("U.S. GAAP"). These non-GAAP financial measures, including, but not limited to, adjusted EPS, adjusted gross profit, adjusted gross margins, adjusted net earnings, EBITDA, adjusted EBITDA, adjusted R&D and as a % of total revenues, adjusted SG&A and as a % of total revenues, adjusted effective tax rate, adjusted net cash provided by operating activities, adjusted free cash flow, constant currency total revenues and constant currency net sales are presented in order to supplement investors' and other readers' understanding and assessment of the financial performance of Mylan N.V. ("Mylan" or the "Company"). Management uses these measures internally for forecasting, budgeting, measuring its operating performance, and incentive-based awards. 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 U.S. GAAP. We believe that non-GAAP financial measures are useful supplemental information for our investors and when considered together with our U.S. GAAP financial measures and the reconciliation to the most directly comparable U.S. GAAP financial measure, provide a more complete understanding of the factors and trends affecting our operations. The financial performance of the Company is measured by senior management, in part, using the adjusted metrics included herein, along with other performance metrics. Management's annual incentive compensation is derived, in part, based on the adjusted EPS metric and the adjusted free cash flow metric. In addition, the Company believes that including EBITDA and supplemental adjustments applied in presenting adjusted EBITDA and Credit Agreement Adjusted EBITDA (as defined below) pursuant to our Credit Agreements is appropriate to provide additional information to investors to demonstrate the Company's ability to comply with financial debt covenants and assess the Company's ability to incur additional indebtedness. We also report sales performance using the non-GAAP financial measures of "constant currency" total revenues and net sales. These measures provide information on the change in total revenues and net sales assuming that foreign currency exchange rates had not changed between the prior and current period. The comparisons presented at constant currency rates reflect comparative local currency sales at the prior year's foreign exchange rates. We routinely evaluate our net sales and total revenues 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. The "Summary of Total Revenues by Segment" table below compares net sales on an actual and constant currency basis for each reportable segment for the three and nine months ended September 30, 2018 and 2017 as well as for total revenues. Also, set forth below, Mylan has provided reconciliations of such non-GAAP financial measures to the most directly comparable U.S. GAAP financial measures. Investors and other readers are encouraged to review the related U.S. GAAP financial measures and the reconciliations of the non-GAAP measures to their most directly comparable U.S. GAAP measures set forth below, 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 U.S. GAAP.

For additional information regarding the components and uses of Non-GAAP financial measures refer to Management's Discussion and Analysis of Financial Condition and Results of Operations-- Use of Non-GAAP

Financial Measures section of Mylan's Quarterly Report on Form 10-Q for the three months ended September 30, 2018 (the "Form 10-Q").

Mylan is not providing forward looking guidance for U.S. GAAP reported financial measures or a quantitative reconciliation of forward-looking non-GAAP financial measures to the most directly comparable U.S. GAAP measure because it is unable to predict with reasonable certainty the ultimate outcome of certain significant items without unreasonable effort. These items include, but are not limited to, acquisition-related expenses including those related to the acquisition of Meda AB (publ.), restructuring expenses, asset impairments, litigation settlements and other contingencies, including changes to contingent consideration and certain other gains or losses. These items are uncertain, depend on various factors, and could have a material impact on U.S. GAAP reported results for the guidance period.

Reconciliation of Adjusted Net Earnings and Adjusted EPS

Below is a reconciliation of U.S. GAAP net earnings and U.S. GAAP EPS to adjusted net earnings and adjusted EPS for the three and nine months ended September 30, 2018 compared to the prior year period:

(in millions, except per share amounts)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018		2017		2018		2017	
U.S. GAAP net earnings and U.S. GAAP EPS	\$ 176.7	\$ 0.34	\$ 88.3	\$ 0.16	\$ 301.3	\$ 0.58	\$ 451.7	\$ 0.84
Purchase accounting related amortization (primarily included in cost of sales) ^(a)	428.7		370.7		1,282.4		1,074.9	
Litigation settlements and other contingencies, net	(20.4)		15.2		(50.6)		(25.8)	
Interest expense (primarily clean energy investment financing and accretion of contingent consideration)	12.1		10.3		31.0		37.2	
Clean energy investments pre-tax loss	12.6		22.4		58.6		66.4	
Acquisition related costs (primarily included in SG&A and cost of sales) ^(b)	4.9		15.2		17.4		60.2	
Restructuring related costs ^(c)	80.8		73.4		202.3		112.8	
Other special items included in:								
Cost of sales ^(d)	65.4		12.3		139.4		39.2	
Research and development expense ^(e)	3.2		15.1		100.3		89.9	
Selling, general and administrative expense ^(f)	(0.7)		4.0		33.2		12.7	
Other expense, net ^(g)	1.3		(3.1)		25.5		4.8	
Tax effect of the above items and other income tax related items	(116.6)		(34.1)		(445.7)		(244.5)	
Adjusted net earnings and adjusted EPS	\$ 648.0	\$ 1.25	\$ 589.7	\$ 1.10	\$ 1,695.1	\$ 3.28	\$ 1,679.5	\$ 3.13
Weighted average diluted ordinary shares outstanding	516.5		537.0		516.5		537.0	

Significant items for the three and nine months ended September 30, 2018 include the following:

- (a) The increase in purchase accounting related amortization is primarily due to the increase in amortization expense as a result of the full impact of certain product rights acquisitions which occurred in 2017, the current year impact of the 2018 product rights acquisitions and IPR&D impairment charges of \$15.5 million and \$87.5 million during the three and nine months ended September 30, 2018, respectively.
- (b) Acquisition related costs incurred in 2017 and through the nine months ended September 30, 2018 consist primarily of integration activities.
- (c) For the three months ended September 30, 2018, approximately \$51.8 million is included in cost of sales, \$0.3 million is included in R&D, and \$28.7 million is included in SG&A. For the nine months ended September 30, 2018, approximately \$97.2 million is included in cost of sales, \$17.0 million is included in R&D, and \$88.4 million is included in SG&A. Refer to Note 17 *Restructuring* included in Part I, Item 1 of the Form 10-Q for additional information.
- (d) The three and nine months ended September 30, 2018 increases relate primarily to expenses of \$48.9 million and \$104.9 million, respectively, for certain incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown facility.
- (e) R&D expense for the three months ended September 30, 2018 includes expenses related to on-going collaboration agreements, including Momenta. For the nine months ended September 30, 2018, R&D expense

includes \$73.5 million related to four non-refundable upfront payments for development agreements entered into during the current period. The remaining expense relates to the on-going collaboration agreements, including Momenta. R&D expense for the three months ended September 30, 2017 includes \$8.0 million related to Momenta collaboration expense. For the nine months ended September 30, 2017, R&D expense includes an upfront expense of approximately \$50.0 million related to a joint development and marketing agreement for a respiratory product, \$22.5 million related to Momenta collaboration expense, and other similar smaller agreements.

- (f) The decrease for the three months ended September 30, 2018 is primarily related to a gain from the sale of assets. The increase for the nine months ended September 30, 2018 is primarily related to bad debt expense of approximately \$26.5 million related to a special business interruption event for one customer.
- (g) The increase for the nine months ended September 30, 2018 is primarily related to mark-to-market losses of investments in equity securities historically accounted for as available-for-sale securities and the cumulative realized gains on such investments.

Below is a reconciliation of U.S. GAAP net earnings to EBITDA and adjusted EBITDA for the three and nine months ended September 30, 2018 compared to the prior year period (in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP net earnings	\$ 176.7	\$ 88.3	\$ 301.3	\$ 451.7
Add / (subtract) adjustments:				
Net contribution attributable to equity method investments	12.6	22.4	58.6	77.2
Income tax provision (benefit)	15.5	91.3	(79.9)	124.2
Interest expense	136.2	131.8	407.1	406.3
Depreciation and amortization	500.6	443.1	1,501.0	1,279.8
EBITDA	\$ 841.6	\$ 776.9	\$ 2,188.1	\$ 2,339.2
Add / (subtract) adjustments:				
Share-based compensation (income) expense	(29.2)	22.2	(8.6)	64.2
Litigation settlements and other contingencies, net	(20.4)	15.2	(50.6)	(25.8)
Restructuring & other special items	143.9	109.5	487.5	289.6
Adjusted EBITDA	\$ 935.9	\$ 923.8	\$ 2,616.4	\$ 2,667.2

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward-Looking Statements

This release contains "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, reaffirming our 2018 guidance; that our confidence in the company's bright future extends well beyond any single factor or particular quarter, including the current, short-term macro market turbulence our industry is experiencing; that we remain committed to our full-year 2018 guidance ranges, and this confirmation is not dependent on any single product approval or launch; as we look ahead, we're very optimistic about our long-term growth prospects as we have secured almost all regulatory approvals necessary for our key 2019 product drivers around the world; our recent successes demonstrate the strength of our scientific program and our ability to manage and execute on new products, including complex generics and biologics; these milestones are the culmination of years-long scientific investments and reinforce our dedication to enhance access to patients; the Mylan teams managing the science and working closely with our partners have consistently delivered remarkable results, and we look forward to continuing this momentum as we close out 2018; we remain confident in our full year adjusted free cash flow outlook; as anticipated, our capital deployment priority is focused on deleveraging in the second half of 2018, and we expect this to continue into 2019; we intend to repay at least \$1.2 billion of debt maturing through year end 2019; and we remain fully committed to maintaining our investment grade credit rating. These may often be identified by the use of words such as "will," "may," "could," "should," "would," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "pipeline," "intend," "continue," "target" and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: actions and

decisions of healthcare and pharmaceutical regulators; failure to achieve expected or targeted future financial and operating performance and results; uncertainties regarding future demand, pricing and reimbursement for our products; any regulatory, legal, or other impediments to Mylan's ability 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"); success of clinical trials and Mylan's ability to execute on new product opportunities; any changes in or difficulties with our manufacturing facilities, supply chain or inventory or our ability to meet anticipated demand; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our financial condition, results of operations, and/or cash flows; the ability to meet expectations regarding the accounting and tax treatments of acquisitions, including Mylan's acquisition of Mylan Inc. and Abbott Laboratories' non-U.S. developed markets specialty and branded generics business; changes in relevant tax and other laws, including but not limited to changes in the U.S. tax code and healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any significant breach of data security or data privacy or disruptions to our information technology systems; 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; the impact of competition; identifying, acquiring, and integrating complementary or strategic acquisitions of other companies, products, or assets being more difficult, time-consuming or costly than anticipated; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with strategic acquisitions or restructuring programs within the expected time-frames or at all; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions and global exchange rates; 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 U.S. GAAP and related standards or on an adjusted basis. For more detailed information on the risks and uncertainties associated with Mylan's business activities, see the risks described in Mylan's Annual Report on Form 10-K for the year ended December 31, 2017, as amended, and our other filings with the Securities and Exchange Commission (the "SEC"). You can access Mylan's filings with the SEC through the SEC website at www.sec.gov or through our website, and Mylan strongly encourages you to do so. Mylan routinely posts information that may be important to investors on our website at investor.mylan.com, 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 (Reg FD). The contents of our website are not incorporated into this release. Mylan undertakes no obligation to update any statements herein for revisions or changes after the date of this release.

Mylan N.V. and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited; in millions, except per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues:				
Net sales	\$ 2,827.3	\$ 2,956.3	\$ 8,233.2	\$ 8,570.2
Other revenues	35.1	30.8	122.0	98.6
Total revenues	2,862.4	2,987.1	8,355.2	8,668.8
Cost of sales	1,823.2	1,809.0	5,369.2	5,180.3
Gross profit	1,039.2	1,178.1	2,986.0	3,488.5
Operating expenses:				
Research and development	144.1	182.3	555.7	580.9
Selling, general and administrative	577.3	664.1	1,808.1	1,915.4
Litigation settlements and other contingencies, net	(20.4)	15.2	(50.6)	(25.8)
Total operating expenses	701.0	861.6	2,313.2	2,470.5
Earnings from operations	338.2	316.5	672.8	1,018.0
Interest expense	136.2	131.8	407.1	406.3
Other expense, net	9.8	5.1	44.3	35.8
Earnings before income taxes	192.2	179.6	221.4	575.9
Income tax provision (benefit)	15.5	91.3	(79.9)	124.2
Net earnings	176.7	88.3	301.3	451.7
Earnings per ordinary share:				
Basic	\$ 0.34	\$ 0.17	\$ 0.59	\$ 0.84
Diluted	\$ 0.34	\$ 0.16	\$ 0.58	\$ 0.84
Weighted average ordinary shares outstanding:				
Basic	514.5	535.2	514.4	534.9
Diluted	516.5	537.0	516.5	537.0

Mylan N.V. and Subsidiaries
Condensed Consolidated Balance Sheets
(Unaudited; in millions)

	September 30, 2018	December 31, 2017
ASSETS		
Assets		
Current assets:		
Cash and cash equivalents	\$ 449.2	\$ 292.1
Accounts receivable, net	2,948.7	3,612.4
Inventories	2,560.6	2,542.7
Prepaid expenses and other current assets	583.2	766.1
Total current assets	6,541.7	7,213.3
Intangible assets, net	14,239.0	15,245.8
Goodwill	9,796.6	10,205.7
Other non-current assets	2,878.3	3,141.5
Total assets	\$ 33,455.6	\$ 35,806.3
LIABILITIES AND EQUITY		
Liabilities		
Current portion of long-term debt and other long-term obligations	\$ 1,176.4	\$ 1,808.9
Current liabilities	4,005.6	4,576.4
Long-term debt	13,291.4	12,865.3
Other non-current liabilities	2,916.0	3,248.1
Total liabilities	21,389.4	22,498.7
Mylan N.V. shareholders' equity	12,066.2	13,307.6
Total liabilities and equity	\$ 33,455.6	\$ 35,806.3

Mylan N.V. and Subsidiaries
Reconciliation of Non-GAAP Financial Measures
(Unaudited; in millions)

Summary of Total Revenues by Segment

<i>(In millions)</i>	Three Months Ended September 30,					
	2018	2017	% Change	2018 Currency Impact ⁽¹⁾	2018 Constant Currency Revenues	Constant Currency % Change ⁽²⁾
Net sales						
North America	\$ 1,012.3	\$ 1,172.2	(14)%	\$ 2.5	\$ 1,014.8	(13)%
Europe	1,041.3	1,040.8	— %	17.2	1,058.5	2 %
Rest of World	773.7	743.3	4 %	55.0	828.7	11 %
Total net sales	2,827.3	2,956.3	(4)%	74.7	2,902.0	(2)%
Other revenues ⁽³⁾	35.1	30.8	14 %	0.3	35.4	15 %
Consolidated total revenues ⁽⁴⁾	<u>\$ 2,862.4</u>	<u>\$ 2,987.1</u>	(4)%	<u>\$ 75.0</u>	<u>\$ 2,937.4</u>	(2)%

<i>(In millions)</i>	Nine Months Ended September 30,					
	2018	2017	% Change	2018 Currency Impact ⁽¹⁾	2018 Constant Currency Revenues	Constant Currency % Change ⁽²⁾
Net sales						
North America	\$ 2,998.4	\$ 3,666.7	(18)%	\$ (3.2)	\$ 2,995.2	(18)%
Europe	3,070.3	2,887.1	6 %	(184.0)	2,886.3	— %
Rest of World	2,164.5	2,016.4	7 %	33.4	2,197.9	9 %
Total net sales	8,233.2	8,570.2	(4)%	(153.8)	8,079.4	(6)%
Other revenues ⁽³⁾	122.0	98.6	24 %	(2.6)	119.4	21 %
Consolidated total revenues ⁽⁴⁾	<u>\$ 8,355.2</u>	<u>\$ 8,668.8</u>	(4)%	<u>\$ (156.4)</u>	<u>\$ 8,198.8</u>	(5)%

⁽¹⁾ Currency impact is shown as unfavorable (favorable).

⁽²⁾ The constant currency percentage change is derived by translating net sales or revenues for the current period at prior year comparative period exchange rates, and in doing so shows the percentage change from 2018 constant currency net sales or revenues to the corresponding amount in the prior year.

⁽³⁾ For the three months ended September 30, 2018, other revenues in North America, Europe, and Rest of World were approximately \$20.9 million, \$7.4 million, and \$6.8 million, respectively. For the nine months ended September 30, 2018, other revenues in North America, Europe, and Rest of World were approximately \$84.5 million, \$19.8 million, and \$17.7 million, respectively.

⁽⁴⁾ Amounts exclude intersegment revenue that eliminates on a consolidated basis.

Reconciliation of Income Statement Line Items

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP cost of sales	\$ 1,823.2	\$ 1,809.0	\$ 5,369.2	\$ 5,180.3
Deduct:				
Purchase accounting amortization and other related items	(426.9)	(361.4)	(1,275.2)	(1,054.9)
Acquisition related items	(1.4)	0.2	(2.4)	(1.9)
Restructuring and related costs	(51.8)	(21.0)	(97.2)	(37.3)
Other special items	(65.4)	(12.3)	(139.4)	(39.2)
Adjusted cost of sales	\$ 1,277.7	\$ 1,414.5	\$ 3,855.0	\$ 4,047.0
Adjusted gross profit ^(a)	\$ 1,584.7	\$ 1,572.6	\$ 4,500.2	\$ 4,621.8
Adjusted gross margin ^(a)	55%	53%	54%	53%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP R&D	\$ 144.1	\$ 182.3	\$ 555.7	\$ 580.9
Deduct:				
Acquisition related costs	(0.2)	(0.8)	(0.7)	(1.5)
Restructuring and related costs	(0.3)	(1.1)	(17.0)	(2.5)
Purchase accounting amortization and other related items	(0.1)	(0.2)	(0.2)	(0.2)
Other special items	(3.2)	(15.1)	(100.3)	(89.9)
Adjusted R&D	\$ 140.3	\$ 165.1	\$ 437.5	\$ 486.8
Adjusted R&D as % of total revenues	5%	6%	5%	6%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP SG&A	\$ 577.3	\$ 664.1	\$ 1,808.1	\$ 1,915.4
Add / (deduct):				
Acquisition related costs	(3.2)	(14.5)	(14.3)	(56.1)
Restructuring and related costs	(28.7)	(51.4)	(88.4)	(73.0)
Purchase accounting amortization and other related items	(1.7)	(9.1)	(7.0)	(14.1)
Other special items	0.7	(4.0)	(33.2)	(12.7)
Adjusted SG&A	\$ 544.4	\$ 585.1	\$ 1,665.2	\$ 1,759.5
Adjusted SG&A as % of total revenues	19%	20%	20%	20%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP total operating expenses	\$ 701.0	\$ 861.6	\$ 2,313.2	\$ 2,470.5
Add / (deduct):				
Litigation settlements and other contingencies, net	20.4	(15.2)	50.6	25.8
R&D adjustments	(3.8)	(17.2)	(118.2)	(94.1)
SG&A adjustments	(32.9)	(79.0)	(142.9)	(155.9)
Adjusted total operating expenses	\$ 684.7	\$ 750.2	\$ 2,102.7	\$ 2,246.3
Adjusted earnings from operations ^(b)	\$ 900.0	\$ 822.4	\$ 2,397.5	\$ 2,375.5

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP interest expense	\$ 136.2	\$ 131.8	\$ 407.1	\$ 406.3
Deduct:				
Interest expense related to clean energy investments	(2.1)	(3.0)	(6.5)	(9.4)
Accretion of contingent consideration liability	(5.3)	(5.5)	(16.3)	(22.2)
Acquisition related costs	—	—	—	(0.2)
Other special items	(4.7)	(1.8)	(8.2)	(5.4)
Adjusted interest expense	\$ 124.1	\$ 121.5	\$ 376.1	\$ 369.1

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP other expense, net	\$ 9.8	\$ 5.1	\$ 44.3	\$ 35.8
Add / (deduct):				
Clean energy investments pre-tax loss ^(c)	(12.6)	(22.4)	(58.6)	(66.4)
Net loss on Sagent Agila joint venture termination	—	—	—	(5.7)
Acquisition related costs	—	—	—	(0.8)
Restructuring and related costs	—	—	0.3	—
Other items ^(d)	(1.3)	3.1	(25.5)	(4.8)
Adjusted other income	\$ (4.1)	\$ (14.2)	\$ (39.5)	\$ (41.9)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
U.S. GAAP earnings before income taxes	\$ 192.2	\$ 179.6	\$ 221.4	\$ 575.9
Total pre-tax non-GAAP adjustments	587.8	535.5	1,839.5	1,472.3
Adjusted earnings before income taxes	\$ 780.0	\$ 715.1	\$ 2,060.9	\$ 2,048.2
U.S. GAAP income tax (benefit) provision	\$ 15.5	\$ 91.3	\$ (79.9)	\$ 124.2
Adjusted tax expense	116.5	34.1	445.7	244.5
Adjusted income tax provision	\$ 132.0	\$ 125.4	\$ 365.8	\$ 368.7
Adjusted effective tax rate	16.9%	17.5%	17.7%	18.0%

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
U.S. GAAP net cash provided by operating activities	\$ 653.6	\$ 548.6	\$ 1,705.6	\$ 1,569.3
Add:				
Restructuring and related costs ^(e)	75.8	14.9	203.2	104.4
Financing related expense	—	—	2.6	—
Corporate contingencies	5.5	275.2	115.7	307.7
Acquisition related costs	—	2.0	3.7	54.3
R&D expense	25.0	22.4	125.0	27.4
Other	—	—	5.0	—
Adjusted net cash provided by operating activities	<u>\$ 759.9</u>	<u>\$ 863.1</u>	<u>\$ 2,160.8</u>	<u>\$ 2,063.1</u>
Deduct:				
Capital expenditures	(61.5)	(47.1)	(137.4)	(156.4)
Adjusted free cash flow	<u>\$ 698.4</u>	<u>\$ 816.0</u>	<u>\$ 2,023.4</u>	<u>\$ 1,906.7</u>

^(a) U.S. GAAP gross profit is calculated as total revenues less U.S. GAAP cost of sales. U.S. GAAP gross margin is calculated as U.S. GAAP gross profit divided by total revenues. Adjusted gross profit is calculated as total revenues less adjusted cost of sales. Adjusted gross margin is calculated as adjusted gross profit divided by total revenues.

^(b) U.S. GAAP earnings from operations is calculated as U.S. GAAP gross profit less U.S. GAAP total operating expenses. Adjusted net earnings from operations is calculated as adjusted gross profit less adjusted total operating expenses.

^(c) Adjustment represents exclusion of activity related to Mylan's clean energy investments, the activities of which qualify for income tax credits under section 45 of the U.S. Internal Revenue Code of 1986, as amended.

^(d) Primarily related to mark-to-market losses of investments in equity securities historically accounted for as available-for-sale securities and the cumulative realized gains on such investments.

^(e) For the three and nine months ended September 30, 2018 includes approximately \$48.9 million and \$104.9 million, respectively, of certain incremental manufacturing variances and site remediation expenses as a result of the activities at the Company's Morgantown facility.

Reconciliation of EBITDA and Adjusted EBITDA

Below is a reconciliation of U.S. GAAP net earnings to EBITDA and adjusted EBITDA for the respective quarterly periods (in millions):

<i>(in millions, except ratio)</i>	Three Months Ended			
	December 31, 2017	March 31, 2018	June 30, 2018	September 30, 2018
U.S. GAAP net earnings	\$ 244.3	\$ 87.1	\$ 37.5	\$ 176.7
Add / (subtract) adjustments:				
Net contribution attributable to equity method investments	(19.2)	23.1	22.9	12.6
Income tax provision (benefit)	82.8	(76.6)	(18.8)	15.5
Interest expense	128.3	131.7	139.2	136.2
Depreciation and amortization	526.0	498.5	501.9	500.6
EBITDA	\$ 962.2	\$ 663.8	\$ 682.7	\$ 841.6
Add / (subtract) adjustments:				
Share-based compensation expense (income)	10.5	21.4	(0.8)	(29.2)
Litigation settlements and other contingencies, net	12.7	16.2	(46.4)	(20.4)
Restructuring & other special items	138.2	112.5	231.1	143.9
Adjusted EBITDA	\$ 1,123.6	\$ 813.9	\$ 866.6	\$ 935.9

September 30, 2018 Notional Debt to Twelve Months Ended September 30, 2018 Mylan N.V. Adjusted EBITDA as calculated under our Credit Agreements ("Credit Agreement Adjusted EBITDA") Leverage Ratio

The stated non-GAAP financial measure September 30, 2018 notional debt to twelve months ended September 30, 2018 Credit Agreement Adjusted EBITDA leverage ratio is based on the sum of (i) Mylan's adjusted EBITDA for the quarters ended December 31, 2017, March 31, 2018, June 30, 2018 and September 30, 2018 and (ii) certain adjustments permitted to be included in Credit Agreement Adjusted EBITDA as of September 30, 2018 pursuant to the Company's revolving credit facility dated as of July 27, 2018 (as amended, supplemented or otherwise modified from time to time), among Mylan Inc., as borrower, the Company, as guarantor, certain affiliates and subsidiaries of the Company from time to time party thereto as guarantors, each lender from time to time party thereto and Bank of America, N.A., as administrative agent and the Company's term loan credit facility dated as of November 22, 2016 (as amended, supplemented or otherwise modified from time to time), among the Company, certain affiliates and subsidiaries of the Company from time to time party thereto as guarantors, each lender from time to time party thereto and Goldman Sachs Bank USA, as administrative agent (together, the "Credit Agreements") as compared to Mylan's September 30, 2018 total debt and other current obligations at notional amounts.

	Three Months Ended				Twelve Months Ended
	December 31, 2017	March 31, 2018	June 30, 2018	September 30, 2018	September 30, 2018
Mylan N.V. Adjusted EBITDA	\$ 1,123.6	\$ 813.9	\$ 866.6	\$ 935.9	\$ 3,740.0
Add: other adjustments including estimated synergies					118.7
Credit Agreement Adjusted EBITDA					<u>\$ 3,858.7</u>
Reported debt balances:					
Long-term debt, including current portion					\$ 14,427.0
Short-term borrowings and other current obligations					283.4
Total					<u>\$ 14,710.4</u>
Add:					
Net discount on various debt issuances					38.0
Deferred financing fees					77.9
Fair value of hedged debt					11.8
Total debt at notional amounts					<u>\$ 14,838.1</u>
Notional debt to Credit Agreement Adjusted EBITDA Leverage Ratio					3.8

Long-term average debt to Credit Agreement Adjusted EBITDA leverage ratio target of ~3.0x

The stated forward-looking non-GAAP financial measure, targeted long term average leverage of ~3.0x debt-to-Credit Agreement Adjusted EBITDA, is based on the ratio of (i) targeted long-term average debt, and (ii) targeted long-term Credit Agreement Adjusted EBITDA. However, the Company has not quantified future amounts to develop the target but has stated its goal to manage long-term average debt and adjusted earnings and EBITDA over time in order to generally maintain the target. This target does not reflect Company guidance.