

MYLAN N.V.

FORM 8-K (Current report filing)

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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 6, 2017

MYLAN N.V.

(Exact Name of Registrant as Specified in Charter)

The Netherlands

333-199861

98-1189497

(State or Other Jurisdiction of Incorporation)

(Commission
File Number)

(I.R.S. Employer Identification No.)

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 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 6, 2017, Mylan N.V. (“Mylan” or the “Company”) issued a press release reporting the Company's financial results for the period ended September 30, 2017. 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 10:30 a.m. ET to review its financial results for the period ended September 30, 2017.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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99.1	Press release announcing the Company’s financial results for the third quarter of 2017, dated November 6, 2017.
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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 6, 2017

By: /s/ Kenneth S. Parks

Kenneth S. Parks
Chief Financial Officer

Mylan Reports Third Quarter 2017 Results and Updates 2017 Guidance

HERTFORDSHIRE, ENGLAND AND PITTSBURGH - Nov. 6, 2017 - Mylan N.V. (NASDAQ, TASE: MYL) today announced its financial results for the quarter and nine months ended September 30, 2017 .

Third Quarter 2017 Financial Highlights

- Total revenues of \$2.99 billion , down 2% compared to the prior year period
 - North America segment third party net sales of \$1.17 billion , down 22% ; and down approximately 6% excluding the decrease in sales of the EpiPen® Auto-Injector of \$245.1 million
 - Europe segment third party net sales of \$1.04 billion , up 24%
 - Rest of World segment third party net sales of \$743.3 million , up 9%
- U.S. GAAP diluted earnings per ordinary share ("U.S. GAAP EPS") of \$0.16 , up 170% over the prior year period.
- Adjusted diluted earnings per ordinary share ("adjusted EPS") of \$1.10 in line with our expectations, down 20% over the prior year period.
- U.S. GAAP net cash provided by operating activities for the nine months ended September 30, 2017 of \$1.57 billion , down 8% compared to \$1.70 billion in the prior year period.
- Adjusted free cash flow for the nine months ended September 30, 2017 of \$1.91 billion , up 13% compared to \$1.69 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 commented, "Our third quarter results, which included adjusted EPS of \$1.10, were especially strong considering the ongoing challenges we experienced in the U.S., including accelerated deceleration of EpiPen sales - both from our launch of an authorized generic as well as the contraction of the overall epinephrine auto-injector market.

"Our third quarter results also continue to show the durability of our resilient global platform, where we now believe that approximately 75% of our more-than-\$2 billion adjusted operating cash flows stems from more predictable, recurring revenues across all markets around the world.

"As impressive, we recently received approval from the U.S. Food and Drug Administration of our Glatiramer Acetate product. Being first to market with the 40-mg strength - as well as offering the 20-mg strength - is a milestone because it underscores our scientific, regulatory and commercialization capabilities for this very complex product; it also paves the path for the many other complex products we have in our pipeline.

"Given that, and the stability of our global platform, we see a strong finish ahead for the year. As a result, we are increasing the low end of our adjusted EPS guidance range, where we now expect to generate between \$4.45 and \$4.70 per share.

"We also see sustainable momentum globally as we head into the new year, which is why we remain confident in our 2018 target of at least \$5.40 in adjusted EPS."

Mylan President Rajiv Malik said, "We continue to see the benefits of our geographic, product, channel and pipeline diversification as well as the integration of Mylan.

Malik continued: "We also continue to see the strength of our science, especially as it relates to complex products, and we now believe Mylan is well-positioned to deliver on future opportunities. The submission of Insulin Glargine in the U.S., which currently is under active review with FDA; our continued work with FDA on generic Advair; and our progress with several of our biosimilar programs are great opportunities for us to bring additional value to our shareholders as we continue to execute on our promising complex product pipeline."

Mylan CFO Ken Parks added, "We are pleased with our continued strong adjusted free cash flow generation of \$1.9 billion for the first nine months of 2017. This strength reflects our stable and durable cash flow profile and provides us with the opportunity to continue to reduce debt levels, while at the same time allowing for financial flexibility as we continue to execute on our business strategy and maintain our commitment to an investment grade credit rating."

Financial Summary

<i>(Unaudited; in millions, except per share amounts)</i>	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2017	2016	Percent Change	2017	2016	Percent Change
Total Revenues	\$ 2,987.1	\$ 3,057.1	(2)%	\$ 8,668.8	\$ 7,809.1	11%
North America ⁽¹⁾	1,172.2	1,505.5	(22)%	3,666.7	4,064.5	(10)%
Europe ⁽¹⁾	1,040.8	841.2	24%	2,887.1	2,026.4	42%
Rest of World ⁽¹⁾	743.3	682.8	9%	2,016.4	1,654.6	22%
Other Revenues	30.8	27.6	12%	98.6	63.6	55%
US GAAP Gross Profit	1,178.1	1,283.3	(8)%	3,488.5	3,362.0	4%
US GAAP Gross Margin	39.4%	42.0%	(6)%	40.2%	43.1%	(7)%
Adjusted Gross Profit ⁽²⁾	1,572.6	1,735.0	(9)%	4,621.8	4,364.5	6%
Adjusted Gross Margin ⁽²⁾	52.6%	56.8%	(7)%	53.3%	55.9%	(5)%
US GAAP Net Earnings (Loss)	88.3	(119.8)	174%	451.7	62.5	623%
US GAAP EPS	\$ 0.16	\$ (0.23)	170%	\$ 0.84	\$ 0.12	600%
Adjusted Net Earnings ⁽²⁾	589.7	726.4	(19)%	1,679.5	1,705.1	(2)%
Adjusted EPS ⁽²⁾	\$ 1.10	\$ 1.38	(20)%	\$ 3.13	\$ 3.31	(5)%
EBITDA ⁽²⁾	\$ 776.9	\$ 294.7	164%	\$ 2,339.2	\$ 1,333.7	75%
Adjusted EBITDA ⁽²⁾	\$ 923.8	\$ 1,060.9	(13)%	\$ 2,667.2	\$ 2,466.0	8%

⁽¹⁾ As previously reported, effective October 1, 2016, we expanded our reportable segments as follows: North America, Europe and Rest of World. As a result, the amounts previously reported under the Specialty segment have been recast to North America and amounts related to Brazil are included in Rest of World for all periods presented. Segment amounts represent third party net sales.

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

Third Quarter 2017 Financial Results

Total revenues were \$2.99 billion in the third quarter of 2017, compared to \$3.06 billion in the prior year period. Third party net sales for the current quarter were \$2.96 billion compared to \$3.03 billion for the prior year period, representing a decrease of \$73.2 million, or 2%. The incremental impact on third party net sales from the acquisition of Meda AB (publ) ("Meda") totaled approximately \$163.6 million. Below is a summary of third party net sales in each of our segments for the three months ended September 30, 2017:

- Third party net sales in the **North America** segment totaled \$1.17 billion, a decrease of \$333.3 million or 22% from the prior year period. Third party net sales were negatively impacted in the current quarter due to a decline in sales of existing products as a result of lower pricing and volume, partially offset by new product introductions. As anticipated, our North American generics business experienced higher price

erosion than previous quarters, including the impact of the loss of market exclusivity of armodafinil. Sales of the EpiPen® Auto-Injector declined in the current quarter by \$245.1 million as a result of the impact of the launch of the authorized generic, higher governmental rebates as a result of Mylan agreeing to the terms of a \$465 million settlement, plus interest, with the U.S. Department of Justice and other government agencies related to the classification of the EpiPen® Auto-Injector for purposes of the Medicaid Drug Rebate Program (the "Medicaid Drug Rebate Program Settlement"), and increased competition. The impact of foreign currency translation on current period third party net sales was not significant.

- Partially offsetting the decrease in North America was third party net sales growth in the **Europe** segment of \$199.6 million , or 24% , in the quarter. Third party net sales in Europe totaled \$1.04 billion in the current quarter. The increase was primarily the result of the incremental net sales from the acquisition of Meda , which totaled approximately \$117.2 million , new product introductions and favorable volume and pricing on existing products. The favorable impact of foreign currency translation on current period third party net sales was \$45.5 million or 5% within Europe.
- Third party net sales in the **Rest of World** segment totaled \$743.3 million in the current quarter, an increase of \$60.5 million , or 9% . This increase was primarily driven by incremental net sales from the acquisition of Meda which totaled approximately \$38.2 million . In addition, net sales were positively impacted by new products and increased net sales in emerging markets, which were driven primarily by higher volumes. These increases were partially offset by lower pricing and volumes on existing products from our anti-retroviral ("ARV") franchise, including active pharmaceutical ingredients. The favorable impact of foreign currency translation was \$6.2 million , or 1% .

Gross profit was \$1.18 billion and \$1.28 billion for the third quarter of 2017 and 2016 , respectively. Gross margins were 39% and 42% in the third quarter of 2017 and 2016 , respectively. Gross margins were negatively impacted in the current quarter by lower gross profit from the sales of existing products in North America, including the EpiPen® Auto-Injector, partially offset by lower purchase accounting amortization as a result of the prior year amortization of the step-up in the fair value of acquired inventory. Adjusted gross profit was \$1.57 billion and adjusted gross margins were 53% for the third quarter of 2017 compared to adjusted gross profit of \$1.74 billion and adjusted gross margins of 57% in the prior year period. Adjusted 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, partially offset by the contributions from acquired businesses and new product introductions.

R&D expense decreased slightly from the comparable prior year period due to lower expenditures related to the Company's respiratory programs due to the timing of clinical activities, partially offset by the incremental impact of the Meda acquisition.

SG&A expense increased from the comparable prior year period primarily due to the additional expense related to the incremental impact of the Meda acquisition, partially offset by lower acquisition related costs, including consulting and legal costs, and the benefit of integration activities in the current quarter.

Litigation settlements and other contingencies, net decreased from the prior year period primarily as a result of the prior year litigation charge for the Medicaid Drug Rebate Program Settlement and the Company's settlement with Strides Arcolab regarding substantially all outstanding regulatory, warranty and indemnity claims (the "Strides Settlement") related to the acquisition of Agila Specialties Private Limited.

U.S. GAAP net earnings increased by \$208.1 million to \$88.3 million for the three months ended September 30, 2017 , compared to a loss of \$119.8 million for the prior year period and U.S. GAAP EPS increased from a loss per share of \$0.23 in the prior year period to \$0.16 in the current quarter. Adjusted net earnings decreased to \$589.7 million compared to \$726.4 million for the prior year period. Adjusted EPS decreased to \$1.10 from \$1.38 in the prior year period.

Cash Flow

Net cash provided by operating activities was \$1.57 billion for the nine months ended September 30, 2017 compared to \$1.70 billion for the prior year period. Capital expenditures were approximately \$156.4 million for the nine months ended September 30, 2017 compared to approximately \$239.5 million for the comparable prior year. Adjusted net cash provided by operating activities was \$2.06 billion for the nine months ended September 30, 2017 compared to \$1.93 billion for the prior year period. Adjusted free cash flow, defined as adjusted net cash provided by operating activities less capital expenditures, was \$1.91 billion for the nine months ended September 30, 2017 , compared to \$1.69 billion in the prior year.

Guidance

Primarily as a result of the launch of generic Copaxone, Mylan is increasing the midpoint of its previous 2017 Adjusted EPS guidance and total revenue range by increasing the low end of the ranges. Mylan now expects 2017 total revenues in the range of \$11.75 billion to \$12.5 billion , which represents an increase of 9% at the midpoint versus full-year 2016 . As discussed in the "Non-GAAP Financial Measures" section below, 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. For 2017, Mylan continues to expect to generate \$2.0 billion to \$2.4 billion of adjusted free cash flow, net of our revised capital expenditures range of \$300 million to \$350 million . Adjusted EPS for 2017 is now expected to be in the range of \$4.45 to \$4.70 per share, a decrease of 6% at the midpoint when compared to the prior year.

Conference Call and Earnings Materials

Mylan N.V. will host a conference call and live webcast, today at 10:30 a.m. ET, to review the company's financial results for the third quarter ended September 30, 2017 . The briefing can be accessed live by calling 800.514.4861 or 678.809.2405 for international callers (ID#: 99489678) or at the following address on the company's website: investor.mylan.com. The "Q3 2017 Earnings Call" presentation and a presentation titled "Built to Last," 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 net cash provided by operating activities and adjusted free cash flow 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 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 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 we believe that this presentation also provides useful information to investors for the same reason. The "Summary of Total Revenues by Segment" table below compares third party net sales on an actual and constant currency basis for each reportable segment for the three and nine months ended September 30, 2017 and 2016. 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, 2017 (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 Meda transaction, 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. With respect to the targeted adjusted EPS in 2018, the target does not represent Company guidance and the Company is not providing a U.S. GAAP target or reconciliation because the Company has not quantified all future amounts, including U.S. GAAP amounts, related to this target.

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, 2017 compared to the prior year period:

(in millions, except per share amounts)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2017		2016		2017		2016	
U.S. GAAP net earnings and U.S. GAAP EPS	\$ 88.3	\$ 0.16	\$ (119.8)	\$ (0.23)	\$ 451.7	\$ 0.84	\$ 62.5	\$ 0.12
Purchase accounting related amortization (primarily included in cost of sales) ^(a)	370.7		427.1		1,074.9		931.8	
Litigation settlements, net ^(b)	15.2		468.0		52.5		466.4	
Interest expense (primarily related to clean energy investment financing)	5.5		5.5		19.5		18.9	
Accretion of contingent consideration liability and other fair value adjustments ^(c)	4.9		100.4		(57.6)		120.7	
Clean energy investments pre-tax loss	22.4		23.8		66.4		69.4	
Acquisition related costs (primarily included in SG&A and cost of sales) ^(d)	15.2		110.5		60.1		346.7	
Restructuring related costs ^(e)	73.4		24.2		112.7		45.1	
Other special items included in:								
Cost of sales	12.3		12.0		39.2		34.1	
Research and development expense ^(f)	15.2		22.0		90.1		98.4	
Selling, general and administrative expense	4.0		(2.0)		12.7		0.3	
Other expense, net	(3.3)		(1.4)		1.8		1.3	
Tax effect of the above items and other income tax related items	(34.1)		(343.9)		(244.5)		(490.5)	
Adjusted net earnings and adjusted EPS	\$ 589.7	\$ 1.10	\$ 726.4	\$ 1.38	\$ 1,679.5	\$ 3.13	\$ 1,705.1	\$ 3.31
Weighted average diluted ordinary shares outstanding	537.0		523.6		537.0		515.2	

Significant items for the three and nine months ended September 30, 2017 include the following:

- ^(a) The increase in purchase accounting related amortization for the nine month period is due to the amortization expense associated with the intangible assets related to the Topicals Business and Meda acquisitions. The decrease in purchase accounting related amortization for the three month period is primarily related to approximately \$56 million of inventory step-up amortization related to the Topicals Business and Meda acquisitions in the prior year period.
- ^(b) Litigation settlements, net decrease is due to an accrual for the Medicaid Drug Rebate Settlement in the prior year periods.
- ^(c) Change to contingent consideration liability is due to a gain recognized for the fair value adjustment of \$88.1 million for the respiratory delivery platform contingent liability included in the nine months ended September 30, 2017. The three and nine months ended September 30, 2016 include approximately \$90 million related to the Strides Settlement.
- ^(d) Acquisition related costs incurred in 2016 primarily relate to the acquisition of the Topicals Business (June 2016) and costs related to the Meda acquisition. These costs primarily related to consulting, professional, and legal costs. Acquisition related costs incurred in 2017 consist primarily of integration activities.
- ^(e) Refer to Note 17 *Restructuring* included in Item 1 in the Form 10-Q. Of the total amount, approximately \$21.0 million is included in cost of sales, \$1.1 million is included in R&D, and \$51.3 million is included in SG&A for the three months ended September 30, 2017. For the nine months ended September 30, 2017, approximately \$37.3 million is included in cost of sales, \$2.4 million is included in R&D and \$73.0 million is included in SG&A.
- ^(f) 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 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. For the nine months ended September 30, 2016, R&D expense includes a \$45 million upfront payment to Momenta and \$15 million of milestone payments to Theravance Biopharma. In addition, included in this amount for the three and nine months ended September 30, 2016 is approximately \$9.0 million and \$22.3 million, respectively, of R&D expense incurred related to the Company's collaboration with Momenta.

Below is a reconciliation of U.S. GAAP net earnings to EBITDA and adjusted EBITDA for the three and nine months ended September 30, 2017 compared to the prior year period (in millions):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP net earnings	\$ 88.3	\$ (119.8)	\$ 451.7	\$ 62.5
Add adjustments:				
Net contribution attributable to equity method investments	22.4	29.7	77.2	85.5
Income tax provision (benefit)	91.3	(205.5)	124.2	(165.7)
Interest expense	131.8	144.4	406.3	305.0
Depreciation and amortization	443.1	445.9	1,279.8	1,046.4
EBITDA	\$ 776.9	\$ 294.7	\$ 2,339.2	\$ 1,333.7
Add / (deduct) adjustments:				
Share-based compensation expense	22.2	19.2	64.2	71.1
Litigation settlements and other contingencies, net	15.2	558.0	(25.8)	556.4
Restructuring & other special items	109.5	189.0	289.6	504.8
Adjusted EBITDA	\$ 923.8	\$ 1,060.9	\$ 2,667.2	\$ 2,466.0

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 more than 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, 2017 financial guidance; that Mylan's third quarter results also continue to show the durability of our resilient global platform, where we now believe that approximately 75% of our more-than-\$2 billion adjusted operating cash flows stems from more predictable, recurring revenues across all markets around the world; that being first to market with the 40-mg strength of Mylan's Glatiramer Acetate product, as well as offering the 20-mg strength, is a milestone because it underscores our scientific, regulatory and commercialization capabilities for this very complex product and it paves the path for the many other complex products Mylan has in its pipeline; that Mylan sees a strong finish ahead for the year; Mylan is increasing the low end of its full-year adjusted EPS guidance range and now expects to generate between \$4.45 and \$4.70 per share adjusted EPS for 2017; that Mylan also sees sustainable momentum globally as we head into the new year, which is why we remain confident in our 2018 target of at least \$5.40 in adjusted EPS; that Mylan continues to see the benefits of its geographic, product, channel and pipeline diversification as well as the integration of Mylan; that Mylan believes it is well-positioned to deliver on future opportunities; the submission of Insulin Glargine in the U.S., which currently is under active review with FDA, our continued work with FDA on generic Advair, and our progress with several of our biosimilar programs are great opportunities for us to bring additional value to our shareholders as we continue to execute on our promising complex product pipeline; and that the strength of our adjusted free cash flows reflects our stable and durable cash flow profile and provides us with the opportunity to continue to reduce debt levels, while at the same time allowing for financial flexibility as we continue to execute on our business strategy and maintain our commitment to an 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," "intend," "continue," "target," and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences

include, but are not limited to: the ability to meet expectations regarding the accounting and tax treatments of 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") and the acquisition of Meda by Mylan (the "Meda Transaction"); changes in relevant tax and other laws, including but not limited to changes in the U.S. tax code and healthcare and pharmaceutical laws and regulations in the U.S. and abroad; actions and decisions of healthcare and pharmaceutical regulators; the integration of the EPD Business and Meda being more difficult, time-consuming, or costly than expected; operating costs, customer loss, and business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, clients, or suppliers) being greater than expected following the EPD Transaction and the Meda Transaction; the retention of certain key employees of the EPD Business and Meda being difficult; the possibility that Mylan may be unable to achieve expected synergies and operating efficiencies in connection with the EPD Transaction, the Meda Transaction, and the December 2016 announced restructuring program in certain locations, within the expected time-frames or at all and to successfully integrate the EPD Business and Meda; expected or targeted future financial and operating performance and results; the capacity to bring new products to market, including but not limited to where Mylan uses its business judgment and decides to manufacture, market, and/or sell products, directly or through third parties, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts (i.e., an "at-risk launch"); any regulatory, legal, or other impediments to Mylan's ability to bring new products, including but not limited to generic Advair and Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL, to market, including ongoing and unresolved allegations of patent infringement around our launch of Glatiramer Acetate Injection 40 mg/mL; success of clinical trials and Mylan's ability to execute on new product opportunities, including but not limited to generic Advair and Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL; any changes in or difficulties with our inventory of, and our ability to manufacture and distribute, the EpiPen® Auto-Injector and EpiPen Jr® Auto-Injector (collectively, "EpiPen® Auto-Injector") to meet anticipated demand; the potential impact of any change in patient access to the EpiPen® Auto-Injector and the introduction of a generic version of the EpiPen® Auto-Injector; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on financial condition, results of operations, and/or cash flows; the ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in customer and supplier relationships and customer purchasing patterns; the ability to attract and retain key personnel; changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan; the inherent challenges, risks, and costs in identifying, acquiring, and integrating complementary or strategic acquisitions of other companies, products, or assets and in achieving anticipated synergies; uncertainties and matters beyond the control of management; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with 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, 2016, as amended, and our other filings with the Securities and Exchange Commission (the "SEC"). You can access Mylan's filings with the SEC through the SEC website at www.sec.gov, 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,	
	2017	2016	2017	2016
Revenues:				
Net sales	\$ 2,956.3	\$ 3,029.5	\$ 8,570.2	\$ 7,745.5
Other revenues	30.8	27.6	98.6	63.6
Total revenues	2,987.1	3,057.1	8,668.8	7,809.1
Cost of sales	1,809.0	1,773.8	5,180.3	4,447.1
Gross profit	1,178.1	1,283.3	3,488.5	3,362.0
Operating expenses:				
Research and development	182.3	199.1	580.9	632.2
Selling, general and administrative	664.6	656.9	1,916.8	1,787.6
Litigation settlements and other contingencies, net	15.2	558.0	(25.8)	556.4
Total operating expenses	862.1	1,414.0	2,471.9	2,976.2
Earnings (loss) from operations	316.0	(130.7)	1,016.6	385.8
Interest expense	131.8	144.4	406.3	305.0
Other expense, net	4.6	50.2	34.4	184.0
Earnings (loss) before income taxes	179.6	(325.3)	575.9	(103.2)
Income tax provision (benefit)	91.3	(205.5)	124.2	(165.7)
Net earnings (loss)	88.3	(119.8)	451.7	62.5
Earnings (loss) per ordinary share:				
Basic	\$ 0.17	\$ (0.23)	\$ 0.84	\$ 0.12
Diluted	\$ 0.16	\$ (0.23)	\$ 0.84	\$ 0.12
Weighted average ordinary shares outstanding:				
Basic	535.2	523.6	534.9	505.9
Diluted	537.0	523.6	537.0	515.2

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

	September 30, 2017	December 31, 2016
ASSETS		
Assets		
Current assets:		
Cash and cash equivalents	\$ 614.9	\$ 998.8
Accounts receivable, net	3,220.2	3,310.9
Inventories	2,548.1	2,456.4
Prepaid expenses and other current assets	883.4	756.4
Total current assets	7,266.6	7,522.5
Intangible assets, net	15,270.5	14,447.8
Goodwill	9,984.7	9,231.9
Other non-current assets	3,297.1	3,524.0
Total assets	<u>\$ 35,818.9</u>	<u>\$ 34,726.2</u>
LIABILITIES AND EQUITY		
Liabilities		
Current portion of long-term debt and other long-term obligations	\$ 793.0	\$ 290.0
Current liabilities	4,191.0	4,750.7
Long-term debt	13,992.4	15,202.9
Other non-current liabilities	3,550.9	3,365.0
Total liabilities	22,527.3	23,608.6
Noncontrolling interest	—	1.4
Mylan N.V. shareholders' equity	13,291.6	11,116.2
Total liabilities and equity	<u>\$ 35,818.9</u>	<u>\$ 34,726.2</u>

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

Summary of Total Revenues by Segment

Three Months Ended						
September 30,						
(In millions)	2017	2016	% Change	2017 Currency Impact ⁽¹⁾	2017 Constant Currency Revenues	Constant Currency % Change ⁽²⁾
Third party net sales						
North America ⁽³⁾	\$ 1,172.2	\$ 1,505.5	(22)%	\$ (3.1)	\$ 1,169.1	(22)%
Europe ⁽³⁾	1,040.8	841.2	24 %	(45.5)	995.3	18 %
Rest of World ⁽³⁾	743.3	682.8	9 %	(6.2)	737.1	8 %
Total third party net sales ⁽³⁾	2,956.3	3,029.5	(2)%	\$ (54.8)	2,901.5	(4)%
Other third party revenues	30.8	27.6	12 %	(0.5)	30.3	10 %
Consolidated total revenues	<u>\$ 2,987.1</u>	<u>\$ 3,057.1</u>	(2)%	<u>\$ (55.3)</u>	<u>\$ 2,931.8</u>	(4)%
Nine Months Ended						
September 30,						
(In millions)	2017	2016	% Change	2017 Currency Impact ⁽¹⁾	2017 Constant Currency Revenues	Constant Currency % Change ⁽²⁾
Third party net sales						
North America ⁽³⁾	\$ 3,666.7	\$ 4,064.5	(10)%	\$ (2.3)	\$ 3,664.4	(10)%
Europe ⁽³⁾	2,887.1	2,026.4	42 %	(2.4)	2,884.7	42 %
Rest of World ⁽³⁾	2,016.4	1,654.6	22 %	(27.0)	1,989.4	20 %
Total third party net sales ⁽³⁾	8,570.2	7,745.5	11 %	(31.7)	8,538.5	10 %
Other third party revenues	98.6	63.6	55 %	—	98.6	55 %
Consolidated total revenues	<u>\$ 8,668.8</u>	<u>\$ 7,809.1</u>	11 %	<u>\$ (31.7)</u>	<u>\$ 8,637.1</u>	11 %

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

⁽²⁾ The constant currency percentage change is derived by translating third party net sales or revenues for the current period at prior year comparative period exchange rates, and in doing so shows the percentage change from 2017 constant currency third party net sales or revenues to the corresponding amount in the prior year.

⁽³⁾ Effective October 1, 2016, the Company expanded its reportable segments as follows: North America, Europe and Rest of World. As a result, the amounts previously reported under the Specialty segment have been recast to North America and amounts related to Brazil are included in Rest of World for all periods presented.

Reconciliation of Income Statement Line Items

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP cost of sales	\$ 1,809.0	\$ 1,773.8	\$ 5,180.3	\$ 4,447.1
Deduct:				
Purchase accounting amortization and other related items	(361.4)	(421.5)	(1,054.9)	(914.8)
Acquisition related costs	0.2	(8.5)	(1.9)	(39.8)
Restructuring related costs	(21.0)	(9.7)	(37.3)	(13.8)
Other special items	(12.3)	(12.0)	(39.2)	(34.1)
Adjusted cost of sales	\$ 1,414.5	\$ 1,322.1	\$ 4,047.0	\$ 3,444.6
Adjusted gross profit ^(a)	\$ 1,572.6	\$ 1,735.0	\$ 4,621.8	\$ 4,364.5
Adjusted gross margin ^(a)	53%	57%	53%	56%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP R&D	\$ 182.3	\$ 199.1	\$ 580.9	\$ 632.2
Deduct:				
Acquisition related costs	(0.9)	(0.2)	(1.5)	(0.4)
Restructuring related costs	(1.1)	(0.2)	(2.5)	(0.3)
Other special items	(15.2)	(22.0)	(90.1)	(98.4)
Adjusted R&D	\$ 165.1	\$ 176.7	\$ 486.8	\$ 533.1
Adjusted R&D as % of total revenues	6%	6%	6%	7%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP SG&A	\$ 664.6	\$ 656.9	\$ 1,916.8	\$ 1,787.6
Add / (deduct):				
Acquisition related costs	(14.6)	(39.7)	(56.1)	(102.4)
Restructuring related costs	(51.4)	(14.3)	(73.0)	(31.0)
Purchase accounting amortization and other related items	(9.0)	—	(14.1)	—
Other special items	(4.0)	2.0	(12.7)	(0.3)
Adjusted SG&A	\$ 585.6	\$ 604.9	\$ 1,760.9	\$ 1,653.9
Adjusted SG&A as % of total revenues	20%	20%	20%	21%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP total operating expenses	\$ 862.1	\$ 1,414.0	\$ 2,471.9	\$ 2,976.2
Add / (deduct):				
Litigation settlements and other contingencies, net	(15.2)	(558.0)	25.8	(556.4)
R&D adjustments	(17.2)	(22.4)	(94.1)	(99.1)
SG&A adjustments	(79.0)	(52.0)	(155.9)	(133.7)

Adjusted total operating expenses	<u>\$ 750.7</u>	<u>\$ 781.6</u>	<u>\$ 2,247.7</u>	<u>\$ 2,187.0</u>
Adjusted earnings from operations ^(b)	<u>\$ 821.9</u>	<u>\$ 953.4</u>	<u>\$ 2,374.1</u>	<u>\$ 2,177.5</u>

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP interest expense	\$ 131.8	\$ 144.4	\$ 406.3	\$ 305.0
Deduct:				
Interest expense related to clean energy investments	(3.0)	(3.6)	(9.4)	(11.0)
Accretion of contingent consideration liability	(5.1)	(10.4)	(21.1)	(30.7)
Acquisition related costs	—	(19.7)	(0.2)	(45.6)
Other special items	(2.2)	(2.1)	(6.5)	(8.0)
Adjusted interest expense	\$ 121.5	\$ 108.6	\$ 369.1	\$ 209.7

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP other expense, net	\$ 4.6	\$ 50.2	\$ 34.4	\$ 184.0
(Add) / deduct:				
Clean energy investments pre-tax loss ^(c)	(22.4)	(23.8)	(66.4)	(69.4)
Purchase accounting related amortization	—	(5.7)	—	(17.0)
Acquisition related costs	—	(42.3)	(0.8)	(158.5)
Financing related costs	2.8	—	(0.7)	—
Other items	0.2	1.4	(9.8)	(1.3)
Adjusted other income	\$ (14.8)	\$ (20.2)	\$ (43.3)	\$ (62.2)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP earnings (loss) before income taxes	\$ 179.6	\$ (325.3)	\$ 575.9	\$ (103.2)
Total pre tax non-GAAP adjustments	535.5	1,190.1	1,472.3	2,133.1
Adjusted earnings before income taxes	\$ 715.1	\$ 864.8	\$ 2,048.2	\$ 2,029.9
U.S. GAAP income tax provision (benefit)	\$ 91.3	\$ (205.5)	\$ 124.2	\$ (165.7)
Adjusted tax expense	34.1	343.9	244.5	490.5
Adjusted income tax provision	\$ 125.4	\$ 138.4	\$ 368.7	\$ 324.8
Adjusted effective tax rate	17.5%	16.0%	18.0%	16.0%

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
U.S. GAAP net cash provided by operating activities	\$ 548.6	\$ 1,200.6	\$ 1,569.3	\$ 1,697.7
Add:				
Restructuring related costs	14.9	—	104.4	—
Financing related expense	—	—	—	66.9
Corporate contingencies	275.2	—	307.7	—
Acquisition related costs	2.0	36.7	54.3	125.0
R&D expense	22.4	3.2	27.4	63.2
Income tax items	—	—	—	(25.8)
Adjusted net cash provided by operating activities	\$ 863.1	\$ 1,240.5	\$ 2,063.1	\$ 1,927.0

Deduct:				
Capital expenditures	(47.1)	(118.5)	(156.4)	(239.5)
Adjusted free cash flow	\$ 816.0	\$ 1,122.0	\$ 1,906.7	\$ 1,687.5

- (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 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 Code.

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):

	Three Months Ended			
	December 31, 2016	March 31, 2017	June 30, 2017	September 30, 2017
U.S. GAAP net earnings	\$ 417.5	\$ 66.4	\$ 297.0	\$ 88.3
Add adjustments:				
Net contribution attributable to equity method investments	27.2	33.2	21.7	22.4
Income tax provision (benefit)	(192.6)	5.2	27.7	91.3
Interest expense	149.8	138.2	136.3	131.8
Depreciation and amortization	476.6	415.5	421.2	443.1
EBITDA	\$ 878.5	\$ 658.5	\$ 903.9	\$ 776.9
Add / (deduct) adjustments:				
Share-based compensation expense	17.8	23.1	18.9	22.2
Litigation settlements and other contingencies, net	116.1	9.0	(50.0)	15.2
Restructuring & other special items	199.5	122.1	58.1	109.5
Adjusted EBITDA	\$ 1,211.9	\$ 812.7	\$ 930.9	\$ 923.8

September 30, 2017 Notional Debt to Twelve Months Ended September 30, 2017 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, 2017 notional debt to twelve months ended September 30, 2017 Credit Agreement Adjusted EBITDA leverage ratio is based on the sum of (i) Mylan's adjusted EBITDA for the quarters ended December 31, 2016, March 31, 2017, June 30, 2017 and September 30, 2017 and (ii) certain adjustments permitted to be included in Credit Agreement Adjusted EBITDA as of September 30, 2017 pursuant to the Company's revolving 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 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, 2017 total debt at notional amounts.

	Three Months Ended				Twelve Months Ended
	December 31, 2016	March 31, 2017	June 30, 2017	September 30, 2017	September 30, 2017
Mylan N.V. Adjusted EBITDA	\$ 1,211.9	\$ 812.7	\$ 930.9	\$ 923.8	\$ 3,879.3
Add: other adjustments including estimated synergies					197.9
Credit Agreement Adjusted EBITDA					\$ 4,077.2
Reported debt balances:					
Long-term debt, including current portion					\$ 14,715.2
Short-term borrowings					—
Total reported debt balances					\$ 14,715.2
Add / (deduct):					
Net discount on various debt issuances					38.2
Deferred financing fees					79.6
Fair value of hedged debt					(25.3)
Total debt at notional amounts					\$ 14,807.7
Notional debt to Credit Agreement Adjusted EBITDA Leverage Ratio					3.6

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.