

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): May 7, 2019

MYLAN N.V.

(Exact name of registrant as specified in its 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 (§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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value €0.01	MYL	The NASDAQ Stock Market

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Mylan N.V. (“Mylan” or the “Company”) issued a press release reporting the Company's financial results for the period ended March 31, 2019. 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 10:00 a.m. ET to review the Company's financial results for the first quarter ended March 31, 2019.

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 first quarter of 2019, dated May 7, 2019.

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: May 7, 2019

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

Mylan Reports First Quarter 2019 Results and Reaffirms 2019 Guidance

HERTFORDSHIRE, ENGLAND AND PITTSBURGH - May 7, 2019 - Mylan N.V. (NASDAQ: MYL) today announced its financial results for the three months ended March 31, 2019.

First Quarter 2019 Financial Highlights

- U.S. GAAP diluted loss per ordinary share ("U.S. GAAP EPS") of \$(0.05) as compared to earnings of \$0.17 per ordinary share in the prior year period.
- Total revenues of \$2.50 billion, down 7% compared to the prior year period and adjusted diluted earnings per ordinary share ("adjusted EPS") of \$0.82, down 15% over the prior year period.
- Revenue Highlights:
 - Rest of World segment net sales of \$642.4 million, up 3%, up 11% on a constant currency basis.
 - Europe segment net sales of \$895.3 million, down 14%, down 6% on a constant currency basis.
 - North America segment net sales of \$922.9 million, down 6% on an actual and constant currency basis, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities.
- U.S. GAAP net cash used in operating activities for the three months ended March 31, 2019 of \$(39.7) million, compared to U.S. GAAP net cash provided by operating activities of \$621.8 million in the prior year period and adjusted free cash flow for the three months ended March 31, 2019 of \$27.1 million, compared to \$663.6 million in the prior year period, driven primarily by an increased investment in working capital.
- 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: "Mylan's first quarter represents a solid start to the year and we remain positioned to reaffirm our guidance for 2019. We continue to manage an increasingly diverse portfolio of products across all three segments of our business, and given the evolution of our commercial and geographic mix see opportunities to enhance our investments for certain areas of our portfolio. In the U.S., where the industry continues to experience volatility, we are leveraging past experience and applying key learnings to our largest launches, like Wixela, even as we advocate for policies that seek to put the patient first.

With that said, our top-line results fell within the range of where we thought they would be at \$2.5 billion. On the bottom line, we came in ahead of where we expected at \$0.82 of adjusted EPS, mainly due to gross margins coming in at the high end of our guidance range while also having some positive offsets from a timing perspective in G&A against our increased sales and marketing spend. We look forward to continue delivering on our mission of access in the remaining quarters of the year and investing in a Mylan that's built to last."

Mylan CFO Ken Parks added: "During the first quarter, adjusted free cash flow of \$27 million was slightly ahead of our expectations. Our results reflect an anticipated increase in net working capital required to support our topline growth expectations for 2019, which includes over \$1 billion in new product launches, as previously communicated. Given our stable and durable cash flow profile, we remain committed to deleveraging and intend to repay \$1.1 billion of debt during 2019. We also remain fully committed to maintaining our investment grade credit rating. For the full year 2019, we are reaffirming our guidance and business outlook, including our total revenue range of \$11.5 billion to \$12.5 billion, adjusted EPS guidance range of \$3.80 to \$4.80 and adjusted free cash flow range of \$1.9 billion to \$2.3 billion."

Financial Summary

	Three Months Ended		
	March 31,		
<i>(Unaudited; in millions, except per share amounts and %s)</i>	2019	2018	Percent Change
Total Revenues ⁽¹⁾	\$ 2,495.5	\$ 2,684.5	(7)%
North America Net Sales	922.9	985.3	(6)%
Europe Net Sales	895.3	1,038.4	(14)%
Rest of World Net Sales	642.4	626.7	3%
Other Revenues	34.9	34.1	2%
U.S. GAAP Gross Profit	\$ 805.2	\$ 984.3	(18)%
U.S. GAAP Gross Margin	32.3%	36.7%	
Adjusted Gross Profit ⁽²⁾	\$ 1,340.7	\$ 1,419.8	(6)%
Adjusted Gross Margin ⁽²⁾	53.7%	52.9%	
U.S. GAAP Net (Loss) Earnings	\$ (25.0)	\$ 87.1	(129)%
U.S. GAAP EPS	\$ (0.05)	\$ 0.17	(129)%
Adjusted Net Earnings ⁽²⁾	\$ 421.9	\$ 495.6	(15)%
Adjusted EPS ⁽²⁾	\$ 0.82	\$ 0.96	(15)%
EBITDA ⁽²⁾	\$ 534.2	\$ 663.8	(20)%
Adjusted EBITDA ⁽²⁾	\$ 710.2	\$ 813.9	(13)%

⁽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.

Three Months Ended March 31, 2019 Financial Results

Total Revenues for the three months ended March 31, 2019 were \$2.50 billion, compared to \$2.68 billion for the comparable prior year period, representing a decrease of \$189.0 million, or 7%. Total revenues include both net sales and other revenues from third parties. **Net sales** for the three months ended March 31, 2019 were \$2.46 billion, compared to \$2.65 billion for the comparable prior year period, representing a decrease of \$189.8 million, or 7%. **Other revenues** for the three months ended March 31, 2019 were \$34.9 million, compared to \$34.1 million for the comparable prior year period.

The decrease in net sales included a decrease in the Europe segment of 14% and a decrease in the North America segment of 6%. These decreases were partially offset by an increase in the Rest of World segment of 3%. Mylan's net sales 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 year net sales was approximately \$132.0 million, or 5%, resulting in a decrease in constant currency net sales of approximately \$57.8 million, or 2%. This decrease was primarily driven by net sales from existing products, partially offset by new product sales, primarily as a result of lower volumes, and to a lesser extent, pricing. Below is a summary of net sales in each of our segments for the three months ended March 31, 2019:

- Net sales from **North America** segment totaled \$922.9 million during the three months ended March 31, 2019, a decrease of \$62.4 million or 6% when compared to the prior year period. This decrease was due primarily to lower volumes on existing products, primarily driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities, partially offset by new product sales, including Wixela™ Inhub™ and Fulphila™ (biosimilar to Neulasta®), and increased market share on Glatiramer Acetate Injection. Pricing also declined 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 from **Europe** segment totaled \$895.3 million during the three months ended March 31, 2019, a decrease of \$143.1 million or 14% when compared to the prior year period. This decrease was primarily the result of the unfavorable impact of foreign currency translation, lower volumes of existing products driven by the timing of purchases of our products by customers and temporary business disruptions due to the adoption of serialization across Europe and, to a lesser extent, pricing. The unfavorable impact of foreign currency translation was approximately \$77.5 million or 8%. Partially offsetting these items were new product sales in the current period. Constant currency net sales decreased by approximately \$65.6 million or 6%, when compared to the prior year period.
- Net sales from **Rest of World** segment totaled \$642.4 million during the three months ended March 31, 2019, an increase of \$15.7 million or 3% when compared to the prior year period. This increase was primarily the result of new product sales and higher volumes of existing products. The increase in net sales as a result of new product sales was primarily due to new product sales in Australia, Japan and China. Increased volume of existing products was primarily driven by the Company's anti-retroviral therapy franchise. This increase was partially offset primarily by the unfavorable impact of foreign currency translation and, to a lesser extent, by lower pricing on existing products. Overall, net sales from Rest of World were unfavorably impacted by the effect of foreign currency translation of approximately \$51.8 million, or 8%. Constant currency net sales increased by approximately \$67.5 million or 11% when compared to the prior year period.

U.S. GAAP gross profit was \$805.2 million and \$984.3 million for the three months ended March 31, 2019 and 2018, respectively. **U.S. GAAP gross margins** were 32% and 37% for the three months ended March 31, 2019 and 2018, respectively. U.S. GAAP gross margins were negatively impacted by approximately 60 basis points related to the incremental amortization from product acquisitions. U.S. GAAP gross margins were also negatively affected by approximately 280 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 plant. In addition, U.S. GAAP gross margins were negatively impacted as a result of lower gross profit for sales of existing products partially offset by the impact from new product sales, primarily in North America. **Adjusted gross profit** was \$1.34 billion and adjusted gross margins were 54% for the three months ended March 31, 2019 compared to adjusted gross profit of \$1.42 billion and adjusted gross margins of 53% in the prior year period.

R&D expense for the three months ended March 31, 2019 was \$172.6 million, compared to \$204.9 million for the comparable prior year period, a decrease of \$32.3 million. This decrease was primarily due to lower expenditures related to the reprioritization of global programs, and higher payments in the prior year period related to licensing arrangements for products in development.

SG&A expense for the three months ended March 31, 2019 was \$607.9 million, compared to \$607.5 million for the comparable prior year period, an increase of \$0.4 million. This increase was primarily due to continued investment in selling and marketing activities, which was partially offset by savings from restructuring activities.

During the three months ended March 31, 2019 and 2018, the Company recorded net charges of \$0.7 million and \$16.2 million, respectively, in **Litigation settlements and other contingencies, net**. During the three months ended March 31, 2019, the Company recognized litigation related charges of approximately \$4.8 million for a number of matters, which was partially offset by a gain of \$4.1 million for fair value adjustments related to the respiratory delivery platform contingent consideration. During the three months ended March 31, 2018, the Company recorded litigation related charges of approximately \$13.3 million, primarily related to an antitrust matter and a patent infringement matter. In addition, the Company recorded a loss of \$2.7 million for fair value adjustments related to the respiratory development platform contingent consideration.

U.S. GAAP net (loss) earnings decreased by \$112.1 million to a loss of \$(25.0) million for the three months ended March 31, 2019, compared to earnings of \$87.1 million for the prior year period and **U.S. GAAP EPS** decreased from \$0.17 in the prior year period to \$(0.05) for the three months ended March 31, 2019. The Company recognized a **U.S. GAAP income tax benefit** of \$89.5 million compared to \$76.6 million for the comparable prior year period. **Adjusted net earnings** decreased to \$421.9 million compared to \$495.6 million for the prior year period. **Adjusted EPS** decreased to \$0.82 from \$0.96 in the prior year period.

EBITDA was \$534.2 million for the three months ended March 31, 2019, and \$663.8 million for the comparable prior year period. After adjusting for certain items as further detailed in the reconciliation below, **adjusted EBITDA** was \$710.2 million for the three months ended March 31, 2019 and \$813.9 million for the comparable prior year period.

Cash Flow

U.S. GAAP net cash used in operating activities was \$(39.7) million for the three months ended March 31, 2019 compared to U.S. GAAP net cash provided by operating activities \$621.8 million for the prior year period, driven primarily by required investment in working capital. Capital expenditures were approximately \$53.1 million for the three months ended March 31, 2019 compared to approximately \$30.7 million for the comparable prior year period. **Adjusted net cash provided by operating activities** was \$80.2 million for the three months ended March 31, 2019 compared to adjusted net cash provided by operating activities \$694.3 million for the prior year period. **Adjusted free cash flow**, defined as adjusted net cash provided by operating activities less capital expenditures, was \$27.1 million for the three months ended March 31, 2019, compared to \$663.6 million in the prior year period.

Conference Call and Earnings Materials

As previously announced, Mylan N.V. will host a conference call and live webcast, today at 10:00 a.m. ET, to review the Company's financial results for the first quarter ended March 31, 2019. The earnings call can be accessed live by calling 855.493.3607 or 346.354.0950 for international callers (ID#: 4992316) or at the following address on the Company's website: investor.mylan.com. The Q1 2019 "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 earnings from operations, adjusted interest expense, adjusted other income, adjusted effective tax rate, notional debt to Credit Agreement Adjusted EBITDA leverage ratio, long term average debt to Credit Agreement Adjusted EBITDA leverage ratio, 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. Primarily due to acquisitions and other significant events which may impact comparability of our periodic operating results, 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 was 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 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 quarters ended March 31, 2019 and 2018 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 March 31, 2019 (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, 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 U.S. GAAP Net Earnings to Adjusted Net Earnings and U.S. GAAP EPS to 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 months ended March 31, 2019 compared to the prior year period:

<i>(in millions, except per share amounts)</i>	Three Months Ended March 31,			
	2019		2018	
U.S. GAAP net (loss) earnings and U.S. GAAP EPS	\$ (25.0)	\$ (0.05)	\$ 87.1	\$ 0.17
Purchase accounting related amortization (primarily included in cost of sales) ^(a)	435.4		423.4	
Litigation settlements and other contingencies, net	0.7		16.2	
Interest expense (primarily clean energy investment financing and accretion of contingent consideration)	7.3		9.7	
Clean energy investments pre-tax loss	17.0		23.0	
Acquisition related costs (primarily included in SG&A) ^(b)	8.1		2.3	
Restructuring related costs ^(c)	19.9		45.4	
Share-based compensation expense ^(d)	18.0		—	
Other special items included in:				
Cost of sales ^(e)	85.1		10.0	
Research and development expense ^(f)	33.1		46.6	
Selling, general and administrative expense	13.9		1.8	
Other expense, net ^(g)	—		17.4	
Tax effect of the above items and other income tax related items	(191.6)		(187.3)	
Adjusted net earnings and adjusted EPS	\$ 421.9	\$ 0.82	\$ 495.6	\$ 0.96
Weighted average diluted ordinary shares outstanding	516.7		516.8	

Significant items for the three months ended March 31, 2019 include the following:

- ^(a) The increase in purchase accounting related amortization is primarily due to amortization expense related to certain product rights acquisitions which occurred in 2018.
- ^(b) Acquisition related costs consist primarily of integration activities.

- (c) For the three months ended March 31, 2019, approximately \$14.5 million is included in cost of sales, approximately \$0.1 million is included in R&D, and approximately \$5.3 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) Beginning in 2019, share-based compensation expense is excluded from adjusted net earnings and adjusted EPS. The full year impact for the year ended December 31, 2018 was insignificant. As such, the 2018 quarterly amount was not added back to U.S. GAAP net earnings for the quarter ended March 31, 2018.
- (e) The three months ended March 31, 2019 increases relate primarily to expenses of \$58.8 million for certain incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown plant.
- (f) For the three months ended March 31, 2019, R&D expense includes \$23.3 million related to non-refundable upfront licensing amounts for products in development with the remaining expense relating on-going development collaborations. Refer to Note 4 *Acquisitions and Other Transactions* included in Part I, Item 1 of the Form 10-Q for additional information. R&D expense for the three months ended March 31, 2018 includes two non-refundable upfront payments totaling approximately \$43.0 million for development agreements entered into during the quarter.
- (g) The 2018 amount 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.

Reconciliation of U.S. GAAP Net Earnings to EBITDA and Adjusted EBITDA

Below is a reconciliation of U.S. GAAP net earnings to EBITDA and adjusted EBITDA for the three months ended March 31, 2019 compared to the prior year period (in millions):

	Three Months Ended March 31,	
	2019	2018
U.S. GAAP net (loss) earnings	\$ (25.0)	\$ 87.1
Add / (subtract) adjustments:		
Net contribution attributable to equity method investments	17.0	23.1
Income tax benefit	(89.5)	(76.6)
Interest expense	131.2	131.7
Depreciation and amortization	500.5	498.5
EBITDA	\$ 534.2	\$ 663.8
Add adjustments:		
Share-based compensation expense	18.0	21.4
Litigation settlements and other contingencies, net	0.7	16.2
Restructuring & other special items	157.3	112.5
Adjusted EBITDA	\$ 710.2	\$ 813.9

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, our reaffirming our 2019 financial guidance and business outlook; that Mylan's first quarter represents a solid start to the year and we remain positioned to reaffirm our guidance for 2019; we continue to manage an increasingly diverse portfolio of products across all three segments of our business, and given the evolution of our commercial and geographic mix see opportunities to enhance our investments for certain areas of our portfolio; we look forward to continue delivering on our mission of access in the remaining quarters of the year and investing in a Mylan that's built to last; that our results reflect an anticipated increase in net working capital required to support our topline growth expectations for 2019, which includes over \$1 billion in new product launches; that given our stable and durable cash flow profile, we remain committed to deleveraging and intend to repay \$1.1 billion of debt during 2019; that we also remain fully committed to maintaining our investment grade credit rating; and any other statements about Mylan's future operations, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competition, and other expectations and targets for future periods. These may often be identified by the use of words such as "will," "may," "could," "should," "would," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "pipeline," "intend," "continue," "target," "seek," 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, including with respect to our remediation and restructuring activities, 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, strategic initiatives 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, 2018, 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 other than as required by law.

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Net sales	\$ 2,460.6	\$ 2,650.4
Other revenues	34.9	34.1
Total revenues	2,495.5	2,684.5
Cost of sales	1,690.3	1,700.2
Gross profit	805.2	984.3
Operating expenses:		
Research and development	172.6	204.9
Selling, general and administrative	607.9	607.5
Litigation settlements and other contingencies, net	0.7	16.2
Total operating expenses	781.2	828.6
Earnings from operations	24.0	155.7
Interest expense	131.2	131.7
Other expense, net	7.3	13.5
(Loss) Earnings before income taxes	(114.5)	10.5
Income tax benefit	(89.5)	(76.6)
Net (loss) earnings	(25.0)	87.1
(Loss) Earnings per ordinary share:		
Basic	\$ (0.05)	\$ 0.17
Diluted	\$ (0.05)	\$ 0.17
Weighted average ordinary shares outstanding:		
Basic	515.0	514.4
Diluted	515.0	516.8

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

	March 31, 2019	December 31, 2018
ASSETS		
Assets		
Current assets:		
Cash and cash equivalents	\$ 229.8	\$ 388.1
Accounts receivable, net	2,778.5	2,881.0
Inventories	2,708.8	2,580.2
Prepaid expenses and other current assets	545.2	518.4
Total current assets	6,262.3	6,367.7
Intangible assets, net	12,955.5	13,664.6
Goodwill	9,607.9	9,747.8
Other non-current assets	3,080.9	2,954.8
Total assets	\$ 31,906.6	\$ 32,734.9
LIABILITIES AND EQUITY		
Liabilities		
Current portion of long-term debt and other long-term obligations	\$ 703.5	\$ 699.8
Current liabilities	3,454.1	3,888.0
Long-term debt	13,086.9	13,161.2
Other non-current liabilities	2,770.5	2,818.8
Total liabilities	20,015.0	20,567.8
Mylan N.V. shareholders' equity	11,891.6	12,167.1
Total liabilities and equity	\$ 31,906.6	\$ 32,734.9

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

Summary of Total Revenues by Segment

	Three Months Ended					
	March 31,					
	2019	2018	% Change	2019 Currency Impact ⁽¹⁾	2019 Constant Currency Revenues	Constant Currency % Change ⁽²⁾
Net sales						
North America	\$ 922.9	\$ 985.3	(6)%	\$ 2.7	\$ 925.6	(6)%
Europe	895.3	1,038.4	(14)%	77.5	972.8	(6)%
Rest of World	642.4	626.7	3 %	51.8	694.2	11 %
Total net sales	2,460.6	2,650.4	(7)%	132.0	2,592.6	(2)%
Other revenues ⁽³⁾	34.9	34.1	2 %	0.9	35.8	5 %
Consolidated total revenues ⁽⁴⁾	\$ 2,495.5	\$ 2,684.5	(7)%	\$ 132.9	\$ 2,628.4	(2)%

⁽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 2019 constant currency net sales or revenues to the corresponding amount in the prior year.

⁽³⁾ For the three months ended March 31, 2019, other revenues in North America, Europe, and Rest of World were approximately \$22.1 million, \$4.7 million, and \$8.1 million, respectively.

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

Reconciliation of Income Statement Line Items

	Three Months Ended	
	March 31,	
	2019	2018
U.S. GAAP cost of sales	\$ 1,690.3	\$ 1,700.2
Deduct:		
Purchase accounting amortization and other related items	(435.4)	(420.9)
Acquisition related items	(0.5)	(0.2)
Restructuring and related costs	(14.5)	(4.4)
Other special items	(85.1)	(10.0)
Adjusted cost of sales	\$ 1,154.8	\$ 1,264.7
Adjusted gross profit ^(a)	\$ 1,340.7	\$ 1,419.8
Adjusted gross margin ^(a)	54%	53%

		Three Months Ended March 31,	
		2019	2018
U.S. GAAP R&D		\$ 172.6	\$ 204.9
Deduct:			
Acquisition related costs		(0.3)	(0.1)
Restructuring and related costs		(0.1)	(4.9)
Share-based compensation expense		(0.1)	—
Other special items		(33.1)	(46.6)
Adjusted R&D		<u>\$ 139.0</u>	<u>\$ 153.3</u>
Adjusted R&D as % of total revenues		<u>6%</u>	<u>6%</u>

		Three Months Ended March 31,	
		2019	2018
U.S. GAAP SG&A		\$ 607.9	\$ 607.5
Deduct:			
Acquisition related costs		(7.3)	(2.0)
Restructuring and related costs		(5.3)	(36.1)
Purchase accounting amortization and other related items		—	(2.4)
Share-based compensation expense		(17.9)	—
Other special items		(13.9)	(1.8)
Adjusted SG&A		<u>\$ 563.5</u>	<u>\$ 565.2</u>
Adjusted SG&A as % of total revenues		<u>23%</u>	<u>21%</u>

		Three Months Ended March 31,	
		2019	2018
U.S. GAAP total operating expenses		\$ 781.2	\$ 828.6
Deduct:			
Litigation settlements and other contingencies, net		(0.7)	(16.2)
R&D adjustments		(33.6)	(51.6)
SG&A adjustments		(44.4)	(42.3)
Adjusted total operating expenses		<u>\$ 702.5</u>	<u>\$ 718.5</u>
Adjusted earnings from operations ^(b)		<u>\$ 638.2</u>	<u>\$ 701.3</u>

		Three Months Ended March 31,	
		2019	2018
U.S. GAAP interest expense		\$ 131.2	\$ 131.7
Deduct:			
Interest expense related to clean energy investments		(1.7)	(2.3)
Accretion of contingent consideration liability		(4.3)	(5.5)
Other special items		(1.3)	(1.9)
Adjusted interest expense		<u>\$ 123.9</u>	<u>\$ 122.0</u>

	Three Months Ended	
	March 31,	
	2019	2018
U.S. GAAP other expense, net	\$ 7.3	\$ 13.5
Deduct:		
Clean energy investments pre-tax loss ^(c)	(17.0)	(23.0)
Other items ^(d)	—	(17.4)
Adjusted other income	\$ (9.7)	\$ (26.9)
	Three Months Ended	
	March 31,	
	2019	2018
U.S. GAAP (loss) earnings before income taxes	\$ (114.5)	\$ 10.5
Total pre-tax non-GAAP adjustments	638.5	595.8
Adjusted earnings before income taxes	\$ 524.0	\$ 606.3
U.S. GAAP income benefit provision	\$ (89.5)	\$ (76.6)
Adjusted tax expense	191.7	187.2
Adjusted income tax provision	\$ 102.2	\$ 110.6
Adjusted effective tax rate	19.5%	18.2%
	Three Months Ended	
	March 31,	
	2019	2018
U.S. GAAP net cash (used in) provided by operating activities	\$ (39.7)	\$ 621.8
Add:		
Restructuring and related costs ^(e)	83.7	31.5
Acquisition related costs	—	1.5
R&D expense	36.2	39.5
Adjusted net cash provided by operating activities	\$ 80.2	\$ 694.3
Deduct:		
Capital expenditures	(53.1)	(30.7)
Adjusted free cash flow	\$ 27.1	\$ 663.6

^(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 U.S. Internal Revenue Code of 1986, as amended.

^(d) 2018 adjustment 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 months ended March 31, 2019 includes approximately \$69.6 million of certain incremental manufacturing variances and site remediation expenses as a result of the activities at the Company's Morgantown plant.

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:

	Three Months Ended			
	June 30, 2018	September 30, 2018	December 31, 2018	March 31, 2019
U.S. GAAP net (loss) earnings	\$ 37.5	\$ 176.7	\$ 51.2	\$ (25.0)
Add / (deduct) adjustments:				
Net contribution attributable to equity method investments	22.9	12.6	20.1	17.0
Income tax (benefit) provision	(18.8)	15.5	25.8	(89.5)
Interest expense	139.2	136.2	135.2	131.2
Depreciation and amortization	501.9	500.6	608.9	500.5
EBITDA	\$ 682.7	\$ 841.6	\$ 841.2	\$ 534.2
Add / (deduct) adjustments:				
Share-based compensation (income) expense	(0.8)	(29.2)	5.3	18.0
Litigation settlements and other contingencies, net	(46.4)	(20.4)	1.1	0.7
Restructuring & other special items	231.1	143.9	158.9	157.3
Adjusted EBITDA	\$ 866.6	\$ 935.9	\$ 1,006.5	\$ 710.2

March 31, 2019 Notional Debt to Twelve Months Ended March 31, 2019 Mylan N.V. Adjusted EBITDA as calculated under our Credit Agreements ("Credit Agreement Adjusted EBITDA") Leverage Ratio

The stated non-GAAP financial measure March 31, 2019 notional debt to twelve months ended March 31, 2019 Credit Agreement Adjusted EBITDA leverage ratio is based on the sum of (i) Mylan's adjusted EBITDA for the quarters ended June 30, 2018, September 30, 2018, December 31, 2018 and March 31, 2019 and (ii) certain adjustments permitted to be included in Credit Agreement Adjusted EBITDA as of March 31, 2019 pursuant to the 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 March 31, 2019 total debt and other current obligations at notional amounts.

	Three Months Ended				Twelve Months Ended
	June 30, 2018	September 30, 2018	December 31, 2018	March 31, 2019	March 31, 2019
Mylan N.V. Adjusted EBITDA	\$ 866.6	\$ 935.9	\$ 1,006.5	\$ 710.2	\$ 3,519.2
Add: other adjustments including estimated synergies					48.3
Credit Agreement Adjusted EBITDA					<u>\$ 3,567.5</u>
Reported debt balances:					
Long-term debt, including current portion					\$ 13,741.8
Short-term borrowings and other current obligations					263.4
Total					<u>\$ 14,005.2</u>
Add / (deduct):					
Net discount on various debt issuances					35.0
Deferred financing fees					71.1
Fair value adjustment for hedged debt					(10.5)
Total debt at notional amounts					<u>\$ 14,100.8</u>
Notional debt to Credit Agreement Adjusted EBITDA Leverage Ratio					4.0

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.