Mylan Reports Third Quarter 2019 Results and Updates 2019 Guidance

November 5, 2019

HERTFORDSHIRE, England and PITTSBURGH, Nov. 5, 2019 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced its financial results for the three and nine months ended September 30, 2019.

Third Quarter 2019 Financial Highlights

- U.S. GAAP diluted earnings per ordinary share ("U.S. GAAP EPS") of $0.37, up 9% compared to U.S. GAAP EPS of $0.34 in the prior year period and adjusted diluted earnings per ordinary share ("adjusted EPS") of $1.17 compared to $1.25 in the prior year period.
- Total revenues of $2.96 billion, up 3%, up 6% on a constant currency basis, compared to the prior year period.
- Revenue Highlights:
  - North America segment net sales of $1.09 billion, up 8% on an actual and constant currency basis.
  - Europe segment net sales of $1.05 billion, up less than 1%, up 6% on a constant currency basis.
  - Rest of World segment net sales of $793.7 million, up 3%, up 4% on a constant currency basis.
- U.S. GAAP net cash provided by operating activities for the three months ended September 30, 2019 of $487.8 million, compared to $653.6 million in the prior year period, and adjusted free cash flow for the three months ended September 30, 2019 of $542.1 million, compared to $698.4 million in the prior year period.
- U.S. GAAP net cash provided by operating activities for the nine months ended September 30, 2019 of $1.12 billion, compared to $1.71 billion in the prior year period, and adjusted free cash flow for the nine months ended September 30, 2019 of $1.29 billion, compared to $2.02 billion in the prior year period, both driven primarily by the expected increased investment in working capital to support new product launches.
- 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 achieved healthy revenue growth across all segments of our business during the third quarter, supporting solid year-to-date revenue growth as compared with last year on a constant currency basis. Also, this quarter, we continued the purposeful work of transforming our business by applying a highly disciplined financial lens to further maximize the value of our asset base. We will continue to execute and remain laser-focused as we now set our sights on year-end commitments, including the upcoming launch of our biosimilar to Herceptin®, Ogivri™, and as we continue to make progress toward a successful deal close with Pfizer's Upjohn business, which we continue to expect will occur in mid-2020."

Mylan President Rajiv Malik continued, "During the third quarter, we benefited from continued momentum on key products, including Yupelri®, Copaxone®, Fulphila® and Wixela ™ Inhub™ We also were pleased with the overall performance of our global key brands and anticipate continued growth across these areas of our portfolio as we head into the fourth quarter. We expect to finish the year from a position of strength as we have reached all of the product milestones necessary to meet our performance commitments, including approval on our Ogivri ™product, which we expect to launch in the coming weeks."

Mylan CFO Ken Parks added, "During the third quarter, we delivered adjusted free cash flow of $542 million, bringing total year-to-date adjusted free cash flow to approximately $1.3 billion, and are reaffirming our commitment to deliver $1.9 billion to $2.3 billion for the full year 2019. As of the end of the third quarter, we have repaid approximately $650 million of debt and remain committed to repay at least $1.1 billion of debt during 2019. Our commitment to delever and maintain our investment grade credit rating, while maintaining our financial flexibility to execute on our business strategies, is supported by our stable and durable cash flow profile. For the full year 2019, we also are narrowing certain of our financial guidance range metrics, and now expect total revenues to be in the range of $11.5 billion to $12.0 billion, and adjusted EPS to be in the range of $4.20 to $4.40."

Financial Summary

	Three Months Ended September 30,			Nine Months Ended September 30,		
(Unaudited; in millions, except per share amounts and %s)	**2019**	**2018**	**Percent Change**	**2019**	**2018**	**Percent Change**
Total Revenues [1]	$ 2,961.7	$ 2,862.4	3%	$ 8,308.7	$ 8,355.2	(1)%
North America Net Sales	1,088.6	1,012.3	8%	3,035.0	2,998.4	1%
Europe Net Sales	1,045.9	1,041.3	— %	2,930.7	3,070.3	(5)%
Rest of World Net Sales	793.7	773.7	3%	2,241.3	2,164.5	4%
Other Revenues	33.5	35.1	(5)%	101.7	122.0	(17)%
U.S. GAAP Gross Profit	$ 1,072.4	$ 1,039.2	3%	$ 2,810.2	$ 2,986.0	(6)%
U.S. GAAP Gross Margin	36.2 %	36.3 %		33.8 %	35.7 %	
Adjusted Gross Profit [2]	$ 1,564.4	$ 1,584.7	(1)%	$ 4,438.2	$ 4,500.2	(1)%
Adjusted Gross Margin [2]	52.8 %	55.4 %		53.4 %	53.9 %	
U.S. GAAP Net Earnings (Loss)	$ 189.8	$ 176.7	7%	$ (3.7)	$ 301.3	(101)%
U.S. GAAP EPS	$ 0.37	$ 0.34	9%	$ (0.01)	$ 0.58	(102)%
Adjusted Net Earnings [2]	$ 604.4	$ 648.0	(7)%	$ 1,559.1	$ 1,695.1	(8)%
Adjusted EPS [2]	$ 1.17	$ 1.25	(6)%	$ 3.02	$ 3.28	(8)%
EBITDA [2]	$ 794.8	$ 841.6	(6)%	$ 1,925.7	$ 2,188.1	(12)%
Adjusted EBITDA [2]	$ 922.8	$ 935.9	(1)%	$ 2,480.4	$ 2,616.4	(5)%

(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.

Third Quarter 2019 Financial Results

Total revenues for the three months ended September 30, 2019 were $2.96 billion, compared to $2.86 billion for the comparable prior year period, representing an increase of $99.3 million, or 3%. Total revenues include both net sales and other revenues from third parties. **Net sales** for the current quarter were $2.93 billion, compared to $2.83 billion for the

comparable prior year period, representing an increase of $100.9 million, or 4%. **Other revenues** for the current quarter were $33.5 million, compared to $35.1 million for the comparable prior year period.

The increase in net sales included an increase in the North America segment of 8% and in the Rest of World segment of 3%. Net sales in the Europe segment increased less than 1% when compared to the prior year period. 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 the European Union and Australia. The unfavorable impact of foreign currency translation on current period net sales was approximately $62.0 million, or 2%. On a constant currency basis, net sales increased by approximately $162.9 million, or 6%. This increase was primarily driven by new product sales, partially offset by a decrease in net sales from existing products as the impact of lower pricing exceeded the benefit of higher volumes. Below is a summary of net sales in each of our segments for the three months ended September 30, 2019:

- Net sales from **North America** segment totaled $1.09 billion in the current quarter, an increase of $76.3 million or 8% when compared to the prior year period. This increase was primarily driven by new product sales partially offset by lower sales of existing products due to lower pricing and lower volumes. New product sales were primarily driven by sales of the Wixela ™Inhub ™and Yupelri®. Lower sales of existing products was due to changes in the competitive environment, including the loss of exclusivity on tadalafil. The impact of foreign currency translation on current period net sales was insignificant within North America.
- Net sales from **Europe** segment totaled $1.05 billion in the current quarter, an increase of $4.6 million, or less than 1%, when compared to the prior year period. Net sales in the current period were negatively affected by the unfavorable impact of foreign currency translation of approximately $53.3 million or 5%, and to a lesser extent, lower pricing on existing products. The unfavorable impact of these items was offset by new product sales, including Hulio™, and higher volumes of existing products. Constant currency net sales increased by approximately $57.9 million, or 6%, when compared to the prior year period.
- Net sales from **Rest of World** segment totaled $793.7 million in the current quarter, an increase of $20.0 million or 3% when compared to the prior year period. This increase was primarily driven by new product sales in Australia and emerging markets and higher volumes of existing products primarily driven by products sold in emerging markets. These increases were partially offset by lower pricing on existing products and, to a lesser extent, the unfavorable impact of foreign currency translation. Overall, net sales from Rest of World were unfavorably impacted by the effect of foreign currency translation by approximately $8.0 million, or 1%. Constant currency net sales increased by approximately $28.0 million, or 4% when compared to the prior year period.

U.S. GAAP gross profit was $1.07 billion and $1.04 billion for the third quarter of 2019 and 2018, respectively. **U.S. GAAP gross margins** were 36% in the third quarter of 2019 and 2018. U.S. GAAP gross margins were negatively impacted as a result of lower gross profit for sales of existing products, including higher sales of the authorized generic version of EpiPen®, which has a lower than company average margin, as well as changes in the competitive environment on certain products. In addition, there were certain inventory write-offs, the largest of which is dated Wixela ™Inhub ™product resulting from the later than expected approval date. These decreases were offset by the impact from new product sales and lower site remediation expenses and restructuring charges related to activities at the Company's Morgantown plant. **Adjusted gross profit** was $1.56 billion and adjusted gross margins were 53% for the third quarter of 2019 compared to adjusted gross profit of $1.58 billion and adjusted gross margins of 55% in the prior year period. Adjusted gross margins were also negatively impacted by EpiPen® and the Wixela ™Inhub ™, partially offset by the impact from new product sales.

R&D expense for the three months ended September 30, 2019 was $167.9 million, compared to $144.1 million for the comparable prior year period, an increase of $23.8 million. This increase was primarily due to higher payments in the current year period related to licensing arrangements for products in development partially offset by lower expenditures related to the reprioritization of global programs.

SG&A expense for the three months ended September 30, 2019 was $632.7 million, compared to $577.3 million for the comparable prior year period, an increase of $55.4 million. The increase was due to continued investment in selling and marketing activities. Also contributing to the increase were higher consulting fees and other expenses primarily related to the pending Upjohn transaction totaling approximately $41.2 million in the current quarter. In addition, the increase included the impact of the reversal of cumulative expense in the prior year period related to the Company's One-Time Special Performance-Based Five-Year Realizable Value Incentive Program that resulted in the Company recognizing a reduction in share-based compensation expense of approximately $47.1 million during the three months ended September 30, 2018. Partially offsetting these items was compensation expense of $20.0 million recognized in the prior year period for an additional discretionary bonus for a certain group of employees and lower restructuring expenses in the current quarter when compared to the prior year period. None of the employees who received the 2018 discretionary bonus were named executive officers.

During the third quarter of 2019, the Company recorded a net gain of $51.9 million **in Litigation settlements and other contingencies, net** compared to a net gain of $20.4 million in the comparable prior year period. The favorable litigation settlement for the three months ended September 30, 2019, consists primarily of a gain related to the Celgene Corporation settlement of $62.0 million partially offset by certain litigation related charges. The net gain recognized in the prior year period primarily relates to a gain of approximately $19.3 million for a contingent consideration fair value adjustment due to changes to assumptions relating to the timing of product launch along with other competitive and market factors related to the Wixela ™Inhub ™.

U.S. GAAP net earnings increased by $13.1 million to earnings of $189.8 million for the three months ended September 30, 2019, compared to earnings of $176.7 million for the prior year period and **U.S. GAAP EPS** increased from $0.34 in the prior year period to $0.37 in the current quarter. The Company recognized a **U.S. GAAP income tax benefit** of $4.0 million in the current year period, compared to a U.S. GAAP income tax provision of $15.5 million for the comparable prior year period, an increase of $19.5 million. During the current quarter, the Company recorded a $42.0 million benefit resulting from refinements to previous estimates in conjunction with the filing of the Company's 2018 U.S. federal tax return, which revised the estimated impact of the Company's valuation allowance on its interest limitation deductions and the estimate of available foreign tax credits. Also impacting the current year income tax benefit was the changing mix of income earned in jurisdictions with differing tax rates. **Adjusted net earnings** decreased to $604.4 million compared to $648.0 million for the prior year period. **Adjusted EPS** decreased to $1.17 from $1.25 in the prior year period.

EBITDA was $794.8 million for the current quarter and $841.6 million for the comparable prior year period. After adjusting for certain items as further detailed in the reconciliation below, **adjusted EBITDA** was $922.8 million for the current quarter and $935.9 million for the comparable prior year period.

Nine Months Ended September 30, 2019 Financial Results

Total revenues for the nine months ended September 30, 2019 were $8.31 billion, compared to $8.36 billion for the comparable prior year period, representing a decrease of $46.5 million, or 1%. Total revenues include both net sales and other revenues from third parties. **Net sales** for the nine months ended September 30, 2019 were $8.21 billion, compared to $8.23 billion for the comparable prior year period, representing a decrease of $26.2 million, or less than 1%. **Other revenues** for the nine months ended September 30, 2019 were $101.7 million, compared to $122.0 million for the comparable prior year period.

The decrease in net sales was primarily the result of a decrease in net sales in the Europe segment of 5%, partially offset by an increase in net sales in the Rest of World segment of 4% and an increase in net sales in the North America segment of 1%. 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 $287.6 million, or 4%. On a constant currency basis, the increase in net sales was approximately $261.4 million, or 3% for the nine months ended September 30, 2019. This increase was primarily driven by new product sales, partially offset by a decrease in net sales from existing products as a result of lower pricing and volumes. Below is a summary of net sales in each of our segments for the nine months ended September 30, 2019:

- Net sales from **North America** segment totaled $3.04 billion during the nine months ended September 30, 2019, an increase of $36.6 million or 1% when compared to the prior year period. This increase was due primarily to new product sales, including the Wixela ™Inhub ™and Fulphila® (biosimilar to Neulasta®). This increase was partially offset by lower pricing and volumes of existing products, driven by changes in the competitive environment and the impact of the Morgantown plant remediation activities. The impact of foreign currency translation on current period net sales was insignificant within North America.
- Net sales from **Europe** segment totaled $2.93 billion during the nine months ended September 30, 2019, a decrease of $139.6 million or 5% when compared to the prior year period. This decrease was primarily the result of the unfavorable impact of foreign currency translation of approximately

$190.4 million or 6%. Sales of existing products were also negatively impacted by lower pricing. This decrease was partially offset by new product sales and higher volumes. Constant currency net sales increased by approximately $50.8 million or 2% when compared to the prior year period.

- Net sales from **Rest of World** segment totaled $2.24 billion during the nine months ended September 30, 2019, an increase of $76.8 million or 4% when compared to the prior year period. This increase was primarily the result of new product sales, primarily in Australia and emerging markets, and higher volumes of existing products. Increased volumes of existing products were primarily driven by the Company's anti-retroviral therapy franchise. This increase was partially offset 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 $91.7 million, or 4%. Constant currency net sales increased by approximately $168.5 million or 8% when compared to the prior year period.

U.S. GAAP gross profit was $2.81 billion and $2.99 billion for the nine months ended September 30, 2019 and 2018, respectively. **U.S. GAAP gross margins** were 34% and 36% for the nine months ended September 30, 2019 and 2018, respectively. U.S. GAAP gross margins were negatively impacted by lower gross profit for sales of existing products. In addition, gross margins were negatively impacted by approximately 65 basis points for higher site remediation expenses related to activities at the Company's Morgantown plant, by approximately 10 basis points related to the incremental amortization from product acquisitions and by approximately 40 basis points for recall related costs, including inventory write-offs. These items were partially offset by the impact of new product sales. **Adjusted gross profit** was $4.44 billion and adjusted gross margins were 53% for the nine months ended September 30, 2019 compared to adjusted gross profit of $4.50 billion and adjusted gross margins of 54% in the prior year period.

R&D expense for the nine months ended September 30, 2019 was $488.1 million, compared to $555.7 million for the comparable prior year period, a decrease of $67.6 million. This decrease was primarily due to lower expenditures related to the reprioritization of global programs and lower restructuring related costs.

SG&A expense for the nine months ended September 30, 2019 was $1.91 billion, compared to $1.81 billion for the comparable prior year period, an increase of $101.1 million. The increase was due to continued investment in selling and marketing activities. Also contributing to the increase were higher consulting fees and other expenses primarily related to the pending Upjohn transaction totaling approximately $45.3 million in the current year period. In addition, the current year period was impacted by higher share-based compensation expense due to a reduction of approximately $70.6 million during the nine months ended September 30, 2018 related to certain performance-based awards. Partially offsetting these increases was a decrease in bad debt expense of approximately $23.0 million related to a special business interruption event for one customer in the prior year period and $20.0 million of compensation expense for an additional discretionary bonus for a certain group of employees in the prior year period. None of the employees who received the 2018 discretionary bonus were named executive officers.

During the nine months ended September 30, 2019 the Company recorded a net gain of $30.3 million in **Litigation settlements and other contingencies, net** compared to a net gain of $50.6 million in the comparable prior year period. During the nine months ended September 30, 2019, the Company recognized a net gain of approximately $1.4 million primarily related to a favorable litigation settlement related to the Celgene matter of $62.0 million recognized during the nine months ended September 30, 2019 offset by litigation related charges for settlements reached related to the modafinil antitrust matter of $18.0 million and the settlement with the SEC in connection with the SEC staff's investigation of the Company's public disclosures regarding its 2016 settlement with the Department of Justice concerning the EpiPen Medicaid Drug Rebate Program of $30.0 million. In addition, a $28.9 million gain was recognized for the reduction of contingent consideration related to the respiratory delivery platform. Litigation settlements for the nine months ended September 30, 2018, consisted primarily of a gain of approximately $14.7 million related to a favorable litigation settlement, which was partially offset by litigation related charges of approximately $13.3 million related to an antitrust and a patent infringement matter. In addition, a $49.3 million gain was recognized for the reduction of contingent consideration related to the respiratory delivery platform.

U.S. GAAP net (loss) earnings decreased by $305.0 million to a loss of $3.7 million for the nine months ended September 30, 2019, compared to earnings of $301.3 million for the prior year period and **U.S. GAAP EPS** decreased from $0.58 in the prior year period to $(0.01) for the nine months ended September 30, 2019. The Company recognized a **U.S. GAAP income tax provision** of $22.9 million, compared to a U.S. GAAP income tax benefit of $79.9 million for the comparable prior year period, an increase of $102.8 million. During the nine months ended September 30, 2019, primarily due to the settlement reached with the U.S. Internal Revenue Service, partially offset by the expiration of federal and foreign statutes of limitations, the Company increased its net liability for unrecognized tax benefits by approximately $50.9 million. Additionally, during the nine months ended September 30, 2019, the Company recorded a $42.0 million benefit resulting from refinements to previous estimates in conjunction with the filing of the Company's 2018 U.S. federal tax return, which revised the estimated impact of the Company's valuation allowance on its interest limitation deductions and the estimate of available foreign tax credits. In the prior year period, as a result of federal and state audits and settlements and expirations of certain state, federal, and foreign statutes of limitations, the Company reduced its liability for unrecognized tax benefits by approximately $86.0 million, which resulted in a net benefit to the income tax provision of approximately $53.0 million. Partially offsetting this benefit was an increase in the reserve for uncertain tax benefits of approximately $18.0 million for certain other matters. Additionally, during the nine months ended September 30, 2018, income tax benefits of approximately $30.0 million were recognized upon revaluations of certain deferred tax items upon statutory rate changes in certain non-U.S. jurisdictions, $6.9 million of valuation allowance releases in certain jurisdictions, and a benefit of approximately $6.2 million related to the finalization of previously recorded 2017 tax estimates upon the filing of tax returns. Also impacting the current year income tax expense was the changing mix of income earned in jurisdictions with differing tax rates. **Adjusted net earnings** decreased to $1.56 billion compared to $1.70 billion for the prior year period. **Adjusted EPS** decreased to $3.02 from $3.28 in the prior year period.

EBITDA was $1.93 billion for the nine months ended September 30, 2019, and $2.19 billion for the comparable prior year period. After adjusting for certain items as further detailed in the reconciliation below, **adjusted EBITDA** was $2.48 billion for the nine months ended September 30, 2019 and $2.62 billion for the comparable prior year period.

Cash Flow

U.S. GAAP net cash provided by operating activities for the three and nine months ended September 30, 2019 was $487.8 million and $1.12 billion, compared to $653.6 million and $1.71 billion in the comparable prior year periods. Capital expenditures were approximately $42.3 million and $139.6 million for the three and nine months ended September 30, 2019 compared to approximately $61.5 million and $137.4 million for the comparable prior year periods.

Adjusted net cash provided by operating activities for the three and nine months ended September 30, 2019 was $584.4 million and $1.43 billion compared to adjusted net cash provided by operating activities of $759.9 million and $2.16 billion for the comparable prior year periods. **Adjusted free cash flow**, defined as adjusted net cash provided by operating activities less capital expenditures, was $542.1 million and $1.29 billion for the three and nine months ended September 30, 2019, compared to $698.4 million and $2.02 billion in comparable the prior year periods.

Updated Full Year 2019 Financial Guidance

Mylan is updating certain of its previous full year 2019 guidance by narrowing certain guidance metric's ranges. 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 2019, Mylan continues to expect to generate $1.9 billion to $2.3 billion of adjusted free cash flow. Adjusted EPS for 2019 is now expected to be in the range of $4.20 to $4.40. Mylan now expects 2019 total revenues in the range of $11.50 billion to $12.00 billion.

(In millions, except for Adjusted EPS)	**2019 Updated Guidance Range**	**2019 Updated Midpoint**
Total Revenues	$11,500 - $12,000	$11,750
Adjusted EPS	$4.20 - $4.40	$4.30
Adjusted Free Cash Flow	$1,900 - $2,300	$2,100

Conference Call and Earnings Materials

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 third quarter ended September 30, 2019. The earnings call can be accessed live by calling 855.493.3607 or 346.354.0950 for international callers (ID#: 1519969) or at the following address on the Company's website: investor.mylan.com. The Q3 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 target, 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 Agreement 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 and year to date periods ended September 30, 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 September 30, 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, including integration, 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 (loss) and U.S. GAAP EPS to adjusted net earnings and adjusted EPS for the three and nine months ended September 30, 2019 compared to the prior year period:

	Three Months Ended September 30,				Nine Months Ended September 30,			
(in millions, except per share amounts)	**2019**		**2018**		**2019**		**2018**	
U.S. GAAP net earnings (loss) and U.S. GAAP EPS	$ 189.8	$ 0.37	$ 176.7	$ 0.34	$ (3.7)	$ (0.01)	$ 301.3	$ 0.58
Purchase accounting related amortization (primarily included in cost of sales)	408.5		428.7		1,283.9		1,282.4	
Litigation settlements and other contingencies, net	(51.9)		(20.4)		(30.3)		(50.6)	
Interest expense (primarily clean energy investment financing and accretion of contingent consideration)	6.6		12.1		20.8		31.0	
Clean energy investments pre-tax loss	10.4		12.6		43.6		58.6	
Acquisition related costs (primarily included in SG&A) [(a)]	43.0		4.9		56.6		17.4	
Restructuring related costs [(b)]	0.8		80.8		78.3		202.3	
Share-based compensation expense [(c)]	16.1		—		50.9		—	
Other special items included in:								
Cost of sales [(d)]	70.9		65.4		268.1		139.4	
Research and development expense [(e)]	40.3		3.2		100.5		100.3	
Selling, general and administrative expense	8.4		(0.7)		33.1		33.2	
Other expense, net [(f)]	—		1.3		—		25.5	
Tax effect of the above items and other income tax related items [(g)]	(138.5)		(116.6)		(342.7)		(445.7)	
Adjusted net earnings and adjusted EPS	$ 604.4	$ 1.17	$ 648.0	$ 1.25	$ 1,559.1	$ 3.02	$ 1,695.1	$ 3.28
Weighted average diluted ordinary shares outstanding	516.2		516.5		516.4		516.5	

Significant items for the three and nine months ended September 30, 2019 include the following:

(a) Acquisition related costs consist primarily of transaction costs including legal and consulting fees and integration activities. The increase for the three and nine months ended September 30, 2019 relates to transaction costs for the pending Upjohn transaction.

(b) For the three months ended September 30, 2019, charges of approximately $11.4 million are included in cost of sales and a net gain of $10.5 million is included in SG&A. For the nine months ended September 30, 2019, charges of approximately $72.2 million are included in cost of sales and net charges of approximately $6.1 million are included in SG&A. Refer to Note 17 *Restructuring* included in Part I, Item 1 of the Form 10-Q for additional information.

(c) 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 three and nine months ended September 30, 2018 amounts were not added back to U.S. GAAP net earnings.

(d) Costs incurred during the three months ended September 30, 2019 primarily relate to incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown plant of approximately $50.0 million. The nine months ended September 30, 2019 increased $128.7 million primarily due to $54.4 million for certain incremental manufacturing variances and site remediation activities as a result of the activities at the Company's Morgantown plant, approximately $35.1 million for product recall costs, including inventory write-offs, and charges related to the cancellation of a contract, each of which were higher during the nine months ended September 30, 2019 compared to the prior year period.

(e) R&D expense for the three months ended September 30, 2019 consists primarily of expenses for product development arrangements of approximately $39.8 million. 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 September 30, 2018 includes expenses relating to on-going collaboration agreements, including Momenta Pharmaceuticals, Inc.

(f) 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.

(g) The impact of changes related to uncertain tax positions is excluded from adjusted earnings.

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

Below is a reconciliation of U.S. GAAP net earnings (loss) to EBITDA and adjusted EBITDA for the three and nine months ended September 30, 2019 compared to the prior year period (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP net earnings (loss)	$ 189.8	$ 176.7	$ (3.7)	$ 301.3
Add / (deduct) adjustments:				
Net contribution attributable to equity method investments	10.4	12.6	43.6	58.6
Income tax (benefit) provision	(4.0)	15.5	22.9	(79.9)
Interest expense	128.9	136.2	391.3	407.1
Depreciation and amortization	469.7	500.6	1,471.6	1,501.0
EBITDA	$ 794.8	$ 841.6	$ 1,925.7	$ 2,188.1
Add / (deduct) adjustments:				
Share-based compensation expense (income)	16.1	(29.2)	50.9	(8.6)
Litigation settlements and other contingencies, net	(51.9)	(20.4)	(30.3)	(50.6)
Restructuring & other special items	163.8	143.9	534.1	487.5
Adjusted EBITDA	$ 922.8	$ 935.9	$ 2,480.4	$ 2,616.4

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 approximately 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." Such forward-looking statements may include, without limitation, updating our 2019 financial guidance and business outlook; that we will continue to execute and remain laser-focused as we now set our sights on year-end commitments, including the upcoming launch of our biosimilar to Herceptin®, Ogivri™, and as we continue to make progress toward a successful deal close with Pfizer's Upjohn business, which we continue to expect will occur in mid-2020; we were pleased with the overall performance of our global key brands and anticipate continued growth across these areas of our portfolio as we head into the fourth quarter; we expect to finish the year from a position of strength as we have reached all of the product milestones necessary to meet our performance commitments, including approval on our Ogivri ™product, which we expect to launch in the coming weeks; we are reaffirming our commitment to deliver $1.9 billion to $2.3 billion in adjusted free cash flow for the full year 2019; as of the end of the third quarter we have repaid approximately $650 million of debt and remain committed to repay at least $1.1 billion of debt during 2019; our commitment to delever and maintain our investment grade credit rating, while maintaining our financial flexibility to execute on our business strategies, is supported by our stable and durable cash flow profile; for the full year 2019, we are also narrowing certain of our financial guidance range metrics, and now expect total revenues to be in the range of $11.5 billion to $12.0 billion, and adjusted EPS to be in the range of $4.20 to $4.40; and any other statements about the proposed transaction pursuant to which Mylan will combine with Pfizer Inc.'s Upjohn Business (the "Upjohn Business") in a Reverse Morris Trust transaction (the "Combination"), the expected timetable for completing the Combination, the benefits and synergies of the Combination, future opportunities for the combined company and products and any other statements regarding Mylan's, the Upjohn Business's or the combined company's future operations, financial or operating results, capital allocation, dividend policy, debt ratio, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, 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: with respect to the Combination, the parties' ability to meet expectations regarding the timing, completion and accounting and tax treatments of the Combination, changes in relevant tax and other laws, the parties' ability to consummate the Combination, the conditions to the completion of the Combination, including receipt of approval of Mylan's shareholders, not being satisfied or waived on the anticipated timeframe or at all, the regulatory approvals required for the Combination not being obtained on the terms expected or on the anticipated schedule or at all, the integration of Mylan and the Upjohn Business being more difficult, time consuming or costly than expected, Mylan's and the Upjohn Business's failure to achieve expected or targeted future financial and operating performance and results, the possibility that the combined company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with the Combination within the expected time frames or at all or to successfully integrate Mylan and the Upjohn Business, customer loss and business disruption being greater than expected following the Combination, the retention of key employees being more difficult following the Combination, changes in third-party relationships and changes in the economic and financial conditions of the business of Mylan or the Upjohn Business; 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 or the Upjohn Business's products; any regulatory, legal or other impediments to Mylan's or the Upjohn Business's ability to bring new products to market, including, but not limited to, where Mylan or the Upjohn Business 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 or the Upjohn Business's ability to execute on new product opportunities; any changes in or difficulties with our or the Upjohn Business's manufacturing facilities, including with respect to remediation and restructuring activities, supply chain or inventory or the 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 or the Upjohn Business's 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 or the Upjohn Business's 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, Mylan's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and our other filings with the Securities and Exchange Commission (the "SEC"). These risks, as well as other risks associated with Mylan, the Upjohn Business, the combined company and the Combination are also more fully discussed in the registration statement on Form S-4 which includes a proxy statement/prospectus (the "Form S-4"), and Form 10 which includes an information statement (the "Form 10"), each of which has been filed by Upjohn Inc. ("Newco") with the SEC on October 25, 2019 (and has not yet been declared effective) in connection with the Combination. You can access Pfizer's, Newco's and Mylan's filings with the SEC through the SEC website at www.sec.gov or through Pfizer's or 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. Pfizer, Newco and Mylan undertake no obligation to update any statements herein for revisions or changes after the date of this release other than as required by law.

Additional Information and Where to Find It

This release shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offer of securities shall be

made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. In connection with the proposed transaction, Newco and Mylan have filed certain materials with the SEC, including, among other materials, the Form S-4 and Form 10 filed by Newco. The registration statements have not yet become effective. After the Form S-4 is effective, a definitive proxy statement/prospectus will be sent to the Mylan shareholders seeking approval of the proposed transaction, and after the Form 10 is effective, a definitive information statement will be made available to the Pfizer stockholders relating to the proposed transaction. Newco and Mylan intend to file additional relevant materials with the SEC in connection with the proposed transaction, including a proxy statement of Mylan in definitive form. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT MYLAN, NEWCO AND THE PROPOSED TRANSACTION. The documents relating to the proposed transaction (when they are available) can be obtained free of charge from the SEC's website at www.sec.gov. These documents (when they are available) can also be obtained free of charge from Mylan, upon written request to Mylan, at (724) 514-1813 or investor.relations@mylan.com or from Pfizer on Pfizer's internet website at https://investors.Pfizer.com/financials/sec-filings/default.aspx or by contacting Pfizer's Investor Relations Department at (212) 733-2323, as applicable.

Participants in the Solicitation

This release is not a solicitation of a proxy from any investor or security holder. However, Pfizer, Mylan, Newco and certain of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies in connection with the proposed transaction under the rules of the SEC. Information about the directors and executive officers of Pfizer may be found in its Annual Report on Form 10-K filed with the SEC on February 28, 2019 and its definitive proxy statement and additional proxy statement relating to its 2019 Annual Meeting filed with the SEC on March 14, 2019 and on April 2, 2019, respectively, and Current Report on Form 8-K filed with the SEC on June 27, 2019. Information about the directors and executive officers of Mylan may be found in its amended Annual Report on Form 10-K filed with the SEC on April 30, 2019, and its definitive proxy statement relating to its 2019 Annual Meeting filed with the SEC on May 24, 2019. Additional information regarding the interests of these participants can also be found in the Form S-4 and will also be included in the definitive proxy statement of Mylan in connection with the proposed transaction when it becomes available. These documents (when they are available) can be obtained free of charge from the sources indicated above.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Net sales	$ 2,928.2	$ 2,827.3	$ 8,207.0	$ 8,233.2
Other revenues	33.5	35.1	101.7	122.0
Total revenues	2,961.7	2,862.4	8,308.7	8,355.2
Cost of sales	1,889.3	1,823.2	5,498.5	5,369.2
Gross profit	1,072.4	1,039.2	2,810.2	2,986.0
Operating expenses:				
Research and development	167.9	144.1	488.1	555.7
Selling, general and administrative	632.7	577.3	1,909.2	1,808.1
Litigation settlements and other contingencies, net	(51.9)	(20.4)	(30.3)	(50.6)
Total operating expenses	748.7	701.0	2,367.0	2,313.2
Earnings from operations	323.7	338.2	443.2	672.8
Interest expense	128.9	136.2	391.3	407.1
Other expense, net	9.0	9.8	32.7	44.3
Earnings before income taxes	185.8	192.2	19.2	221.4
Income tax (benefit) provision	(4.0)	15.5	22.9	(79.9)
Net earnings (loss)	189.8	176.7	(3.7)	301.3
Earnings (Loss) per ordinary share:				
Basic	$ 0.37	$ 0.34	$ (0.01)	$ 0.59
Diluted	$ 0.37	$ 0.34	$ (0.01)	$ 0.58
Weighted average ordinary shares outstanding:				
Basic	516.0	514.5	515.5	514.4
Diluted	516.2	516.5	515.5	516.5

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

	September 30, 2019	December 31, 2018
ASSETS		
Assets		
Current assets:		
Cash and cash equivalents	$ 358.9	$ 388.1
Accounts receivable, net	2,948.0	2,881.0
Inventories	2,763.5	2,580.2
Prepaid expenses and other current assets	574.7	518.4
Total current assets	6,645.1	6,367.7
Intangible assets, net	11,824.3	13,664.6
Goodwill	9,387.1	9,747.8
Other non-current assets	3,197.0	2,954.8
Total assets	$ 31,053.5	$ 32,734.9
LIABILITIES AND EQUITY		
Liabilities		
Current portion of long-term debt and other long-term obligations	$ 605.3	$ 699.8
Current liabilities	4,039.7	3,888.0
Long-term debt	12,460.5	13,161.2
Other non-current liabilities	2,484.6	2,818.8
Total liabilities	19,590.1	20,567.8

Mylan N.V. shareholders' equity	11,463.4	12,167.1
Total liabilities and equity	$ 31,053.5	$ 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 September 30,					
(In millions)	**2019**	**2018**	**% Change**	**2019 Currency Impact [1]**	**2019 Constant Currency Revenues**	**Constant Currency % Change [2]**
Net sales						
North America	$ 1,088.6	$ 1,012.3	8 %	$ 0.7	$ 1,089.3	8 %
Europe	1,045.9	1,041.3	— %	53.3	1,099.2	6 %
Rest of World	793.7	773.7	3 %	8.0	801.7	4 %
Total net sales	2,928.2	2,827.3	4 %	62.0	2,990.2	6 %
Other revenues [3]	33.5	35.1	(5) %	0.4	33.9	(3) %
Consolidated total revenues [4]	$ 2,961.7	$ 2,862.4	3 %	$ 62.4	$ 3,024.1	6 %

	Nine Months Ended September 30,					
	2019	**2018**	**% Change**	**2019 Currency Impact [1]**	**2019 Constant Currency Revenues**	**Constant Currency % Change [2]**
Net sales						
North America	$ 3,035.0	$ 2,998.4	1 %	$ 5.5	$ 3,040.5	1 %
Europe	2,930.7	3,070.3	(5) %	190.4	3,121.1	2 %
Rest of World	2,241.3	2,164.5	4 %	91.7	2,333.0	8 %
Total net sales	8,207.0	8,233.2	— %	287.6	8,494.6	3 %
Other revenues [3]	101.7	122.0	(17) %	2.0	103.7	(15) %
Consolidated total revenues [4]	$ 8,308.7	$ 8,355.2	(1) %	$ 289.6	$ 8,598.3	3 %

(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 September 30, 2019, other revenues in North America, Europe, and Rest of World were approximately $17.6 million, $3.8 million, and $12.1 million, respectively. For the nine months ended September 30, 2019, other revenues in North America, Europe, and Rest of World were approximately $58.8 million, $12.3 million, and $30.6 million, respectively.

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

Reconciliation of Income Statement Line Items

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
U.S. GAAP cost of sales	$ 1,889.3	$ 1,823.2	$ 5,498.5	$ 5,369.2
Deduct:				
Purchase accounting amortization and other related items	(408.6)	(426.9)	(1,284.0)	(1,275.2)
Acquisition related items	(0.8)	(1.4)	(2.9)	(2.4)
Restructuring and related costs	(11.4)	(51.8)	(72.2)	(97.2)
Share-based compensation expense	(0.3)	—	(0.8)	—
Other special items	(70.9)	(65.4)	(268.1)	(139.4)
Adjusted cost of sales	$ 1,397.3	$ 1,277.7	$ 3,870.5	$ 3,855.0
Adjusted gross profit [a]	$ 1,564.4	$ 1,584.7	$ 4,438.2	$ 4,500.2
Adjusted gross margin [a]	53 %	55 %	53 %	54 %

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
U.S. GAAP R&D	$ 167.9	$ 144.1	$ 488.1	$ 555.7
Add / (Deduct):				
Acquisition related costs	(0.3)	(0.2)	(0.6)	(0.7)
Restructuring and related costs	0.1	(0.3)	—	(17.0)
Purchase accounting amortization and other related items	—	(0.1)	—	(0.2)
Share-based compensation expense	(0.6)	—	(1.6)	—
Other special items	(40.3)	(3.2)	(100.5)	(100.3)
Adjusted R&D	$ 126.8	$ 140.3	$ 385.4	$ 437.5

Adjusted R&D as % of total revenues	4 %	5 %	5 %	5 %

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP SG&A	$ 632.7	$ 577.3	$ 1,909.2	$ 1,808.1
Add / (Deduct):				
Acquisition related costs	(41.9)	(3.2)	(53.1)	(14.3)
Restructuring and related costs	10.5	(28.7)	(6.1)	(88.4)
Purchase accounting amortization and other related items	0.1	(1.7)	0.1	(7.0)
Share-based compensation expense	(15.2)	—	(48.5)	—
Other special items	(8.4)	0.7	(33.1)	(33.2)
Adjusted SG&A	$ 577.8	$ 544.4	$ 1,768.5	$ 1,665.2
Adjusted SG&A as % of total revenues	20 %	19 %	21 %	20 %

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP total operating expenses	$ 748.7	$ 701.0	$ 2,367.0	$ 2,313.2
Add / (Deduct):				
Litigation settlements and other contingencies, net	51.9	20.4	30.3	50.6
R&D adjustments	(41.1)	(3.8)	(102.7)	(118.2)
SG&A adjustments	(54.9)	(32.9)	(140.7)	(142.9)
Adjusted total operating expenses	$ 704.6	$ 684.7	$ 2,153.9	$ 2,102.7
Adjusted earnings from operations [b]	$ 859.8	$ 900.0	$ 2,284.3	$ 2,397.5

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP interest expense	$ 128.9	$ 136.2	$ 391.3	$ 407.1
Deduct:				
Interest expense related to clean energy investments	(1.4)	(2.1)	(4.6)	(6.5)
Accretion of contingent consideration liability	(3.8)	(5.3)	(12.0)	(16.3)
Other special items	(1.4)	(4.7)	(4.2)	(8.2)
Adjusted interest expense	$ 122.3	$ 124.1	$ 370.5	$ 376.1

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP other expense, net	$ 9.0	$ 9.8	$ 32.7	$ 44.3
Add / (Deduct):				
Clean energy investments pre-tax loss [c]	(10.4)	(12.6)	(43.6)	(58.6)
Restructuring and related costs	—	—	—	0.3
Other items [d]	—	(1.3)	—	(25.5)
Adjusted other income	$ (1.4)	$ (4.1)	$ (10.9)	$ (39.5)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP earnings before income taxes	$ 185.8	$ 192.2	$ 19.2	$ 221.4
Total pre-tax non-GAAP adjustments	553.0	587.8	1,905.6	1,839.5
Adjusted earnings before income taxes	$ 738.8	$ 780.0	$ 1,924.8	$ 2,060.9
U.S. GAAP income tax (benefit) provision	$ (4.0)	$ 15.5	$ 22.9	$ (79.9)
Adjusted tax expense	138.4	116.5	342.8	445.7
Adjusted income tax provision	$ 134.4	$ 132.0	$ 365.7	$ 365.8
Adjusted effective tax rate	18.2 %	16.9 %	19.0 %	17.7 %

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
U.S. GAAP net cash provided by operating activities	$ 487.8	$ 653.6	$ 1,117.0	$ 1,705.6
Add / (Deduct):				
Restructuring and related costs [e]	58.4	75.8	198.6	203.2
Financing related expense	—	—	—	2.6
Corporate contingencies	(43.5)	5.5	(50.1)	115.7
Acquisition related costs	22.2	—	22.2	3.7
R&D expense	59.5	25.0	125.5	125.0
Other	—	—	19.2	5.0
Adjusted net cash provided by operating activities	$ 584.4	$ 759.9	$ 1,432.4	$ 2,160.8
Deduct:				
Capital expenditures	(42.3)	(61.5)	(139.6)	(137.4)
Adjusted free cash flow	$ 542.1	$ 698.4	$ 1,292.8	$ 2,023.4

(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 and nine months ended September 30, 2019 includes approximately $46.4 million and $147.2 million, respectively, 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			
	December 31, 2018	March 31, 2019	June 30, 2019	September 30, 2019
U.S. GAAP net earnings (loss)	$ 51.2	$ (25.0)	$ (168.5)	$ 189.8
Add / (deduct) adjustments:				
Net contribution attributable to equity method investments	20.1	17.0	16.2	10.4
Income tax provision (benefit)	25.8	(89.5)	116.4	(4.0)
Interest expense	135.2	131.2	131.2	128.9
Depreciation and amortization	608.9	500.5	501.4	469.7
EBITDA	$ 841.2	$ 534.2	$ 596.7	$ 794.8
Add / (deduct) adjustments:				
Share-based compensation expense	5.3	18.0	16.8	16.1
Litigation settlements and other contingencies, net	1.1	0.7	20.9	(51.9)
Restructuring & other special items	158.9	157.3	213.0	163.8
Adjusted EBITDA	$ 1,006.5	$ 710.2	$ 847.4	$ 922.8

September 30, 2019 Notional Debt to Twelve Months Ended September 30, 2019 Mylan N.V. Adjusted EBITDA as calculated under our Credit Agreement ("Credit Agreement Adjusted EBITDA") Leverage Ratio

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

	Three Months Ended				Twelve Months Ended
	December 31, 2018	March 31, 2019	June 30, 2019	September 30, 2019	September 30, 2019
Mylan N.V. Adjusted EBITDA	$ 1,006.5	$ 710.2	$ 847.4	$ 922.8	$ 3,486.9
Add: other adjustments including estimated synergies					20.8
Credit Agreement Adjusted EBITDA					$ 3,507.7
Reported debt balances:					
Long-term debt, including current portion					$ 13,015.0
Short-term borrowings and other current obligations					161.8
Total					$ 13,176.8
Add / (deduct):					
Net discount on various debt issuances					32.3
Deferred financing fees					64.3
Fair value adjustment for hedged debt					(27.4)
Total debt at notional amounts					$ 13,246.0
Notional debt to Credit Agreement Adjusted EBITDA Leverage Ratio					3.8

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

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

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SOURCE Mylan N.V.

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