

Mylan N.V. (MYL)

\$20.87 (As of 01/06/20)

Price Target (6-12 Months): **\$23.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 04/29/19)

Prior Recommendation: Underperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:B

Value: A

Growth: D

Momentum: A

Summary

Solid performance of new products like Fulphila and Wixela Inhub has boosted Mylan's financials in recent times amid a challenging business environment in North America due to price erosion. Meanwhile, the company's decision to merge with Upjohn, Pfizer's off-patent branded and generic established medicines business, is also encouraging. However, rising competition for EpiPen is a concern as Teva has won the FDA approval for the first generic version of EpiPen and EpiPen Jr. Recently, the SEC charged Mylan for accounting and disclosure failures relating to a probe into whether it overcharged Medicaid by hundreds of millions of dollars for EpiPen. Shares have underperformed the industry in the year so far.

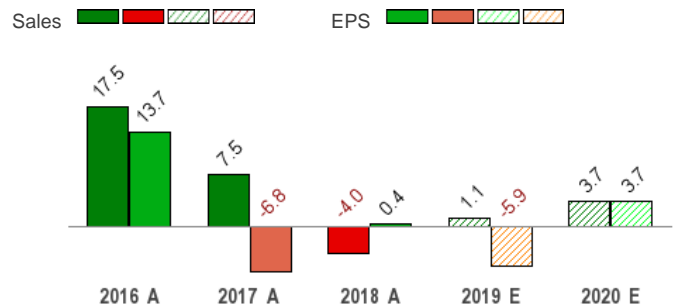
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$32.23 - \$16.63
20 Day Average Volume (sh)	5,969,643
Market Cap	\$10.8 B
YTD Price Change	3.8%
Beta	1.73
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Generic Drugs
Zacks Industry Rank	Top 28% (70 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	2.6%
Last Sales Surprise	-2.4%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	02/25/2020
Earnings ESP	0.0%
P/E TTM	4.8
P/E F1	4.7
PEG F1	1.0
P/S TTM	1.0

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2020	2,594 E	2,940 E	3,110 E	3,355 E	11,987 E
2019	2,496 A	2,852 A	2,962 A	3,248 E	11,558 E
2018	2,685 A	2,808 A	2,862 A	3,079 A	11,434 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	\$0.87 E	\$1.04 E	\$1.22 E	\$1.37 E	\$4.47 E
2019	\$0.82 A	\$1.03 A	\$1.17 A	\$1.29 E	\$4.31 E
2018	\$0.96 A	\$1.07 A	\$1.25 A	\$1.30 A	\$4.58 A

*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 01/06/2020. The reports text is as of 01/07/2020.

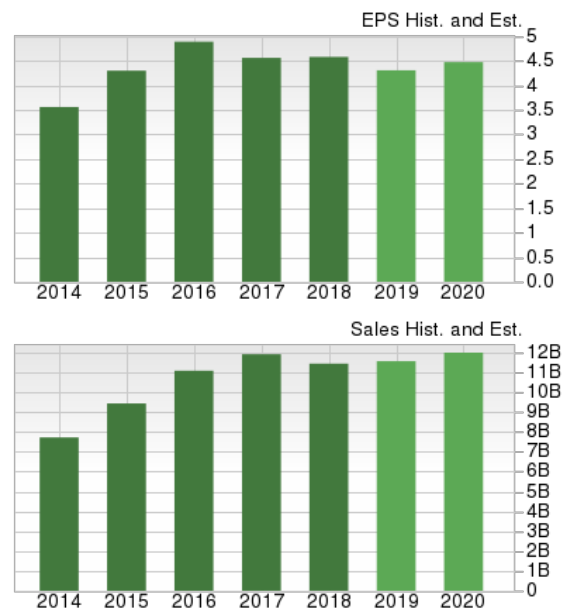
Overview

Mylan N.V. is a global pharmaceutical company with a well-established generics business as well as a presence in specialty pharmaceuticals. The company's business model includes the development, manufacturing and marketing of branded and generic drugs as well as active pharmaceutical ingredients (APIs) in North America, Europe and Rest of World. Notably, Mylan has one of the world's largest API operations.

Mylan has been making prudent acquisitions and inking strategic deals to drive long-term growth. In February 2015, the company acquired Abbott Laboratories' non-U.S. developed markets' specialty and branded generics business. Further, in November 2015, it acquired certain female health care businesses of Famy Care. In June 2016, Mylan acquired the non-sterile, topicals-focused business of privately held Renaissance Acquisition Holdings for about \$1 billion. In August 2016, Mylan acquired Swedish drug manufacturer, Meda, in a deal valued at \$9.9 billion. All these buyouts augmented the company's diversified product portfolio and expanded its range of capabilities.

The company reports results under the following three segments on a geographic basis: (1) North America, (2) Europe and (3) Rest of World. The North America segment accounts for operations in the United States and Canada and includes the results of previously reported Specialty segment. The segment primarily develops, manufactures, sells and distributes pharmaceutical products in tablets, capsules, injectables, transdermal patches, gels, nebulized and creams or ointment forms and accounted for 36% of total sales. Europe accounted for 37% of total sales and Rest of the World accounted for 27%. While Mylan's Specialty portfolio consists mainly of branded specialty injectable and nebulized products and competes primarily in the respiratory and severe allergy markets. The most significant product in this segment is EpiPen auto-injector, used to treat severe allergic reactions like anaphylaxis. The Europe segment comprises operations in 35 countries within the region. The Rest of World segment caters to operations in India, Australia, Japan and New Zealand.

Revenues for 2018 came in at \$11.43 billion, down 4% from 2017.



Reasons To Buy:

- ▲ **Merger with Upjohn Looks Positive:** We are positive on Mylan's merger announcement with Upjohn, Pfizer's off-patent branded and generic established medicines business (includes Lipitor, Celebrex and Viagra), to create a new global pharmaceutical company. Per the agreement, which is structured as an all-stock, Reverse Morris Trust transaction, each Mylan share would be converted into one share of the new company.

Pfizer's shareholders would own 57% of the combined entity, while Mylan's shareholders would own the remaining 43%. The transaction has been unanimously approved by the boards of both the companies. The new company boasts a diverse portfolio across many geographies and focuses on key therapeutic areas. The new company is expected to generate revenues of \$19-\$20 billion for 2020. Mylan has been plagued with various problems of late like lawsuits and pricing pressure among others. Hence, the merger with Upjohn will provide the company a chance to turn over a new leaf and focus more on emerging markets. The combined business (EpiPen, Lipitor, Celebrex and Viagra among others) will be one of the leading generic businesses in the world.

Mylan's Generics segment has been performing impressively. Launch of new generic drugs should boost revenues significantly. Prudent acquisitions also bode well for long-term growth.

- ▲ **Generics Segment Driving Revenues:** Mylan's Generics segment has been performing well, driven by new product launches amid a challenging pricing environment. The addition of Abbott's non-U.S. developed markets' branded generics business also boosted the segment. The company won FDA approval for a generic version of Copaxone (40 mg) in October 2017 and has gained a market share of approximately 35% in this space. Moreover, Mylan received a significant boost, when the FDA approved its generic version of GlaxoSmithKline's Advair Diskus — Wixela Inhub — following a few setbacks. Notably, this was the first approved generic of Advair Diskus, which gave Mylan an edge in the market. Wixela Inhub is indicated for the twice-daily treatment of asthma patients aged four and above, who are not adequately relieved by long-term asthma-control medications or whose disease warrants initiation of therapy with both inhaled corticosteroids and long-acting beta agonists; maintenance treatment of chronic obstructive pulmonary disease (COPD) and the reduction of COPD exacerbations in patients with a history of exacerbations. The market potential is huge for Wixela and the generic has already captured a significant market share. The company recently launched a generic version of AstraZeneca's Faslodex Injection for breast cancer.
- ▲ **Biosimilar Pipeline Progress:** Mylan is also exploring the world of biosimilars, a market that has the potential to grow to \$20 billion in 2020. A partnership with Biocon, and collaborations with Momenta and Mabion has helped Mylan develop a portfolio of 20 biosimilar/insulin analog generic products. The Biocon partnership includes six biosimilar programs — biosimilar versions of Herceptin, Neulasta, Humira, Avastin, Enbrel and Neupogen — and three insulin analogs — Lantus, Humalog and NovoLog. Mylan received a major boost with the FDA approval of Ogivri, the biosimilar version of Herceptin, and expects to launch it shortly. In March 2018, Mylan and Biocon announced that their co-developed biosimilar insulin glargine Semglee has obtained approval from the European Commission (EC). The companies also obtained FDA approval for Fulphila, a biosimilar of Neulasta, which has significant potential. Mylan is on track to submit an application for a biosimilar to Avastin to the FDA by the end of 2019. This will be followed by a submission in Europe in the first quarter of 2020. A phase III study is underway for a biosimilar of Eylea in collaboration with Momenta. Mylan recently launched Ogivri (trastuzumab-dkst), a biosimilar of Roche's blockbuster breast cancer drug, Herceptin (trastuzumab), in the United States.
- ▲ **Acquisitions and Deals to Drive Growth:** Mylan has been undertaking prudent acquisitions and inking strategic deals to drive long-term growth. The Topicals Business gave Mylan a complementary portfolio of commercial and pipeline products, and an established sales and marketing infrastructure targeting dermatologists in the United States. On the other hand, Meda acquisition provided the company with a diversified and expansive portfolio of branded and generic medicines along with a strong and growing portfolio of over-the-counter (OTC) products. The Meda acquisition has also expanded Mylan's OTC presence into a \$1-billion business. Moreover, the acquisition of Meda expanded the company's footprint in key emerging markets, including, China, Russia, Turkey, and Mexico, and in countries in South East Asia, and the Middle East, which complemented Mylan's existing presence in India, Brazil and Africa (including South Africa). In August 2018, Mylan acquired worldwide rights to cystic fibrosis products TOBI Podhaler and TOBI solution from Novartis, which should broaden the former's respiratory portfolio.

Reasons To Sell:

▼ **Share Price Performance:** Mylan's stock has underperformed the industry in the year so far. The decline can be attributed to a lawsuit filed by around 44 state attorneys against a few companies, which make generic drugs. Mylan was one of these companies. The lawsuit alleges a conspiracy to artificially inflate prices and reduce competition.

The EpiPen woes continue to plague Mylan. In addition, the failure of the biosimilar study was also disappointing.

▼ **Increasing Competition:** Competition has stiffened for EpiPen. Rival Teva Pharmaceutical won the FDA approval for the first generic version of Mylan's EpiPen and EpiPen Jr (epinephrine) auto-injector for the emergency treatment of allergic reactions, including those that are life-threatening (anaphylaxis), in adult and pediatric patients. This in turn will impact sales.

Moreover, the SEC charged Mylan for accounting and disclosure failures relating to a Department of Justice (DOJ) probe into whether the company overcharged Medicaid by hundreds of millions of dollars for its largest product, EpiPen. The SEC stated that investors were kept in the dark about EpiPen misclassification and the potential loss the company faced as a result of the pending investigation into the misclassification. Consequently, Mylan has agreed to pay \$30 million as charges for the same. Per SEC's complaint, the company misclassified EpiPen as a "generic" drug under the Medicaid Drug Rebate Program. This led Mylan to pay much lower rebates to the government than what it would have paid if EpiPen had been classified as a "branded" drug. The complaint also states that the Centers for Medicare and Medicaid Services (CMS) informed the company in October 2014 about this misclassification. Thereafter, the DOJ conducted a civil investigation into whether the company misclassified EpiPen and thereby overcharged the government for the drug's sales to Medicaid patients. The investigation started in November 2014 and continued for nearly two years. During the investigation, DOJ issued multiple subpoenas and investigative demands, rejected Mylan's arguments to close the investigation, and indicated its intent to sue the company if it failed to make a settlement offer. Moreover, the complaint alleges that Mylan produced documents and other information to DOJ, including potential damage calculations and offers for settlement. The allegations of misclassification and resultant charges further add to Mylan's woes.

▼ **Pipeline Setbacks:** In a major setback, the company and partner Momenta reported disappointing results from a phase I study on the biosimilar version of Orencia. The study failed to meet primary endpoints. Any additional failures will be detrimental to the company's growth prospects.

▼ **Delay in Generic Approvals:** The company's efforts to get Advair's generic approved suffered a blow, when the FDA issued a complete response letter to its ANDA for generic Advair. Although the FDA has approved the generic, similar setbacks are likely to weigh on the stock.

Last Earnings Report

Mylan's Q3 Earnings Beat Estimates, Revenues Miss

Mylan reported adjusted earnings of \$1.17 per share in the third quarter of 2019, which beat the Zacks Consensus Estimate of \$1.14 but declined from \$1.25 reported in the year-ago quarter.

However, third-quarter revenues of \$2.96 billion missed the Zacks Consensus Estimate of \$3.03 billion. Revenues increased 3% reportedly and 6% at constant exchange rate ("CER") from the prior-year quarter.

Quarter Ending **09/2019**

Report Date	Nov 05, 2019
Sales Surprise	-2.39%
EPS Surprise	2.63%
Quarterly EPS	1.17
Annual EPS (TTM)	4.32

Quarter in Detail

The company posts results in three segments on a geographic basis — North America, Europe and Rest of World.

North America segment's net sales came in at \$1.09 billion, up 8% year over year. The growth was driven by higher sales of new products, especially Wixela Inhub and Yupleri. This was partially offset by lower sales of existing products due to lower volumes as well as lower pricing and changes in the competitive environment, including loss of exclusivity on tadalafil.

Net sales in the Europe segment were \$1.05 billion, up less than 1% on the back of higher sales of new products including Hulio, and higher volumes of existing products. However, it was partially offset by unfavorable impact of foreign currency translation and lower pricing on existing products. Net sales in the segment were up 6% at CER.

Rest of World segment net sales of \$793.7 million were up 3%, driven by new product sales and higher volumes of existing products. This was partially offset by lower pricing on existing products and unfavorable impact of foreign currency translation. Net sales were up 4% at CER.

Adjusted gross margin of 53% declined from 55% in the year-ago quarter.

2019 Guidance

The company updated its guidance for 2019. Revenues are projected between \$11.5 billion and \$12 billion compared with the previously expected range of \$11.5 billion - \$12.5 billion.

The company anticipates adjusted EPS around \$4.20-\$4.40 (previously \$3.80-\$4.80).

Recent News

Launches Herceptin Biosimilar Ogivri in the US – Dec 2

Mylan announced the launch of Ogivri (trastuzumab-dkst), a biosimilar of Roche's blockbuster breast cancer drug, Herceptin (trastuzumab), in the United States.

Ogivri is approved for all indications of the branded drug, including the treatment of HER2-overexpressing breast cancer and metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma). It is available in a 420 mg multi-dose vial and a 150 mg single-dose vial for patient dosing and treatment flexibility.

However, the biosimilar also contains a Boxed Warning for cardiomyopathy, infusion reactions, pulmonary toxicity and embryo-fetal toxicity like Herceptin.

Launch of Generic Faslodex – Sep 17

Mylan announced the U.S. launch of Fulvestrant Injection, 250 mg/5 mL (50 mg/mL) per single-dose prefilled syringe, a generic version of AstraZeneca's Faslodex Injection, for the treatment of certain types of advanced breast cancer in women, who have experienced menopause as monotherapy and in advanced or metastatic breast cancer in combination with other drugs.

Valuation

Mylan's shares are down 29.8% over the trailing 12-month period. Over the past year, the Zacks sub-industry is down 4% while the sector is up 5.4%. The S&P 500 index is up 25.1% in the past year.

The stock is currently trading at 4.66X forward 12-month earnings per share, which compares to 8.74X for the Zacks sub-industry, 21.44X for the Zacks sector and 18.79X for the S&P 500 index.

Over the past five years, the stock has traded as high as 17.62X and as low as 3.83X, with a 5-year median of 7.29X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$23.00 price target reflects 4.89X forward 12-month earnings per share.

The table below shows summary valuation data for MYL

Valuation Multiples - MYL					
		Stock	Sub-Industry	Sector	S&P 500
P/E F 12M	Current	4.66	8.74	21.44	18.79
	5-Year High	17.62	16.24	21.44	19.34
	5-Year Low	3.83	6.55	15.91	15.17
	5-Year Median	7.29	9.87	18.98	17.44
P/S F12M	Current	0.9	1.54	2.81	3.48
	5-Year High	3.8	4.31	3.8	3.48
	5-Year Low	0.73	1.14	2.42	2.54
	5-Year Median	1.63	1.93	2.93	3
P/B TTM	Current	0.94	1.29	4.48	4.43
	5-Year High	7.44	3.7	5.01	4.45
	5-Year Low	0.73	0.86	3.42	2.85
	5-Year Median	1.69	1.32	4.27	3.6

As of 01/06/2020

Industry Analysis Zacks Industry Rank: Top 28% (70 out of 254)



Top Peers

Amgen Inc. (AMGN)	Neutral
Bausch Health Cos Inc. (BHC)	Neutral
GlaxoSmithKline plc (GSK)	Neutral
Mallinckrodt public limited company (MNK)	Neutral
Momenta Pharmaceuticals, Inc. (MNTA)	Neutral
Novartis AG (NVS)	Neutral
Dr. Reddys Laboratories Ltd (RDY)	Neutral
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral

Industry Comparison Industry: Medical - Generic Drugs				Industry Peers		
	MYL Neutral	X Industry	S&P 500	BHC Neutral	MNK Neutral	TEVA Neutral
VGM Score	B	-	-	B	A	B
Market Cap	10.77 B	323.27 M	23.72 B	10.17 B	274.14 M	9.91 B
# of Analysts	8	4	13	9	9	13
Dividend Yield	0.00%	0.00%	1.79%	0.00%	0.00%	0.00%
Value Score	A	-	-	A	A	A
Cash/Price	0.03	0.17	0.04	0.08	1.77	0.13
EV/EBITDA	8.07	-1.54	13.90	76.48	-1.70	-43.59
PEG Ratio	1.04	0.88	2.00	0.32	0.04	0.88
Price/Book (P/B)	0.94	2.91	3.34	3.97	0.09	0.66
Price/Cash Flow (P/CF)	2.40	4.56	13.67	2.34	0.18	1.96
P/E (F1)	4.69	7.75	18.72	6.41	0.48	3.62
Price/Sales (P/S)	0.95	2.74	2.66	1.20	0.09	0.57
Earnings Yield	21.42%	-8.37%	5.31%	15.59%	209.82%	27.67%
Debt/Equity	1.17	0.08	0.72	9.17	1.64	1.62
Cash Flow (\$/share)	8.68	-0.17	6.94	12.32	18.42	4.63
Growth Score	D	-	-	C	B	D
Hist. EPS Growth (3-5 yrs)	3.79%	3.58%	10.56%	-19.56%	3.37%	-17.10%
Proj. EPS Growth (F1/F0)	3.86%	2.35%	7.42%	2.84%	-20.29%	4.99%
Curr. Cash Flow Growth	5.27%	-0.81%	14.83%	-1.15%	-0.48%	-26.03%
Hist. Cash Flow Growth (3-5 yrs)	22.00%	4.21%	9.00%	0.85%	36.60%	-4.41%
Current Ratio	1.43	2.91	1.23	1.15	1.07	0.89
Debt/Capital	53.87%	8.22%	42.92%	90.16%	62.11%	61.86%
Net Margin	0.42%	-56.06%	11.08%	-7.25%	-111.44%	-22.88%
Return on Equity	18.80%	-42.85%	17.16%	56.19%	24.36%	15.41%
Sales/Assets	0.36	0.29	0.55	0.26	0.30	0.29
Proj. Sales Growth (F1/F0)	3.71%	2.79%	4.15%	3.02%	-7.87%	-1.01%
Momentum Score	A	-	-	D	A	B
Daily Price Chg	3.32%	0.00%	0.10%	-1.90%	-2.98%	-0.22%
1 Week Price Chg	2.43%	-0.81%	-0.30%	-0.94%	-2.61%	-8.73%
4 Week Price Chg	9.73%	0.30%	2.33%	-1.20%	-0.61%	-7.64%
12 Week Price Chg	12.69%	6.69%	7.02%	38.09%	57.49%	34.77%
52 Week Price Chg	-29.85%	-13.28%	24.61%	29.07%	-82.06%	-48.67%
20 Day Average Volume	5,969,643	542,154	1,589,897	3,361,046	4,547,732	11,576,092
(F1) EPS Est 1 week change	0.03%	0.00%	0.00%	-0.49%	0.44%	0.00%
(F1) EPS Est 4 week change	0.03%	0.00%	0.00%	-0.66%	0.44%	0.00%
(F1) EPS Est 12 week change	-0.11%	-3.86%	-0.56%	2.40%	-5.36%	0.41%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	A
Growth Score	D
Momentum Score	A
VGM Score	B

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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