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Jun 11, 2020

Mylan N.V. (MYL)

$17.32 (As of 06/10/20)

Price Target (6-12 Months): **$18.00**

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

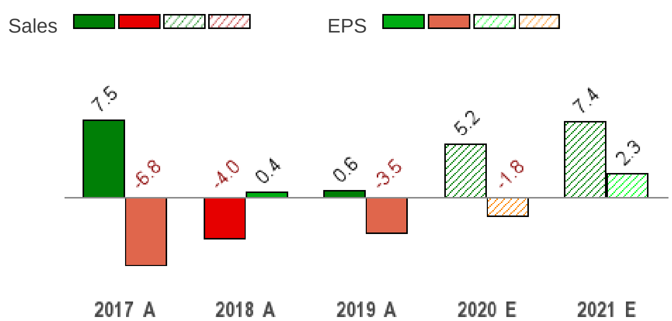
Mylan's biosimilar business continues to gain traction with new approvals. The approval of Fulphila (biosimilar to Neulasta) and the launch of Ogivri, a biosimilar to Herceptin in the United States, should boost demand further. Wixela and Yupelri too have boosted growth. Meanwhile, the company's decision to merge with Upjohn, Pfizer's off-patent branded and generic established medicines business, should positively impact its business, given the downturn in the generic business. The merger with Upjohn will provide the company a chance to turn over a new leaf and focus more on emerging markets In November 2019, Mylan and Pfizer announced the name of the new entity as Viatris. However, the impact of the coronavirus outbreak is likely to negatively impact second-quarter results. Shares have underperformed the industry in the past year.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$23.11 - $12.75**
20 Day Average Volume (sh)	**6,412,532**
Market Cap	**$9.0 B**
YTD Price Change	**-13.9%**
Beta	**1.54**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Generic Drugs**
Zacks Industry Rank	**Top 9% (22 out of 252)**
Last EPS Surprise	**2.3%**
Last Sales Surprise	**-2.2%**
EPS F1 Est- 4 week change	**0.9%**
Expected Report Date	**08/03/2020**
Earnings ESP	**-4.8%**
P/E TTM	**3.9**
P/E F1	**4.0**
PEG F1	**0.9**
P/S TTM	**0.8**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021	2,776 E	2,867 E	3,011 E	3,282 E	12,994 E
2020	2,619 A	2,723 E	3,163 E	3,633 E	12,095 E
2019	2,496 A	2,852 A	2,962 A	3,192 A	11,501 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	$1.05 E	$0.99 E	$1.20 E	$1.34 E	$4.44 E
2020	$0.90 A	$0.97 E	$1.10 E	$1.32 E	$4.34 E
2019	$0.82 A	$1.03 A	$1.17 A	$1.40 A	$4.42 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 06/10/2020. The reports text is as of 06/11/2020.

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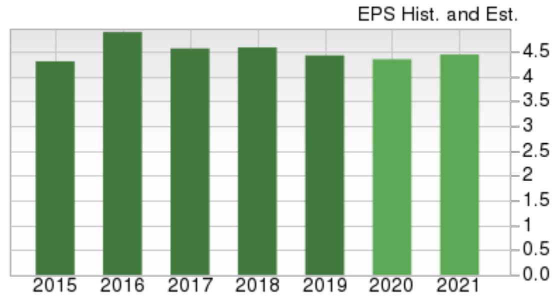
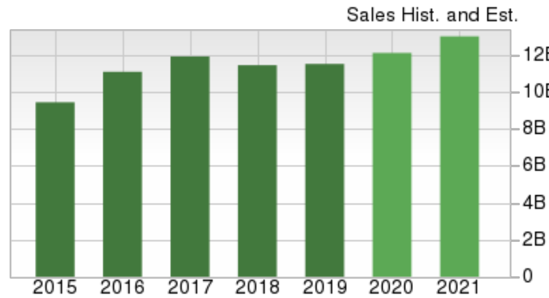
Overview





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 2019 came in at $11.50 billion, up 1% from 2018.

Reasons To Buy:

> Launch of new generic drugs and biosimilars should boost Mylan's revenues significantly. Prudent acquisitions also bode well for long-term growth.

▲ **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. The new company will be named Viatris.

▲ **Generics Segment Driving Revenues***:* Mylan's Generics segment has been boosted by product launches amid a challenging pricing environment. The company won FDA approval for a generic version of Copaxone (40 mg) in October 2017 and has gained significant market share. Moreover, Mylan received a significant boost, when the FDA approved its generic version of GlaxoSmithKline's Advair Diskus — WixelaInhub — following a few setbacks. Notably, this was the first approved generic of Advair Diskus, which gave Mylan an edge in the market. 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 partnership with Biocon, and collaborations with Momenta and Mabion have helped Mylan develop a wide portfolio of 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 Ogiviri, the biosimilar version of Herceptin, and expects to launch it shortly. The companies also obtained FDA approval for Fulphila, a biosimilar of Neulasta, which has significant potential. The biosimilar of Avastin is under review in the United States and Europe. The FDA has accepted the Biologics License Application (BLA) for MYL-1402O, a proposed biosimilar to Avastin (bevacizumab). The company plans to launch its biosimilar to Enbrel in the second half of the year. The company is also developing a biosimilar of Eylea.

▲ **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.

▲ **Favorable Debt Profile**: As of Dec 31, 2019, Mylan's total debt to total capital ratio stood at 51.7X which compares favorably to the industry's 54.8X. A lower ratio indicates greater financial risk and vice versa.

Reasons To Sell:

- **Share Price Performance:** Mylan's stock has underperformed the industry in the past year. The coronavirus pandemic will likely impact results in the upcoming quarters.

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.

- **Unfavorable Debt Profile**: As of Mar 31, 2020, Mylan's total debt to total capital ratio stood at 61.9X which compares unfavorably to the industry's 54.7X. A higher ratio indicates greater financial risk and vice versa.

Last Earnings Report

Mylan Beats on Q1 Earnings

Quarter Ending	03/2020
Report Date	May 11, 2020
Sales Surprise	-2.17%
EPS Surprise	2.27%
Quarterly EPS	0.90
Annual EPS (TTM)	4.50

Mylan reported adjusted earnings of 90 cents per share in the first quarter of 2020, beating the Zacks Consensus Estimate of 88 cents. Also, the reported figure improved from the year-ago quarter's 82 cents.

However, quarterly revenues of $2.62 billion missed the Zacks Consensus Estimate of $2.67 billion. Nevertheless, revenues increased 5% reportedly and 8% at constant exchange rate ("CER") from the prior-year quarter. Overall volume growth in the reported quarter was favorably impacted by increased customer buying patterns and patient prescription trends resulting from the COVID-19 pandemic, primarily in the Europe segment.

Quarter in Detail

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

The North America segment's net sales came in at $955.5 million, up 4% year over year. This increase was primarily driven by higher volumes on existing products and partially due to new product sales. The higher volumes were primarily driven by the expected growth of Yupelri and Wixela.

Net sales in the Europe segment came in at $1.02 billion, up 14% year on year. This upswing primarily resulted from higher net sales of existing products, as a result of increased volumes, and partly from new product sales. In addition to the estimated impact of COVID-19, volumes increased approximately $40.0 million due to the resolution of supply disruptions encountered in the prior-year quarter.

The Rest of the World segment's net sales of $610.8 million were down 5% due to the unfavorable impact of foreign currency translation and the negative impact from COVID-19 in China and Japan. In addition, net sales of existing products were affected by lower pricing, primarily driven by government price cuts in Australia and Japan.

Adjusted gross margin of 53% declined from the year-ago quarter's 54%.

2020 Guidance Reiterated

Mylan reiterated its previously-provided guidance after absorbing approximately $200 million of foreign exchange headwinds. Revenues are projected between $11.5 billion and $12.5 billion.

Recent News

European Marketing Authorization for Biosimilar Etanercept – June 4

Mylan and partner Lupin announced that the European Commission (EC) has granted marketing authorization for Nepexto, a biosimilar to Enbrel, for all indications of the reference product — rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis and pediatric plaque psoriasis.

To Supply Antiviral RemdesivirFor COVID-19 – May 12

Mylan has collaborated with Gilead Sciences to expand access to the investigational antiviral remdesivir for the potential treatment of COVID-19. Per the terms of the license agreement signed with Gilead, Mylan has rights to manufacture and distribute remdesivir in 127 low- and middle-income countries, including India. The agreement is non-exclusive, allowing for multiple licensees to ensure extensive access to this treatment, once approved as safe and effective for COVID-19.

European Commission's Conditional Approval of the Combination of Mylan and Pfizer's Upjohn Division – Apr 22

Mylan announced that it has received the European Commission's (EC) approval of the impending merger of the former and Upjohn, conditioned upon the completion of the sale of certain of Mylan's products in Europe.

Positive CHMP Opinion for Biosimilar Etanercept – Mar 27

Mylan and partner Lupin Limited announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending the approval of Nepexto, a biosimilar to Enbrel for all indications of the branded drug, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.

Update on Combination With Upjohn – Mar 26

Mylan and Pfizer announced that the proposed combination of the former and Upjohn, a division of the latter, is now anticipated to close in the second half of 2020 due to the unprecedented circumstances surrounding the COVID-19 pandemic, including associated delays in the regulatory review process.

Mylan's extraordinary general meeting of shareholders to approve certain matters in connection with the transaction has been rescheduled from Apr 27 to Jun 30.

Support in Response to COVID-19 – Mar 25

Mylan announced that it has voluntarily waived its exclusive rights in the United States to distribute the generic version of Kaletra (lopinavir/ritonavir) antiretroviral 100mg/25mg and 200mg/50mg tablets to help increase the supply of the product, should it prove effective in the treatment of coronavirus.

Ramps Up U.S. Manufacturing of Hydroxychloroquine – Mar 19

Mylan has restarted production of hydroxychloroquine sulfate tablets at its West Virginia manufacturing facility in the United States to meet the potential for increased demand resulting from potential effectiveness of the product in treating COVID-19. Mylan's hydroxychloroquine sulfate tablets are approved by the FDA for the treatment of malaria, lupus erythematosus and rheumatoid arthritis.

Mylan expects that it will be able to ramp up manufacturing to provide 50 million tablets to potentially treat a total of more than 1.5 million patients. The potential use of this medicine for COVID-19-related treatment is pending additional FDA and other regulatory body guidance.

Wins District Court Decision Against Sanofi's Lantus SoloSTAR Patent – Mar 10

Mylan announced that the U.S. District Court of New Jersey found the device patent claims (U.S. Patent No. 9,526,844) asserted by Sanofi against the company's insulin glargine product to be not infringed and invalid for lack of written description.

Valuation

Mylan's shares are shares are down 17.2% in the year-to-date period and 3.1% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 4.3% but up 0.4% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is up 10.9% while the sector is up 4.1%.

The S&P 500 index is down 0.1% in the year-to-date period but up 12.9% in the past year.

Over the past five years, the stock has traded as high as 16.94X and as low as 2.96X, with a 5-year median of 7.04X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $18.00 price target reflects 4.38X 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	3.95	7.59	23.16	23.05
	5-Year High	16.94	15.74	23.16	23.05

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
	5-Year Low	2.96	5.85	15.94	15.23
	5-Year Median	7.04	7.95	19.04	17.49
P/S F12M	Current	0.72	0.87	2.8	3.58
	5-Year High	3.62	3.81	3.74	3.58
	5-Year Low	0.56	0.69	2.21	2.53
	5-Year Median	1.59	1.2	2.91	3.02
P/B TTM	Current	0.79	1.13	4.29	4.36
	5-Year High	3.99	3.8	5.05	4.56
	5-Year Low	0.58	0.72	2.92	2.83
	5-Year Median	1.61	1.28	4.28	3.66

As of 06/10/2020

Industry Analysis **Zacks Industry Rank:** Top 9% (22 out of 252)

Top Peers

Company (Ticker)	Rec	Rank
Amgen Inc. **(AMGN)**	Neutral	3
Bausch Health Cos Inc. **(BHC)**	Neutral	3
GlaxoSmithKline plc **(GSK)**	Neutral	2
Mallinckrodt public limited company **(MNK)**	Neutral	3
Momenta Pharmaceuticals, Inc. **(MNTA)**	Neutral	2
Novartis AG **(NVS)**	Neutral	3
Dr. Reddys Laboratories Ltd **(RDY)**	Neutral	2
Teva Pharmaceutical Industries Ltd. **(TEVA)**	Neutral	3

Industry Comparison Industry: Medical - Generic Drugs

	MYL	X Industry	S&P 500	BHC	MNK	TEVA
				Industry Peers		
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	3
VGM Score	B	-	-	B	A	A
Market Cap	8.95 B	379.29 M	22.63 B	6.66 B	236.48 M	13.16 B
# of Analysts	9	4	14	9	8	11
Dividend Yield	0.00%	0.00%	1.87%	0.00%	0.00%	0.00%
Value Score	A	-	-	A	A	A
Cash/Price	0.06	0.28	0.06	0.28	3.39	0.13
EV/EBITDA	7.62	-4.16	12.91	2.48	-12.58	78.40
PEG Ratio	0.85	0.77	3.07	0.47	0.03	1.06
Price/Book (P/B)	0.79	2.80	3.09	8.37	0.12	0.90
Price/Cash Flow (P/CF)	2.08	3.10	12.15	1.79	0.14	3.10
P/E (F1)	3.83	7.53	22.10	5.02	0.47	4.88
Price/Sales (P/S)	0.77	2.80	2.40	0.77	0.08	0.76
Earnings Yield	25.06%	-12.59%	4.30%	19.91%	211.07%	20.50%
Debt/Equity	1.08	0.01	0.76	0.00	2.50	1.68
Cash Flow ($/share)	8.33	-0.44	7.01	10.49	20.20	3.89
Growth Score	D	-	-	C	A	B
Hist. EPS Growth (3-5 yrs)	1.11%	1.99%	10.87%	-19.16%	1.99%	-19.38%
Proj. EPS Growth (F1/F0)	-1.79%	-7.30%	-10.71%	-15.60%	-33.50%	2.84%
Curr. Cash Flow Growth	-3.91%	9.45%	5.46%	-14.18%	10.71%	-9.67%
Hist. Cash Flow Growth (3-5 yrs)	16.74%	6.77%	8.55%	-4.00%	10.87%	-6.21%
Current Ratio	1.26	2.75	1.29	1.13	1.46	1.05
Debt/Capital	51.83%	8.59%	44.75%	0.00%	71.43%	62.65%
Net Margin	0.54%	-40.60%	10.54%	-21.96%	-39.56%	-4.73%
Return on Equity	20.00%	-43.99%	16.08%	84.58%	29.14%	18.10%
Sales/Assets	0.37	0.33	0.55	0.27	0.30	0.30
Proj. Sales Growth (F1/F0)	5.17%	0.00%	-2.59%	-5.13%	-16.59%	-3.90%
Momentum Score	A	-	-	C	B	A
Daily Price Chg	-6.15%	-1.21%	-1.68%	-5.44%	-6.67%	-4.59%
1 Week Price Chg	3.51%	2.47%	7.51%	4.11%	0.00%	2.47%
4 Week Price Chg	11.42%	8.76%	16.99%	14.72%	-5.41%	9.05%
12 Week Price Chg	22.11%	57.43%	37.11%	44.68%	159.26%	80.12%
52 Week Price Chg	0.90%	-3.35%	0.02%	-13.10%	-69.96%	38.35%
20 Day Average Volume	6,412,532	348,346	2,620,901	5,559,505	4,034,531	9,991,215
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.93%	0.00%	0.00%	-0.27%	0.00%	2.55%
(F1) EPS Est 12 week change	-2.10%	-4.27%	-15.86%	-15.22%	-11.27%	0.25%
(Q1) EPS Est Mthly Chg	0.15%	0.00%	0.00%	-3.92%	0.00%	4.53%

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.

Disclosures

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