

Alexion Pharma (ALXN)

\$100.51 (As of 08/21/20)

Price Target (6-12 Months): \$106.00

Long Term: 6-12 Months	Zacks Recor	Zacks Recommendation:				
	(Since: 02/04/2	20)				
	Prior Recomm	endation: Outpe	rform			
Short Term: 1-3 Months	Zacks Rank:	(1-5)	3-Hold			
	Zacks Style Scores:		VGM:A			
	Value: A	Growth: A	Momentum: B			

Summary

Alexion's second-quarter results were strong despite the COVID-19 pandemic. Its blockbuster drug, Soliris, maintains momentum on the back of recent label expansions. The company's efforts to expand the drug's label further should boost sales. Ultomiris too is performing well. Potential label expansions of the drug should fuel the top line. Meanwhile, the company is also evaluating Ultomiris for COVID-19 infection and a positive outcome will boost prospects. Alexion has been making prudent acquisitions to strengthen its portfolio. It acquired Achillion Pharmaceuticals to fortify its PNH franchise. The company also diversified its commercial-stage portfolio with the acquisition of Portola. However, the company is still highly dependent on Soliris for growth. Shares have underperformed the industry in the past year.

Price, Consensus & Surprise

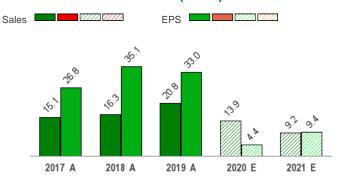


Data Overview

\$125.52 - \$72.67
1,570,669
\$22.1 B
-6.6%
1.39
\$0.00 / 0.0%
Medical - Biomedical and Genetics
Bottom 32% (171 out of 252)

Last EPS Surprise	22.0%
Last Sales Surprise	14.1%
EPS F1 Est- 4 week change	0.7%
Expected Report Date	10/28/2020
Earnings ESP	0.0%
P/E TTM	8.5
P/E F1	9.2
PEG F1	0.8
P/S TTM	4.0

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	1,499 E	1,559 E	1,611 E	1,679 E	6,207 E
2020	1,445 A	1,445 A	1,388 E	1,403 E	5,685 E
2019	1,140 A	1,203 A	1,263 A	1,384 A	4,991 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$2.93 E	\$3.05 E	\$3.10 E	\$3.05 E	\$12.02 E
2020	\$3.22 A	\$3.11 A	\$2.46 E	\$2.26 E	\$10.99 E
2019	\$2.39 A	\$2.64 A	\$2.79 A	\$2.71 A	\$10.53 A
*Quarterl					

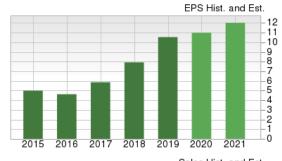
The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 08/21/2020. The reports text is as of 08/21/2020.

Overview

Based in New Haven, CT, Alexion Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of life-transforming drugs, for the treatment of patients with ultra-rare disorders.

The company's complement franchise consists of key growth driver, Soliris, which is approved for the treatment of two severe and ultra-rare disorders resulting from chronic uncontrolled activation of the complement component of the immune system — paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). Soliris is also approved for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody-positive. The FDA also approved its long-acting C5 complement inhibitor, Ultomiris, for the treatment of adult patients with PNH, to be administered every eight weeks. In October 2019, the FDA approved the use of Ultomiris as a treatment for adult and pediatric (one month of age or older) patients with aHUS to inhibit complement-mediated TMA.

Under its metabolic franchise, the company markets Strensiq for the treatment of patients with pediatric-onset hypophosphatasia (HPP) and Kanuma for the treatment of patients with lysosomal acid lipase deficiency (LAL-D).

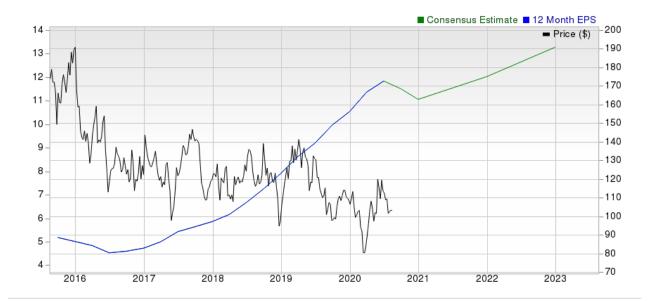




Alexion acquired Sweden-based biopharmaceutical company, Wilson

Therapeutics AB, and clinical-stage biotechnology company, Syntimmune, in 2018. The company recently acquired Achillion Pharmaceuticals. The acquisition adds two oral Factor D inhibitors, danicopan (ACCH-4771) and ACH-5228, to Alexion's clinical-stage pipeline for the treatment of rare diseases associated with the complement alternative pathway. Phase III development is being initiated for danicopan as an add-on therapy for PNH patients with extravascular hemolysis (EVH). Danicopan is also in phase II development for C3 glomerulopathy (C3G) and ACH-5228 is in phase II development for PNH. Alexion also has a robust pipeline of several candidates under development across a range of therapeutic modalities

Revenues for 2019 came in at \$4.9 billion, up 21% from that in 2018. Soliris sales came in at \$3.9 billion.



Reasons To Buy:

▲ Soliris' Label Expansion Efforts Encouraging: Alexion's blockbuster drug, Soliris, maintains momentum. The underlying growth of the drug has been robust for all approved indications — PNH, aHUS, and refractory gMG. Moreover, the FDA approved Soliris to treat neuromyelitis optica spectrum disorder (NMOSD). The drug was also approved in Europe and Japan for NMOSD. Alexion plans to initiate a phase II/III study in children and adolescents with NMOSD in the second half of 2020. To further increase the commercial

Alexion's Soliris maintains momentum and the label expansion of the drug should further boost sales.

potential of the drug, Alexion is working on expanding Soliris' label into additional indications. A phase III study of Soliris in children and adolescents with gMG is underway.

▲ Ultomiris Approval a Significant Boost: Alexion received a significant boost with the FDA approval of its long-acting C5 complement inhibitor, Ultomiris, for the treatment of adult patients with PNH, to be administered every eight weeks. The approval has strengthened the company's PNH franchise and reduced its dependence on Soliris for growth. The conversion rates of Soliris patients to Ultomiris has been encouraging. The drug was also approved in Europe and Japan for the indication of PNH. Meanwhile, Alexion is also working to expand Ultomiris' label. The drug was approved in the United States for the treatment of aHUS in adults and children one month and older. It was also approved in Europe for the same indication. A phase III study of Ultomiris in children and adolescents with PNH is underway. A phase III study in children and adolescents with aHUS is also underway.

In November and December 2019, applications for the approval of the Ultomiris 100mg/mL formulation were submitted in the EU and the United States, respectively. This higher concentration formulation is designed to reduce infusion time by more than 50% to approximately 45 minutes. The FDA has set a Prescription Drug User Fee Act target action date of Oct 11, 2020. A phase III study in adults with gMG is underway. In December 2019, Alexion initiated a phase III study of Ultomiris in NMOSD. It began dosing patients in a phase III study for the indication of Amyotrophic Lateral Sclerosis (ALS).

Meanwhile, Alexion initiated a study to evaluate its rare disease drug, Ultomiris, for COVID-19 infection. The initiation follows FDA's rapid review and acceptance of Alexion's investigational new drug (IND) application for Ultomiris for severe COVID-19. The global phase III study will evaluate Ultomiris in a subset of adults with COVID-19 – those who are hospitalized with severe pneumonia or acute respiratory distress syndrome (ARDS).

▲ Diversification With Acquisitions/Collaborations: Alexion is looking to diversify its portfolio and reduce dependence on its blockbuster drug, Soliris. In line with this strategy, Alexion acquired Sweden-based Wilson Therapeutics for \$855 million. The acquisition added a late-stage candidate, ALXN1840 (formerly WTX101) to Alexion's pipeline. The candidate is being evaluated for the treatment of Wilson disease, a rare genetic disorder, in a phase III study. Enrollment is complete in this study and results are expected in the first half of 2021.

The company also acquired a clinical-stage biotechnology company, Syntimmune, for \$1.2 billion in the fourth quarter of 2018. The acquisition added anti-FcRn antibody, ALXN1830 (formerly SYNT001), to the company's pipeline.

The company also announced a collaboration with Dicerna Pharmaceuticals to jointly discover and develop up to four subcutaneously delivered GalXC RNA interference (RNAi) candidates, currently in preclinical development, for the treatment of complement-mediated diseases.

Alexion announced a partnership with Complement Pharma to co-develop the preclinical C6 complement inhibitor, CP010 for neurodegenerative disorders. CP010 is a humanized monoclonal antibody in preclinical stages that binds to C6 in circulation to inhibit its function throughout the body by preventing MAC formation in both the periphery and the central nervous system. Alexion has also collaborated with Caelum Biosciences to develop CAEL-101 for light chain (AL) amyloidosis. A pivotal phase II/III will investigate CAEL-101 as an add-on to current standard-of-care therapy. In March 2020, the companies began dosing patients in the phase II dose selection portion of the program and the phase III portion of the program is planned to begin later in 2020, pending dose selection.

Alexion holds an exclusive license to develop and commercialize AG10 in Japan. Eidos is currently evaluating AG10 in a phase III study in the United States and Europe for ATTR cardiomyopathy (ATTR-CM) and plans to begin a phase III study in ATTR polyneuropathy (ATTR-PN) in 2020. Alexion plans to expand the AG10 program in Japan in 2020, pending regulatory feedback. The deal expands Alexion's amyloidosis portfolio. In March 2019, Alexion announced a partnership with Affibody AB to co-develop ABY-039 for rare Immunoglobulin G (IgG)-mediated autoimmune diseases. The company is collaborating with Zealand Pharma A/S to discover and develop novel peptide therapies for up to four targets in the complement pathway. In October, Alexion announced an agreement with Stealth BioTherapeutics for an option to co-develop and commercialize elamipretide for mitochondrial disease.

To strengthen its PNH franchise, Alexion acquired clinical-stage biopharmaceutical company, Achillion Pharmaceuticals, Inc., for \$930 million. Achillion primarily focuses on the development of oral small molecule Factor D inhibitors to treat people with complement alternative pathway-mediated rare diseases, such as PNH and C3 glomerulopathy (C3G). The acquisition added two clinical-stage candidates to Alexion's pipeline — lead candidate, danicopan (ALXN2040), in phase II and ACH-5228 in phase I. Alexion plans to initiate a phase III study of ALXN2040 as an add-on therapy for PNH patients with extravascular hemolysis (EVH) by the end of 2020. A potential approval of danicopan will make Alexion a market leader in the PNH space.

Alexion acquired Portola Pharmaceuticals to expand and diversify its hematology, neurology and critical care commercial portfolio. Portola's Andexxa [coagulation factor Xa (recombinant), inactivated-zhzo], marketed as Ondexxya in Europe, is the first and only approved Factor Xa inhibitor reversal agent and has demonstrated transformative clinical value by rapidly reversing the anticoagulant effects of Factor Xa inhibitors, rivaroxaban and apixaban, in severe and uncontrolled bleeding.

▲ Favorable Debt Profile: As of Jun 30, 2020, Alexion's total debt to total capital ratio stood at 19.9X, which was slightly up from the year end's 19.1X. Nevertheless, the company has a sound cash position too with cash, and equivalents of \$2.8 billion against long-term debt of \$2.3 billion. This suggests that Alexion will be able to pay off its debt easily using only cash in hand.

Reasons To Sell:

- ▼ Share Price Performance: Alexion's stock has underperformed the industry in the past year.
- ▼ Overdependence on Soliris: With Soliris accounting for majority of revenues at Alexion, the company relies heavily on the drug for growth. Below-par performance of the product will hurt the stock badly as Soliris is Alexion's key growth driver. Moreover, the drug is expected to lose exclusivity soon.
- ▼ Pipeline Setbacks and Competition: The company has faced significant setbacks in its attempts to expand Soliris' label. With several pipeline-related news expected over the upcoming quarters, any negative development could impact the stock adversely. In Feb 2017, Alexion decided to reduce its investment in SBC-103, (a recombinant form of the NAGLU enzyme) for the treatment of patients with mucopolysaccharidosis IIIB). While patients who are currently enrolled in the phase I/II study will continue to receive SBC-103, the company does not plan to conduct any additional studies. Although Soliris is currently the only approved therapy for the treatment of PNH and aHUS, Strensiq the only product approved for the treatment of HPP, and Kanuma, the only product for the treatment of LAL-D, there are many pharma and biotech companies that are looking to develop drugs for these indications. If successfully developed and approved, competition could affect Alexion's top line considerably.

Alexion relies heavily on Soliris for growth, which is concerning. Moreover, pipeline setbacks and macroeconomic issues remain material headwinds.

Last Earnings Report

Alexion Beats on Q2 Earnings & Sales, Ups '20 Guidance

Alexion's second-quarter adjusted earnings of \$3.11 per share comfortably beat the Zacks Consensus Estimate of \$2.55 and grew from \$2.64 in the year-ago quarter.

Moreover, revenues rose 20.1% year over year to \$1.44 billion in the reported quarter and surpassed the Zacks Consensus Estimate of \$1.27 billion. Revenues were driven by higher sales of Ultomiris, Strensig and Kanuma.

Quarter Ending	06/2020
Report Date	Jul 30, 2020
Sales Surprise	14.12%
EPS Surprise	21.96%
Quarterly EPS	3.11
Annual EPS (TTM)	11.83

Revenues in Detail

Soliris (approved for the treatment of paroxysmal nocturnal hemoglobinuria [PNH], atypical hemolytic uremic syndrome [aHUS] and generalized myasthenia gravis [gMG]) sales were down5.4% year over year to \$975.5million in the reported quarter.

Long-acting C5 complement inhibitor, Ultomiris approved for the treatment of adult patients with PNH and aHUS, generated sales of \$251.1 million compared with \$54.2 million in the year-ago quarter, representing a 363% increase. The company achieved its goal of establishing Ultomiris as a new standard of care in PNH, with more than 70% patient conversion from Soliris in the United States.

Strensig revenues were \$184.3 million (up 30% year over year). Kanuma contributed \$33.6 million (up 28% year over year) to quarterly revenues.

In June, the European Commission approved Ultomiris for adults and children with aHUS.

Cost Summary

Adjusted research and development (R&D) expenses increased to \$204.6 million from \$148.7 million in the year-ago quarter.

Adjusted selling, general and administrative (SG&A) expenses were \$253.6 million, down from \$255.8 million in the year-ago quarter.

2020 Guidance

Alexion increased total revenues and adjusted earnings per share guidance and reducedthe operating margin guidance.

The company now expects adjusted earnings per share of \$10.65-\$10.95 (previous guidance:\$10.45-\$10.75). The company now projects revenues of \$5.50-\$5.60 billion (previous guidance: \$5.23-\$5.33 million).

Combined revenues from Soliris and Ultomiris are now estimated at \$4.73-\$4.76 billion (previous guidance: \$4.49-\$4.57 billion).

Pipeline Update

Alexion plans to initiate a phase II/III study in children and adolescents with Neuromyelitis Optica Spectrum Disorder (NMOSD) in the second half of 2020.

An application for approval of Ultomiris in aHUS is under review in Japan. A phase III study of Ultomiris in children and adolescents with aHUS is underway

Applications for approval of Ultomiris100mg/mL formulation are under review in the EU and the United States. The FDA has set an action date of Oct 11, 2020. This higher concentration formulation is designed to reduce infusion time by more than 50% to approximately 45 minutes. Alexion plans to file for regulatory approval of this formulation in Japan in the third quarter of 2020.

Recent Developments

In July 2020, Alexion announced the completion of its acquisition of Portola. The acquisition added Andexxa [coagulation factor Xa (recombinant), inactivated-zhzo] to the company's commercial and development portfolios. Andexxa has conditional approval in the United States and the EU (marketed as Ondexxya in the EU) for the reversal of anticoagulation in patients experiencing life-threatening or uncontrolled bleeding, who are treated with rivaroxaban or apixaban.

Recent News

Finalizes Settlement with the Securities and Exchange Commission - Jul 24

Alexion finalized its settlement with the U.S. Securities and Exchange Commission (SEC) to resolve the previously disclosed investigation related to the company's compliance in certain countries with the Foreign Corrupt Practices Act (FCPA) and other applicable laws. Alexion will make a payment of approximately \$21.5 million in disgorgement, civil penalties, and pre-judgment interest pursuant to the SEC's Order Instituting Proceedings (OIP). As previously disclosed, the U.S. Department of Justice (DOJ) has closed its inquiry into this matter.

Acquires Portola - Jul 2

Alexion announced that it acquired Portola Pharmaceuticals, Inc.

Ultomiris Approved in Europe - Jun 29

Alexion announced that the European Commission has approved the label expansion of its long-acting C5 complement inhibitor, Ultomiris, for a rare disease. The drug, administered every eight weeks, is approved for the treatment of adults and children with a bodyweight of 10 kg or above suffering from atypical hemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received its other drug, Soliris, for at least three months and have evidence of response to Soliris. The European Commission's approval was based on data from two global, single-arm, open-label studies of Ultomiris — one in adults and another in children.

Valuation

Alexion's shares are down 6.6% in the year-to-date period and down 18.2% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are up 2.3% and 0.7%, respectively in the year-to-date period. Over the past year, the Zacks sub-industry is up 14% while the sector is up 8.5%.

The S&P 500 Index is up 5.1% in the year-to-date period and 16.1% in the past year.

The stock is currently trading at 9.64X forward 12-month earnings per share which compares to 51.83X for the Zacks sub-industry, 22.26X for the Zacks sector and 22.83X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 43.98X and as low as 8.07X, with a 5-year median of 18.72X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$106 price target reflects 10.1X forward 12-month earnings per share.

The table below shows summary valuation data for ALXN.

Valuation Multiples - ALXN						
		Stock	Sub-Industry	Sector	S&P 500	
	Current	9.64	51.83	22.26	22.83	
P/E F12M	5-Year High	43.98	66.15	23.17	22.83	
	5-Year Low	8.07	21.12	15.89	15.25	
	5-Year Median	18.72	37.67	18.97	17.58	
	Current	3.68	2.75	2.81	3.71	
P/S F12M	5-Year High	13.53	3.23	3.41	3.71	
	5-Year Low	2.9	1.93	2.22	2.53	
	5-Year Median	6.42	2.74	2.89	3.05	
	Current	2.11	2.97	3.77	4.55	
P/B TTM	5-Year High	5.26	5.83	5.07	4.56	
	5-Year Low	1.48	2.06	2.94	2.83	
	5-Year Median	3.06	3.85	4.28	3.75	

As of 08/20/2020

Industry Analysis Zacks Industry Rank: Bottom 32% (171 out of 252) ■ Industry Price Industry ➡ Price

Top Peers

Company (Ticker)	Rec R	ank
Amgen Inc. (AMGN)	Neutral	3
Biogen Inc. (BIIB)	Neutral	3
Gilead Sciences, Inc. (GILD)	Neutral	3
Incyte Corporation (INCY)	Neutral	3
Regeneron Pharmaceuticals, Inc. (REGN)	Neutral	2
SINO PHARMACEUT (SBMFF)	Neutral	3
Vertex Pharmaceuticals Incorporated (VRTX)	Neutral	3
Illumina, Inc. (ILMN)	Underperform	5

Industry Comparison Industr	edical And Geneti	cs	Industry Peers			
	ALXN	X Industry	S&P 500	ILMN	INCY	VRTX
Zacks Recommendation (Long Term)	Neutral	-	-	Underperform	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	5	3	3
VGM Score	Α	-	-	D	Α	Α
Market Cap	22.13 B	278.79 M	23.46 B	51.77 B	20.89 B	70.70 B
# of Analysts	15	3	14	7	6	12
Dividend Yield	0.00%	0.00%	1.65%	0.00%	0.00%	0.00%
Value Score	Α	-	-	D	C	С
Cash/Price	0.13	0.23	0.07	0.06	0.08	0.08
EV/EBITDA	8.26	-4.08	13.34	35.50	35.60	42.15
PEG Ratio	0.78	1.85	3.00	11.55	NA	1.43
Price/Book (P/B)	2.11	4.16	3.12	11.42	8.91	9.40
Price/Cash Flow (P/CF)	8.64	18.18	12.60	43.08	38.18	56.95
P/E (F1)	9.15	27.71	21.61	80.83	NA	28.44
Price/Sales (P/S)	4.00	16.00	2.44	15.44	8.75	13.09
Earnings Yield	10.87%	-12.36%	4.43%	1.24%	-0.30%	3.52%
Debt/Equity	0.24	0.02	0.76	0.29	0.01	0.07
Cash Flow (\$/share)	11.68	-1.08	6.93	8.23	2.50	4.77
Growth Score	Α	-	-	С	Α	Α
Hist. EPS Growth (3-5 yrs)	27.70%	19.03%	10.44%	20.27%	52.48%	183.54%
Proj. EPS Growth (F1/F0)	4.32%	16.19%	-5.53%	-33.23%	-110.25%	79.08%
Curr. Cash Flow Growth	28.27%	13.93%	5.20%	13.10%	132.41%	52.02%
Hist. Cash Flow Growth (3-5 yrs)	20.68%	7.73%	8.52%	16.75%	140.30%	31.70%
Current Ratio	4.79	6.03	1.33	3.76	3.73	3.72
Debt/Capital	19.13%	3.39%	44.50%	22.70%	1.34%	6.49%
Net Margin	15.28%	-199.98%	10.13%	20.67%	-8.00%	38.51%
Return on Equity	22.57%	-59.21%	14.67%	19.13%	-8.06%	28.55%
Sales/Assets	0.33	0.19	0.51	0.46	0.76	0.62
Proj. Sales Growth (F1/F0)	13.24%	1.43%	-1.54%	-12.78%	17.06%	42.86%
Momentum Score	В	-	-	F	Α	В
Daily Price Chg	-0.72%	0.00%	-0.59%	0.35%	-0.77%	0.50%
1 Week Price Chg	-0.30%	-1.69%	1.09%	-2.28%	-2.13%	-2.09%
4 Week Price Chg	-3.65%	-1.37%	1.91%	-8.24%	-6.05%	-4.58%
12 Week Price Chg	-11.76%	2.13%	6.82%	-4.94%	-4.99%	-2.15%
52 Week Price Chg	-18.24%	10.00%	1.47%	22.88%	11.65%	47.32%
20 Day Average Volume	1,570,669	314,989	1,873,576	944,915	1,113,687	1,315,514
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.73%	0.00%	1.79%	-28.62%	5.08%	11.98%
(F1) EPS Est 12 week change	0.59%	1.42%	3.35%	-29.78%	13.18%	10.61%
(Q1) EPS Est Mthly Chg	-4.76%	0.00%	0.42%	-55.69%	-32.85%	9.57%

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.

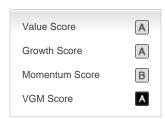
Zacks Rank

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.



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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