

Alexion Pharma (ALXN)

\$88.84 (As of 03/10/20)

Price Target (6-12 Months): **\$95.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 02/04/20)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:C

Value: B

Growth: D

Momentum: C

Summary

Alexion's blockbuster drug, Soliris, maintains momentum. The label expansion of the drug into refractory gMG has further boosted sales. Meanwhile, the approval of its long-acting C5 complement inhibitor, Ultomiris, for the treatment of adults with PNH has strengthened its PNH franchise and the initial uptake has been impressive. The company is taking steps to strengthen the PNH portfolio, which should yield results in the long run. It acquired the clinical-stage biopharmaceutical company, Achillion Pharmaceuticals, Inc., to fortify its PNH franchise. Shares have underperformed the industry in the past year. However, pricing is likely to affect sales. Further, an earlier-than-expected competition might negatively impact sales. The outlook for 2020 was below expectations.

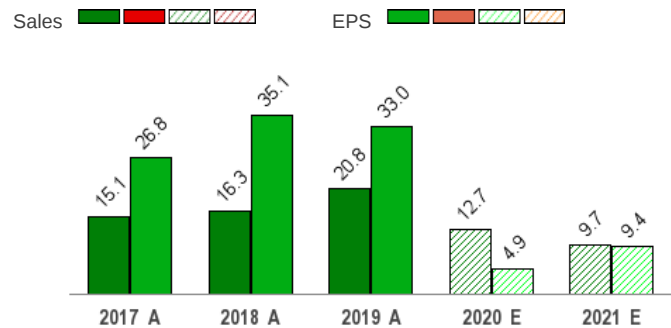
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$141.86 - \$83.04
20 Day Average Volume (sh)	2,570,877
Market Cap	\$19.7 B
YTD Price Change	-17.9%
Beta	1.61
Dividend / Div Yld	\$0.00 / 0.0%
Industry	<u>Medical - Biomedical and Genetics</u>
Zacks Industry Rank	Top 39% (99 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	3.4%
Last Sales Surprise	1.7%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	04/23/2020
Earnings ESP	5.4%
P/E TTM	8.4
P/E F1	8.0
PEG F1	0.7
P/S TTM	3.9

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	1,444 E	1,503 E	1,566 E	1,635 E	6,173 E
2020	1,353 E	1,392 E	1,429 E	1,469 E	5,625 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	\$2.89 E	\$2.98 E	\$3.06 E	\$3.12 E	\$12.09 E
2020	\$2.71 E	\$2.74 E	\$2.82 E	\$2.82 E	\$11.05 E
2019	\$2.39 A	\$2.64 A	\$2.79 A	\$2.71 A	\$10.53 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 03/10/2020. The reports text is as of 03/11/2020.

Overview

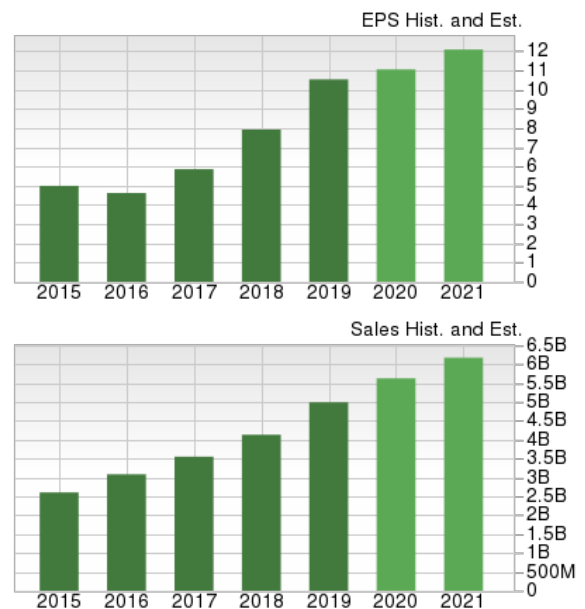
Based in New Haven, CT, Alexion Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of life-transforming drugs, for the treatment of patients with ultra-rare disorders.

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, recording 11% growth in 2019. The underlying growth of the drug has been robust for both indications — PNH and aHUS. The drug is also approved for the treatment of refractory gMG in patients, who are anti-acetylcholine receptor antibody-positive in the United States and Europe. The growth of the drug in this indication has been strong in the United States, driven by strong patient demand. Moreover, the FDA recently approved Soliris to treat neuromyelitis optica spectrum disorder (NMOSD). The drug was also approved in Europe and Japan for NMOSD. Soliris has also been approved for adults with anti-aquaporin-4 (AQP4) auto antibody-positive NMOSD in Japan. Alexion plans to initiate a phase II/III study in children and adolescents with NMOSD in the first quarter of 2020. To further increase the commercial potential of the drug, Alexion is working on expanding Soliris' label into additional indications. Dosing is underway in a phase III study of Soliris in children and adolescents with gMG. A phase III study of Soliris in children and adolescents with gMG is underway.

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

▲ **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 recently approved in the United States for the treatment of aHUS in adults and children one month and older, and is under review in the EU and Japan for the same. 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. Alexion plans to file for regulatory approval of this formulation in Japan in mid-2020. Enrollment is complete in a single, PK-based phase III study of Ultomiris delivered subcutaneously once per week to support registration in PNH and aHUS. Data are expected in the first half of 2020. A phase III study in adults with gMG is underway. In December 2019, Alexion initiated a phase III study of Ultomiris in NMOSD. The company also submitted an investigational new drug application (IND) for Ultomiris in ALS to the FDA and plans to initiate a phase III study in the first quarter of 2020.

▲ **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. Alexion is in the process of completing enrollment 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. Alexion plans to re-initiate a phase II study of ALXN1830 (SYNT001), administered intravenously, in warm autoimmune hemolytic anemia (WAIHA) in early 2020. In December 2019, Alexion initiated a phase 1 study of a subcutaneous formulation of ALXN1830 in healthy volunteers. Pending successful completion of this phase 1 study, Alexion plans to initiate a phase II study of subcutaneous ALXN1830 in gMG in the second half of 2020.

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 AL amyloidosis, a rare systemic disorder that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage. A phase II/III program will investigate CAEL-101 as an add-on to current standard-of-care therapy. The phase II dose selection portion of the program will initiate in the first half of 2020, with the phase III portion of the program planned to begin later in 2020.

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 the first quarter of 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 paroxysmal nocturnal hemoglobinuria (PNH) and C3 glomerulopathy (C3G). The acquisition adds two clinical-stage candidates to Alexion's pipeline — lead candidate, danicopan (ACH-4471), in phase II and ACH-5228 in phase I. Achillion's shareholders will get \$6.30 per share as an initial consideration. A potential approval of danicopan will make Alexion a market leader in the PNH space.

▲ **Pipeline Development Encouraging:** Alexion's efforts to develop its pipeline are impressive. Alexion plans to initiate a proof-of-concept study on ALXN1810 (subcutaneous ALXN1210 co-administered with Halozyme's ENHANZE drug-delivery technology, recombinant human hyaluronidase enzyme [rHuPH20]) in patients with various renal diseases in 2020.

Reasons To Sell:

▼ **Share Price Performance:** Alexion's stock has underperformed the industry in the past year. Moreover, the outlook for 2020 was disappointing as well.

▼ **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 Q4 Earnings Beat Estimates

Alexion posted fourth-quarter 2019 adjusted earnings of \$2.71 per share, which improved 26.6% from the year-ago quarter's \$2.14. Earnings also beat the Zacks Consensus Estimate of \$2.37.

Moreover, revenues rose 22.6% year over year to \$1.38 billion in the reported quarter and surpassed the Zacks Consensus Estimate of \$1.32 billion. Revenues were driven by higher sales of Soliris, Strensiq, Kanuma and Ultomiris.

Quarter Ending **12/2019**

Report Date	Jan 30, 2020
Sales Surprise	1.72%
EPS Surprise	3.44%
Quarterly EPS	2.71
Annual EPS (TTM)	10.53

Revenues in Detail

Soliris (for the treatment of paroxysmal nocturnal hemoglobinuria [PNH] and atypical hemolytic uremic syndrome [aHUS]) sales were up 4% year over year to \$1013.1 million in the reported quarter, driven by strong volume growth.

Strensiq revenues were \$166.8 million (up 32% year over year). Kanuma (lysosomal acid lipase deficiency [LAL-D]) contributed \$34.1 million (up 33% year over year) to quarterly revenues.

Ultomiris' (ravulizumab-cwvz) net product sales were \$170.2 million in the reported quarter, reflecting a sequential increase of 89.3%.

Cost Summary

Adjusted research and development (R&D) expenses were \$226.7 million, up 38.2% year over year.

Adjusted selling, general and administrative (SG&A) expenses were \$340 million, up 22.3% year over year.

2019 Results

Alexion posted 2019 adjusted earnings of \$10.53 per share, up 33% from the last year's figure of \$7.92.

The company reported sales of \$4.99 billion, up 20.8% year over year.

2020 Guidance

Alexion expects adjusted earnings per share of \$10.65-\$10.85. The company projects revenues of \$5.50-\$5.56 billion. The Zacks Consensus Estimate for earnings is pegged at \$11.36 per share and for sales at \$5.62 billion. Both the earnings and sales guidance fall below the estimates.

Combined revenues from Soliris and Ultomiris are expected to be \$4.76-\$4.80 billion.

Pipeline Update

In November 2019, Soliris was approved for adults with anti-aquaporin-4 (AQP4) auto antibody-positive neuromyelitis optica spectrum disorder (NMOSD) in Japan. Alexion plans to initiate a phase II/III study in children and adolescents with NMOSD in the first quarter of 2020. Another phase III study on Soliris is underway for addressing children and adolescents with Generalized Myasthenia Gravis (gMG).

Meanwhile, applications for the approval of Ultomiris in aHUS are under review in the EU and Japan. Another phase III study of Ultomiris in children and adolescents with aHUS is underway. Also, a phase III study on Ultomiris in children and adolescents with PNH is underway.

Enrollment is complete in a single, PK-based phase III study of Ultomiris, delivered subcutaneously once per week, to support registration in PNH and aHUS. Data are expected in the first half of 2020. Another phase III study of the drug for the treatment of gMG is ongoing. In December 2019, Alexion initiated a phase III study of Ultomiris in NMOSD.

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 high-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 mid-2020.

In December 2019, Alexion submitted an investigational new drug application (IND) for Ultomiris in Amyotrophic Lateral Sclerosis (ALS) to the FDA. In January 2020, the company announced the planned initiation of a pivotal phase III study in the first quarter of 2020.

Recent Developments

Alexion acquired clinical-stage biopharmaceutical company Achillion Pharmaceuticals, Inc. for \$930 million.

The acquisition adds Achillion's lead candidate danicopan (ACH-4471), currently in phase II development for C3 glomerulopathy (C3G), and ACH-5228, which is in phase II development for PNH to Alexion's pipeline. Alexion is looking to strengthen its PNH franchise with this buyout as a potential approval of danicopan will make the company a market leader in the PNH space.

Recent News

Acquires Achillion – Jan 28

Alexion acquired Achillion Pharmaceuticals, Inc. The acquisition adds two clinical-stage oral small molecule Factor D inhibitors to Alexion's pipeline.

To Start Pivotal Study on Ultomiris for ALS – Jan 14

Alexion announced plans to start a pivotal phase III study to evaluate its long-acting C5 complement inhibitor, Ultomiris (ravulizumab), in a new indication — amyotrophic lateral sclerosis (ALS). The study will be called CHAMPION-ALS (n~350) and evaluate the efficacy and safety of Ultomiris across a broad ALS patient population. ALS is a neurological disorder characterized by progressive degeneration of nerve cells in the brain and the spinal cord, which control muscles throughout the body.

Alexion submitted an investigational new drug application (IND) for Ultomiris in ALS to the FDA in the fourth quarter of 2019. The company plans to initiate the phase III study in the first quarter of 2020.

Valuation

Alexion's shares are down 23% in the year-to-date period and 38% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 5.7% and 7%, respectively in the year-to-date period. Over the past year, the Zacks sub-industry is down 10.8% while the sector is down 6.5%.

The S&P 500 Index is down 10.5% in the year-to-date period but up 2.2% in the past year.

The stock is currently trading at 9.5X forward 12-month earnings per share which compares to 170.91X for the Zacks sub-industry, 19.33X for the Zacks sector and 16.58X for the S&P 500 Index.

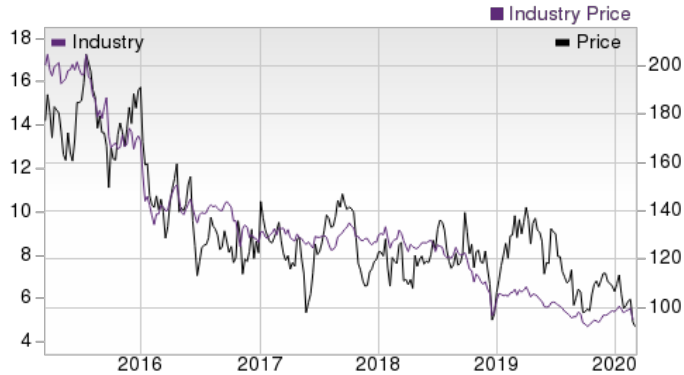
Over the past five years, the stock has traded as high as 43.98X and as low as 9.25X, with a 5-year median of 23.52X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$95 price target reflects 10.16X forward 12-month earnings per share.

The table below shows summary valuation data for ALXN.

Valuation Multiples - ALXN					
		Stock	Sub-Industry	Sector	S&P 500
P/E F12M	Current	9.09	129.07	21.2	18.89
	5-Year High	16.22	132.83	21.25	19.34
	5-Year Low	9.09	20.37	15.84	15.18
	5-Year Median	11.99	38.49	18.9	17.46
P/S F12M	Current	4.02	2.83	2.84	3.5
	5-Year High	6.43	2.96	3.82	3.5
	5-Year Low	3.86	2.01	2.44	2.54
	5-Year Median	4.87	2.55	2.95	3
P/B TTM	Current	2.04	3.8	4.57	4.5
	5-Year High	3.35	5.79	5.03	4.54
	5-Year Low	1.95	2.43	3.43	2.85
	5-Year Median	2.48	3.27	4.29	3.62

As of 02/05/2020

Industry Analysis Zacks Industry Rank: Top 39% (99 out of 253)



Top Peers

Regeneron Pharmaceuticals, Inc. (REGN)	Outperform
Amgen Inc. (AMGN)	Neutral
Biogen Inc. (BIIB)	Neutral
Illumina, Inc. (ILMN)	Neutral
SINO PHARMACEUT (SBMFF)	Neutral
Vertex Pharmaceuticals Incorporated (VRTX)	Neutral
Gilead Sciences, Inc. (GILD)	Underperform
Incyte Corporation (INCY)	Underperform

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	ALXN Neutral	X Industry	S&P 500	ILMN Neutral	INCY Underperform	VRTX Neutral
VGM Score	C	-	-	C	D	C
Market Cap	19.67 B	172.90 M	20.21 B	39.42 B	16.11 B	59.76 B
# of Analysts	14	2	13	9	6	12
Dividend Yield	0.00%	0.00%	2.18%	0.00%	0.00%	0.00%
Value Score	B	-	-	C	D	C
Cash/Price	0.14	0.22	0.05	0.08	0.13	0.06
EV/EBITDA	7.39	-2.72	12.36	26.95	25.82	36.21
PEG Ratio	0.65	1.80	1.78	2.54	0.76	1.07
Price/Book (P/B)	1.75	3.34	2.77	8.55	6.16	9.74
Price/Cash Flow (P/CF)	7.60	13.22	11.04	32.58	29.70	48.37
P/E (F1)	7.58	30.45	16.09	39.16	24.28	30.45
Price/Sales (P/S)	3.94	11.83	2.17	11.12	7.46	14.36
Earnings Yield	12.44%	-17.67%	6.20%	2.55%	4.12%	3.28%
Debt/Equity	0.23	0.02	0.70	0.40	0.01	0.09
Cash Flow (\$/share)	11.68	-1.09	7.01	8.23	2.50	4.77
Growth Score	D	-	-	C	C	A
Hist. EPS Growth (3-5 yrs)	21.33%	18.12%	10.85%	19.06%	52.48%	216.65%
Proj. EPS Growth (F1/F0)	4.96%	6.01%	6.14%	4.23%	8.13%	42.01%
Curr. Cash Flow Growth	28.27%	15.46%	6.09%	13.10%	132.41%	52.02%
Hist. Cash Flow Growth (3-5 yrs)	20.68%	7.56%	8.52%	16.75%	140.30%	31.70%
Current Ratio	4.25	4.83	1.24	6.69	4.83	3.61
Debt/Capital	18.39%	4.29%	42.57%	28.47%	1.21%	8.13%
Net Margin	48.17%	-226.08%	11.69%	28.27%	20.70%	28.27%
Return on Equity	21.29%	-67.43%	16.74%	22.34%	20.05%	20.97%
Sales/Assets	0.33	0.21	0.54	0.49	0.70	0.57
Proj. Sales Growth (F1/F0)	13.44%	14.22%	3.71%	9.74%	14.22%	25.68%
Momentum Score	C	-	-	D	C	F
Daily Price Chg	2.80%	0.00%	4.87%	3.21%	4.53%	4.94%
1 Week Price Chg	-2.18%	0.00%	-0.67%	3.29%	0.84%	4.23%
4 Week Price Chg	-13.29%	-14.91%	-15.65%	-9.41%	-2.40%	-6.98%
12 Week Price Chg	-19.10%	-7.89%	-13.60%	-17.10%	-18.62%	5.92%
52 Week Price Chg	-33.85%	-24.22%	-2.27%	-12.16%	-12.47%	26.26%
20 Day Average Volume	2,570,877	221,783	2,778,843	1,402,344	1,825,613	1,641,866
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	-0.16%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	-0.16%	-0.16%	-14.54%	0.00%
(F1) EPS Est 12 week change	-9.65%	0.00%	-0.57%	-3.25%	-14.70%	9.57%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-0.49%	0.00%	NA	0.00%

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	B
Growth Score	D
Momentum Score	C
VGM Score	C

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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