

Exelixis, Inc.(EXEL)
\$16.65 (As of 04/02/20)

Price Target (6-12 Months): **\$20.00**

Long Term: 6-12 Months

Zacks Recommendation:
Neutral

(Since: 10/03/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

2-Buy

Zacks Style Scores:

VGM:C

Value: B

Growth: C

Momentum: D

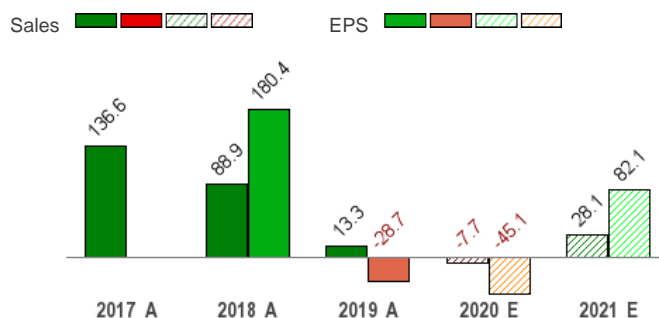
Summary

Exelixis' lead drug, Cabometyx, continues to gain traction in both indications — RCC and HCC. While demand for the RCC indication has been strong, the initial traction for the HCC indication in second and third-line settings was encouraging. The company is on track to expand cabozantinib's label and the drug is already being evaluated in various studies with Tecentriq and Opdivo. Successful outcomes from the ongoing studies should boost demand. However, the company is heavily dependent on Cabometyx for growth. Competition has stiffened with the approval of Opdivo + Yervoy in first-line RCC and other treatments and will impact sales. Shares have underperformed the industry in the past year.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	\$25.00 - \$13.67
20 Day Average Volume (sh)	3,729,454
Market Cap	\$5.1 B
YTD Price Change	-5.5%
Beta	1.28
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 12% (30 out of 254)

Sales and EPS Growth Rates (Y/Y %)


Last EPS Surprise	46.7%
Last Sales Surprise	-0.2%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	05/06/2020
Earnings ESP	0.0%
P/E TTM	15.9
P/E F1	29.7
PEG F1	0.7
P/S TTM	5.3

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	242 E	252 E	257 E	267 E	1,144 E
2020	211 E	222 E	227 E	240 E	893 E
2019	215 A	240 A	272 A	240 A	968 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.27 E	\$0.28 E	\$0.31 E	\$0.29 E	\$1.02 E
2020	\$0.15 E	\$0.15 E	\$0.13 E	\$0.14 E	\$0.56 E
2019	\$0.27 A	\$0.25 A	\$0.31 A	\$0.22 A	\$1.02 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 04/02/2020. The reports text is as of 04/03/2020.

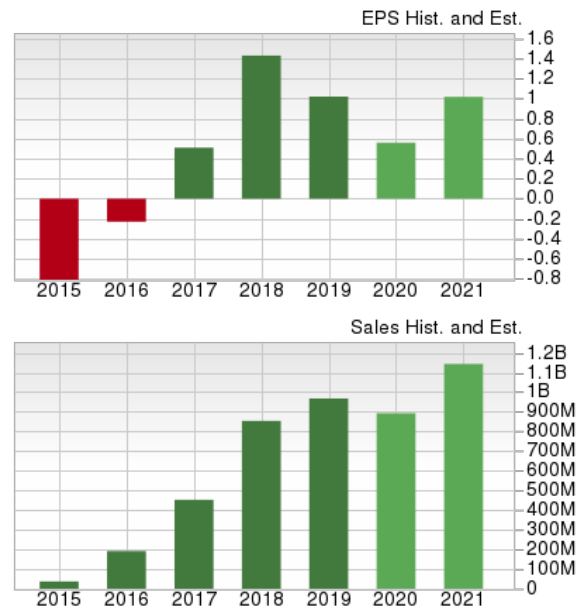
Overview

San Francisco, CA-based Exelixis, Inc. is an oncology-focused biotechnology company, which primarily focuses on the discovery, development and commercialization of new drugs for the treatment of difficult cancers.

The company has four approved drugs in its portfolio. Of these, two are derived from cabozantinib, the company's flagship molecule, which an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET. The approved drugs are Cabometyx (cabozantinib) tablets approved for advanced renal cell carcinoma (RCC) and previously treated hepatocellular carcinoma (HCC); Cometriq (cabozantinib) capsules approved for progressive, metastatic medullary thyroid cancer (MTC); Cotellic (cobimetinib), an inhibitor of MEK approved as part of a combination regimen to treat advanced melanoma, marketed under a collaboration with Genentech, Inc. (a member of the Roche Group) (Genentech); and Minnebros (esaxerenone), an oral, non-steroidal, selective blocker of the mineralocorticoid receptor (MR) approved for the treatment of hypertension in Japan and licensed to Daiichi Sankyo Company, Limited (Daiichi Sankyo).

Exelixis has a licensing agreement with Ipsen, under which the latter has exclusive commercialization rights for current and potential future indications of cabozantinib outside the United States, Canada and Japan. The company also has collaborations with other leading pharmaceutical and biotechnology companies such as Bristol-Myers, Sanofi, Merck and Daiichi Sankyo for various compounds and programs in its portfolio.

The company earns revenues through milestones and royalty payments from these collaborations. Revenues in 2019 came in at \$967.8 million, up from \$853.8 million in 2018.



Reasons To Buy:

▲ **Cabometyx Performance Impressive:** The uptake of Cabometyx, a tablet formulation of cabozantinib, for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy since its approval (April 2016), has been strong. The drug's label was further expanded to include previously-untreated, advanced RCC patients, which has boosted demand. Kidney cancer is among the top ten most commonly diagnosed forms of cancer among both men and women in the United States and RCC is the most common form of kidney cancer in adults. Since the drug is now approved for first-line RCC as well, Exelixis can now target the entire patient population suffering from the disease in the United States. Meanwhile, Exelixis' European partner, Ipsen, also obtained approval for the drug in the region for the first-line treatment of adults with intermediate- or poor-risk advanced RCC. In October 2019, Ipsen announced Health Canada's approval of Cabometyx for the first-line treatment of adults with advanced RCC. The approval has broadened the geographic reach of the drug and targeted patient population.

The approval of Cabometyx for RCC is a great boost for the company. The company's efforts to develop cabozantinib for various other indications are also encouraging.

In addition, Exelixis and Ipsen also obtained EC approval for Cabometyx as a monotherapy for HCC in adults who have previously been treated with Bayer's Nexavar. The FDA also approved Cabometyx for HCC. Sales should get a boost from this label expansion, given the market potential. In November 2019, it was approved in Canada for HCC.

▲ **Developing Cabozantinib for Additional Indications:** Exelixis is working on expanding cabozantinib's label further. The candidate is being evaluated in a broad development program comprising more than 85 clinical studies across multiple indications both as single agent and in combination with other drugs. The successful development of the drug for additional indications will propel sales further.

▲ **Collaborations with Leading Companies:** Exelixis has collaborations with several leading pharmaceuticals such as Bristol-Myers Squibb, Merck and Daiichi Sankyo Company for various compounds and programs in its portfolio. These collaborations allow Exelixis to earn milestone payments and royalties that boost its top line. Exelixis also has an exclusive licensing agreement with Ipsen for the commercialization and further development of cabozantinib. Per the terms of the agreement, Ipsen enjoys exclusive commercialization rights for all current and potential future indications of the drug outside the United States., and Japan. The companies will jointly work on the development of cabozantinib for current and potential future indications. Exelixis, on the other hand, will retain rights to commercialize the drug in the United States. This agreement was recently amended and Ipsen was granted rights in Canada also. Daiichi Sankyo launched Minnebro tablets as a treatment for patients with hypertension in Japan. Consequently, Exelixis received an associated \$20-million milestone payment from Daiichi Sankyo with the first commercial sale of Minnebro. In 2017, Exelixis signed collaboration agreements with Bristol-Myers Squibb and Roche to evaluate cabozantinib in combination with immunotherapy agents.

Exelixis recently collaborated with Roche to evaluate Cabometyx in combination with the latter's PD-L1 immune checkpoint inhibitor, Tecentriq, in patients with locally advanced or metastatic solid tumors. The clinical program, which will be co-funded by the companies, is expected to include three phase III pivotal trials in advanced non-small cell lung cancer (NSCLC), castration-resistant prostate cancer (CRPC) and renal cell carcinoma (RCC).

In July, Exelixis announced an exclusive collaboration, option and license agreement with Aurigene, an India-based biotechnology company focused on oncology and inflammatory disorders, to in-license as many as six programs. Per the agreement, Exelixis made an upfront payment of \$10.0 million for exclusive options to license three pre-existing programs from Aurigene. The companies selected three additional Aurigene-led drug discovery programs on mutually agreed upon targets, in exchange for supplemental option payments totaling \$7.5 million.

In October 2019, Exelixis expanded its collaboration with Invenra to include the development of novel binders against six additional targets. Under the terms of the expanded collaboration agreement, Exelixis will have the opportunity to use these binders to generate multispecific antibodies based on Invenra's B-Body technology platform, or with other platforms and formats, at Exelixis' option.

Reasons To Sell:

▼ **Share Price Performance:** Exelixis' stock has underperformed the industry in the past year.

▼ **Heavily Dependent on the success of Cabometyx for RCC:** The company is heavily dependent on Cabometyx for growth now and the drug might not be able to capture market share, given the competition. Additionally, given the market potential, most pharma/biotech bigwigs are scurrying to grab a larger chunk of this pie. Evidently, the focus is on better and effective treatments. The focus, of late, has shifted to checkpoint inhibitor-containing regimens in combination with a TKI as the first-line option for RCC patients. Merck's PD-L1 inhibitor, Keytruda, is approved in combination with Pfizer's Inlyta for the first-line treatment of advanced RCC. In May, the FDA approved the combination regimen of Bavencio (avelumab) and Inlyta for the first-line treatment of patients with advanced RCC. In particular, competition has stiffened with the approval of Opdivo and Yervoy for the treatment of poor and intermediate risk first-line RCC.

▼ **Pipeline Setbacks:** Exelixis is not new to pipeline setbacks. The company suffered a setback in 2014 when two phase III studies (COMET-1 and COMET-2) on Cometriq for the treatment of metastatic castration-resistant prostate cancer failed to meet its primary endpoint of an increase in overall survival. Meanwhile, the phase III trial, IMblaze370, evaluating the combination of Cotellic and Tecentriq did not meet its primary endpoint. The trial evaluated the combination in patients with difficult-to-treat, locally advanced or metastatic colorectal cancer (CRC) whose disease had progressed or who were intolerant to at least two systemic chemotherapy regimens. Any further setback in the label expansion of Cometriq will adversely impact the company's growth prospects.

The company is heavily dependent on Cabometyx for growth and failure of the drug to capture additional market share amid increasing competition will be detrimental.

Last Earnings Report

Exelixis Beats on Earnings, Misses on Sales in Q4

Exelixis reported earnings of \$0.22, handily beating the Zacks Consensus Estimate of \$0.15. The bottom-line figure, however, declined from the year-ago quarter's \$1.15.

Net revenues came in at \$240.3 million, increasing from the \$228.6 million reported in the year-ago quarter. However, the revenue figure marginally missed the Zacks Consensus Estimate of \$240.7 million.

Quarter Ending **12/2019**

Report Date	Feb 25, 2020
Sales Surprise	-0.15%
EPS Surprise	46.67%
Quarterly EPS	0.22
Annual EPS (TTM)	1.05

Quarter in Detail

Net product revenues came in at \$194.9 million, up 10.6% from the year-ago quarter, on continued growth of Cabometyx in the United States for the treatment of advanced renal cell carcinoma (RCC).

Cabometyx received another FDA approval for the treatment of patients with hepatocellular carcinoma, who have been previously treated with sorafenib, in January 2019. The label expansion of the drug for this indication in the United States also boosted sales.

Cabometyx generated \$181.1 million of revenues. Patient demand grew 11% year over year and up 3% sequentially. Prescriber base grew 35% year over year and 6% sequentially.

Cometriq (cabozantinib capsules), for the treatment of medullary thyroid cancer, generated \$13.8 million in net product revenues.

Exelixis also earned \$17 million in royalty revenues based upon Ipsen's cabozantinib-related revenues in the final quarter of 2019.

Total collaboration revenues were \$45.4 million, down from the \$52.4 million recorded in the year-ago quarter.

In the reported quarter, research and development expenses flared up significantly to \$94.4 million from the \$57.3 million due to rise in clinical trial costs, license and other collaboration costs, and personnel expenses. Selling, general and administrative (SG&A) expenses were \$58 million, up 10.3% year over year, resulting from rise in personnel expenses and stock-based compensation.

Pipeline Update

In December 2019, Exelixis announced a collaboration agreement with Roche to evaluate cabozantinib in combination with Tecentriq, Roche's PD-L1 immune checkpoint inhibitor, in patients with locally advanced or metastatic solid tumors. The clinical program, which will be co-funded by the companies, is expected to include three phase III pivotal trials in advanced non-small cell lung cancer, metastatic castration-resistant prostate cancer (mCRPC) and RCC.

Exelixis also announced positive results from IMspire150, the phase III study of Tecentriq, Cotellic and Zelboraf in patients with previously untreated BRAF V600 mutation-positive advanced melanoma. Genentech, a member of the Roche Group, Exelixis' collaborator and the sponsor of the IMspire150 trial, informed Exelixis that the study met its primary endpoint of progression-free survival.

Based on continued encouraging efficacy and safety data, Exelixis plans to further expand the mCRPC cohort of COSMIC-021, the phase Ib trial of cabozantinib in combination with Tecentriq in patients with locally advanced or metastatic solid tumors. The cohort, which was previously expanded from 30 to 80 patients last July, will now include up to 130 patients.

2019 Results

Revenues for 2019 came in at \$967.8 million, up from the prior year's \$853.8 million. Earnings per share came in at \$1.16 compared with \$1.55 per share reported in 2018.

2020 Guidance

Revenues are projected at \$850-\$900 million, while product revenues are estimated in the range of \$725 million to \$775 million.

Recent News

Cabometyx Approved In Japan For RCC – Mar 25

Exelixis announced that partner Takeda Pharmaceutical Company Limited received approval from the Japanese Ministry of Health, Labor and Welfare to manufacture and market Cabometyx as a treatment for patients with curatively unresectable or metastatic RCC.

Update on the COSMIC-311 Pivotal Study of Cabozantinib – Feb 25

Exelixis announced enrollment of the first 100 patients in COSMIC-311, a phase III study evaluating Cabometyx versus placebo in patients with radioactive iodine-refractory differentiated thyroid cancer who have progressed after up to two vascular endothelial growth factor (VEGF) receptor-targeted therapies.

Exelixis expects to conduct an analysis in the first 100 patients for the co-primary endpoint of objective response rate, and an interim analysis of progression-free survival in the second half of 2020.

Data From Prostate Cancer Study – Feb 10

Exelixis announced encouraging results from the metastatic castration-resistant prostate cancer (CRPC) cohort of COSMIC-021, the phase 1b study of Cabometyx in combination with Tecentriq in patients with locally advanced or metastatic solid tumors.

Takeda Files NDA in Japan for Cabometyx for Advanced HCC – Jan 29

Exelixis announced that partner Takeda Pharmaceutical Company Limited (Takeda) has applied to the Japanese Ministry of Health, Labor and Welfare (MHLW) for Manufacturing and Marketing Approval of Cabometyx as a treatment for patients with unresectable HCC that had progressed after prior systemic therapy.

Data on Combination Trial – Jan 24

Exelixis announced phase I/II study results from the combination of Cabometyx and Opdivo with or without Yervoy in advanced hepatocellular carcinoma.

CheckMate 040 is a phase I/II study that includes an exploratory cohort of patients with advanced HCC who were either treatment naïve (41%) or who were intolerant to or had progressed on prior sorafenib therapy (59%). For the 36 patients treated with the combination of cabozantinib and nivolumab the investigator-assessed objective response rate (ORR) was 19%, and disease control rate (DCR) was 75%. Median progression-free survival (PFS) was 5.4 months, and median overall survival was 21.5 months.

Announces 2019 Preliminary Results – Jan 12

Exelixis announced preliminary results for the fourth quarter of 2019 as well as the full year and provided guidance for 2020. The company reported total preliminary revenues of approximately \$972 million for the full year and \$245 million for fourth-quarter 2019. Preliminary net product revenues were approximately \$765 million for the full year and around \$200 million for the fourth quarter 2019.

2020 Guidance

Total revenues are expected to be in the range of \$850-\$900 million. The Zacks Consensus Estimate is pegged at \$475.9 million.

Plans to Expand Prostate Cancer Cohort of Cabometyx Study – Jan 7

Exelixis announced that it plans to further expand the metastatic castration-resistant prostate cancer (CRPC) cohort of the phase 1b study, COSMIC-021. The study is evaluating the combination of Cabometyx and Roche's Tecentriq in patients with locally advanced or metastatic solid tumors.

The decision to expand the cohort was based on continued encouraging efficacy and safety data. The cohort, which was previously expanded from 30 to 80 patients in July 2019, will now include up to 130 patients.

Collaboration With Roche – Dec 19

Exelixis announced a collaboration agreement with Roche to evaluate Cabometyx in combination with the latter's PD-L1 immune checkpoint inhibitor, Tecentriq, in patients with locally advanced or metastatic solid tumors. The clinical program, which will be co-funded by the companies, is expected to include three phase III pivotal trials in advanced non-small cell lung cancer (NSCLC), castration-resistant prostate cancer (CRPC) and renal cell carcinoma (RCC). Combo Study With Tecentriq – Dec 13

Exelixis announced that the late-stage study on immuno-oncology drug, Tecentriq (atezolizumab), in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib) was successful in skin cancer patients.

The phase III IMspire150 study compared the efficacy and safety of

Tecentriq plus Cotellic and Zelboraf to the combination of placebo plus Cotellic and Zelboraf in patients with previously untreated BRAF V600 mutation-positive advanced melanoma.

The study met its primary endpoint of progression free survival. Results from the study showed that the addition of Tecentriq to Cotellic and Zelboraf helped in the reduction of the risk of disease worsening or death compared to placebo plus Cotellic and Zelboraf. The safety profile observed in IMspire150 was consistent with the known safety profiles of the individual drugs.

Partner Ipsen Announces Health Canada's Approval of Cabometyx – Nov 12

Exelixis announced that its partner Ipsen Biopharmaceuticals Canada Inc. received Health Canada's approval for Cabometyx (cabozantinib) tablets for the treatment of patients with HCC who have been previously treated with sorafenib.

Valuation

Exelixis' shares are down 5.5% in the year-to-date period and 30.9% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 7.6% and 14.3% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 9.6% and 13.4%.

The S&P 500 index is down 21.4% in the year-to-date period and 12.4% in the past year.

The stock is currently trading at 5.32X trailing 12-month sales per share, which compares to 2.79X for the Zacks sub-industry, 2.41X for the Zacks sector and 2.77X for the S&P 500 index.

Over the past five years, the stock has traded as high as 24.16X and as low as 4.45X, with a 5-year median of 10.7X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$20 price target reflects 6.39X trailing 12-month sales per share.

The table below shows summary valuation data for EXEL

Valuation Multiples - EXEL					
		Stock	Sub-Industry	Sector	S&P 500
P/S F12M	Current	5.32	2.79	2.41	2.77
	5-Year High	24.16	2.99	3.84	3.43
	5-Year Low	4.45	2.04	2.41	2.54
	5-Year Median	10.7	2.6	2.96	3
P/B TTM	Current	3	3.36	3.3	3.4
	5-Year High	131.3	5.46	5.05	4.55
	5-Year Low	-19.2	2.45	2.84	2.85
	5-Year Median	4.81	3.28	4.3	3.63

As of 04/02/2020

Industry Analysis Zacks Industry Rank: Top 12% (30 out of 254)



Top Peers

Eli Lilly and Company (LLY)	Outperform
Bayer Aktiengesellschaft (BAYRY)	Neutral
Bristol-Myers Squibb Company (BMY)	Neutral
Merck & Co., Inc. (MRK)	Neutral
Novartis AG (NVS)	Neutral
Pfizer Inc. (PFE)	Neutral
Roche Holding AG (RHHBY)	Neutral
AVEO Pharmaceuticals, Inc. (AVEO)	Underperform

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	EXEL Neutral	X Industry	S&P 500	BMY Neutral	NVS Neutral	PFE Neutral
VGM Score	C	-	-	B	C	D
Market Cap	5.08 B	148.64 M	17.16 B	124.64 B	191.59 B	182.35 B
# of Analysts	4	3	13	5	5	4
Dividend Yield	0.00%	0.00%	2.5%	3.26%	2.40%	4.62%
Value Score	B	-	-	B	C	B
Cash/Price	0.16	0.30	0.06	0.13	0.06	0.06
EV/EBITDA	10.41	-1.98	10.80	22.71	12.98	8.80
PEG Ratio	0.64	1.54	1.74	1.22	1.72	2.65
Price/Book (P/B)	3.00	2.82	2.33	2.38	3.45	2.87
Price/Cash Flow (P/CF)	15.36	12.61	9.11	12.58	10.71	8.00
P/E (F1)	29.59	27.51	14.73	9.00	14.65	11.75
Price/Sales (P/S)	5.25	11.64	1.81	4.77	4.04	3.52
Earnings Yield	3.36%	-20.97%	6.71%	11.12%	6.83%	8.52%
Debt/Equity	0.00	0.02	0.70	0.84	0.40	0.57
Cash Flow (\$/share)	1.08	-1.03	7.01	4.39	7.80	4.11
Growth Score	C	-	-	B	C	F
Hist. EPS Growth (3-5 yrs)	164.77%	18.12%	10.92%	20.53%	0.76%	8.48%
Proj. EPS Growth (F1/F0)	-45.10%	5.05%	1.02%	30.83%	8.89%	-5.17%
Curr. Cash Flow Growth	-26.95%	12.51%	5.93%	36.74%	4.27%	-6.57%
Hist. Cash Flow Growth (3-5 yrs)	27.52%	8.83%	8.55%	22.46%	7.11%	2.54%
Current Ratio	7.08	4.82	1.24	1.60	1.04	0.88
Debt/Capital	0.00%	4.30%	42.33%	45.63%	28.42%	36.17%
Net Margin	33.17%	-227.76%	11.67%	13.15%	24.73%	31.44%
Return on Equity	20.83%	-64.84%	16.70%	31.85%	23.39%	27.01%
Sales/Assets	0.56	0.20	0.54	0.38	0.39	0.32
Proj. Sales Growth (F1/F0)	-7.76%	9.11%	1.54%	59.79%	5.64%	-11.39%
Momentum Score	D	-	-	D	D	D
Daily Price Chg	1.15%	0.36%	1.45%	0.71%	3.30%	3.53%
1 Week Price Chg	13.73%	7.41%	12.29%	9.07%	9.47%	6.51%
4 Week Price Chg	-13.19%	-23.83%	-21.33%	-8.74%	-2.58%	-7.30%
12 Week Price Chg	-10.63%	-28.80%	-28.56%	-15.65%	-11.79%	-15.48%
52 Week Price Chg	-30.86%	-40.30%	-22.55%	18.30%	-11.27%	-23.09%
20 Day Average Volume	3,729,454	272,977	4,257,668	20,089,704	3,847,415	43,242,428
(F1) EPS Est 1 week change	0.00%	0.00%	-0.04%	0.00%	-0.59%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	-4.30%	0.03%	-0.59%	-2.30%
(F1) EPS Est 12 week change	-36.36%	-1.42%	-5.47%	0.63%	0.60%	8.15%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	-5.91%	-2.27%	-2.08%	-4.38%

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	C
Momentum Score	D
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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