Exelixis, Inc.(EXEL)

$20.25 (As of 02/13/20)

Price Target (6-12 Months): **$22.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 10/03/19) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:D
	Value: C | Growth: D | Momentum: F	

Summary

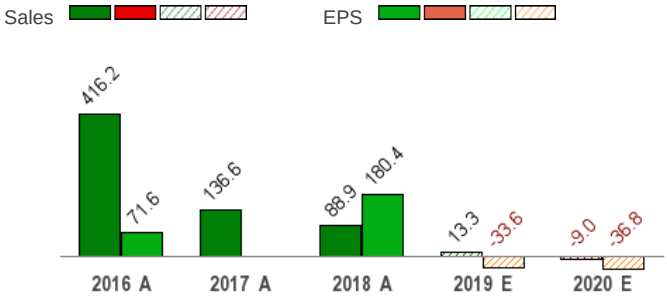
Exelixis' lead drug, Cabometyx, continues to gain traction in both indications — RCC and HCC. While demand for the RCC indication has been strong, the initial traction for the HCC indication in second and third-line settings was encouraging. The company is on track to expand cabozantinib's label further and the drug is already being evaluated in various studies with Roche's immuno-oncology drug, Tecentriq, and Bristol-Myers Squibb Company's Opdivo. Successful outcomes from the ongoing studies should boost demand further. 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. Shares have underperformed the industry in the past year.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$25.31 - $15.02**
20 Day Average Volume (sh)	**3,116,880**
Market Cap	**$6.2 B**
YTD Price Change	**14.9%**
Beta	**1.93**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 29% (73 out of 255)**
Last EPS Surprise	**55.0%**
Last Sales Surprise	**19.0%**
EPS F1 Est- 4 week change	**-15.0%**
Expected Report Date	**02/25/2020**
Earnings ESP	**-18.6%**
P/E TTM	**16.9**
P/E F1	**33.8**
PEG F1	**0.7**
P/S TTM	**6.4**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	221 E	232 E	236 E	253 E	881 E
2019	215 A	240 A	272 A	241 E	968 E
2018	212 A	186 A	225 A	229 A	854 A

EPS Estimates

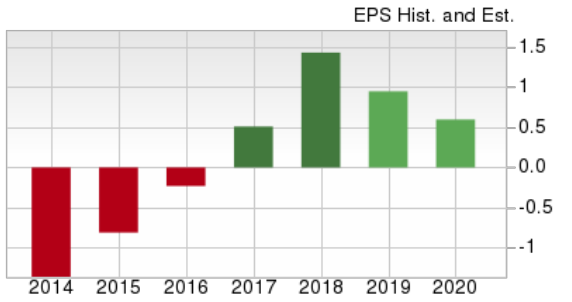
	Q1	Q2	Q3	Q4	Annual*
2020	$0.16 E	$0.17 E	$0.17 E	$0.19 E	$0.60 E
2019	$0.27 A	$0.25 A	$0.31 A	$0.15 E	$0.95 E
2018	$0.37 A	$0.28 A	$0.41 A	$0.37 A	$1.43 A

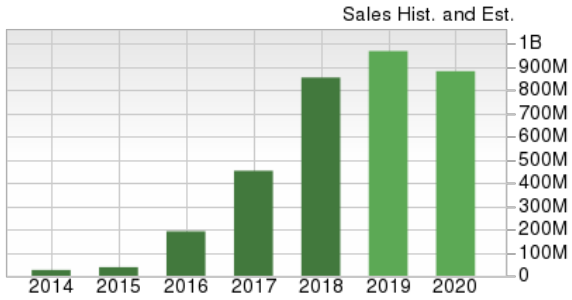
*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 02/13/2020. The reports text is as of 02/14/2020.

Overview

San Francisco, CA-based Exelixis, Inc. is an oncology-focused biotechnology company that aims to accelerate the discovery, development and commercialization of new medicines 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 Minnebro (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 2018 came in at $853.8 million, up from $452.5 million in 2017.

Reasons To Buy:

> 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.

- **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. 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. Cabometyx has already grabbed market share from key drugs — Sutent and Afinitor — in the first-line RCC. Meanwhile, Exelixis' European partner, Ipsen, also obtained approval for the drug in Europe for the first-line treatment of adults with intermediate- or poor-risk advanced RCC. The approval has broadened the geographic reach of the drug and targeted patient population.

  In addition, Exelixis and partner Ipsen also obtained EC approval for Cabometyx as a monotherapy for hepatocellular carcinoma (HCC) in adults who have previously been treated with Bayer's Nexavar. In January, the FDA also approved Cabometyx for HCC. Per estimates, more than 40,000 patients are diagnosed with liver cancer resulting in approximately 29,000 deaths each year in the United States. Sales should get a boost from this label expansion, given the market potential.

- **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 45 clinical studies across multiple indications. In April, CheckMate 9ER, the phase III trial evaluating the combination of cabozantinib and Opdivo compared with Sutent in patients with previously-untreated advanced or metastatic RCC, completed enrollment. Exelixis also initiated a multicenter, randomized, double-blinded, controlled phase III study, COSMIC-313 evaluating cabozantinibin combination with Opdivo and Yervoy as compared to Opdivo and Yervoyin in patients with previously untreated advanced RCC.

- **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.

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 Q3 Earnings Beat on Strong Cabometyx Sales

Quarter Ending	09/2019
Report Date	Oct 30, 2019
Sales Surprise	18.97%
EPS Surprise	55.00%
Quarterly EPS	0.31
Annual EPS (TTM)	1.20

Exelixis delivered better-than-expected results for third-quarter 2019, wherein both earnings and revenues beat estimates on strong performance by Cabometyx.

Exelixis reported earnings of 31 cents, easily beating the Zacks Consensus Estimate of 20 cents. However, the bottom line declined from 41 cents in the year-ago quarter.

Net revenues came in at $271.7 million, increasing from $225.4 million in the year-ago quarter and surpassing the Zacks Consensus Estimate of $228.38 million.

Quarter in Detail

Net product revenues came in at $191.8 million, up 17.7% from the year-ago quarter, driven by 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. The label expansion of the drug for this indication in the United States also boosted sales.

The drug generated $187.4 million of revenues. Patient demand grew 14% year over year but declined 4% sequentially. Prescriber base grew by 40% year over year and 7% sequentially.

Cometriq (cabozantinib capsules), for the treatment of medullary thyroid cancer, generated $4.4 million in net product revenues.

Total collaboration revenues were $79.9 million, up from $62.5 million in the year-ago quarter, primarily owing to the recognition of a $50.0 million milestone from Exelixis' collaboration with Ipsen Pharma SAS for the achievement of $250.0 million of net sales from cabozantinib in its territories over four consecutive fiscal quarters.

In the reported quarter, research and development expenses more than doubled to $97.3 million due to increases in clinical trial costs, license and other collaboration costs, and personnel expenses. Selling, general and administrative (SG&A) expenses were $51.3 million, up 6.6% year over year, driven by increase in personnel expenses and stock-based compensation.

Pipeline Update

The pipeline progress in the year so far has been encouraging.

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 the same month, Exelixis amended the protocol for COSMIC-021, the phase Ib trial of cabozantinib in combination with Roche's Tecentriq (atezolizumab) in patients with locally advanced or metastatic solid tumors. Based on preliminary encouraging activity and safety data, the original immunotherapy-refractory non-small cell lung cancer and metastatic castration-resistant prostate cancer (CRPC) cohorts were expanded to 80 patients each. Additionally, four new cohorts — two expansion and two exploratory — in metastatic CRPC settings were included in the trial.

In October, Ipsen announced Health Canada's approval of Cabometyx for the first-line treatment of adults with advanced RCC. Hence, Exelixis is eligible to receive a milestone payment of $3.0 million, which will be recognized as revenues in the fourth quarter of 2019.

In October, the company filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc, following the receipt of a Paragraph IV certification notice letter from the latter stating that it had filed an ANDA with the FDA requesting the approval to market a generic version of Cabometyx tablets, following the expiration of the Cabometyx composition of matter patent — U.S. Patent No. 7,579,473 — which expires on Aug 14, 2026. Per Exelixis, the effective date of any FDA approval for the ANDA would be a date not earlier than the expiration of U.S. Patent No. 8,877,776 on Oct 8, 2030.

2019 Guidance

R&D expenses are now expected around $350 million (previous guidance: between $330 million and $350 million) and SG&A expenses around $240 million (previous guidance: between $220 million and $240 million).

Recent News

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 Ib 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 up 18.6% in the year-to-date period but down 6.3% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are up 0.1% and 1.9% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 3.2% but the sector is up 3.1%.

The S&P 500 index is up 4.7% in the year-to-date period and up 22% in the past year.

The stock is currently trading at 6.42X trailing 12-month sales per share, which compares to 2.99X for the Zacks sub-industry, 2.84X for the Zacks sector and 3.57X 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 10.95X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $22 price target reflects 6.97X 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	6.42	2.99	2.84	3.57
	5-Year High	24.16	2.99	3.83	3.57
	5-Year Low	4.45	2.01	2.45	2.54
	5-Year Median	10.95	2.56	2.96	3
P/B TTM	Current	3.84	3.86	4.62	4.35
	5-Year High	131.3	5.79	5.04	4.42
	5-Year Low	-19.2	2.43	3.44	2.85
	5-Year Median	4.83	3.27	4.31	3.62

As of 02/13/2020

Industry Analysis **Zacks Industry Rank:** Top 29% (73 out of 255)

Top Peers

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

Industry Comparison Industry: Medical - Biomedical And Genetics

Industry Peers

	EXEL Neutral	X Industry	S&P 500	BMY Outperform	NVS Neutral	PFE Outperform
VGM Score	D	-	-	A	B	D
Market Cap	6.15 B	204.63 M	24.56 B	107.66 B	224.07 B	204.38 B
# of Analysts	4	3	13	4	5	4
Dividend Yield	0.00%	0.00%	1.78%	2.72%	1.88%	4.12%
Value Score	C	-	-	B	B	B
Cash/Price	0.13	0.22	0.04	0.30	0.05	0.04
EV/EBITDA	11.78	-3.70	14.00	15.07	15.06	12.66
PEG Ratio	0.76	1.96	2.10	1.29	2.01	3.01
Price/Book (P/B)	3.84	3.89	3.31	6.06	4.03	3.12
Price/Cash Flow (P/CF)	13.34	14.07	13.68	11.74	12.53	9.58
P/E (F1)	34.73	33.52	19.23	10.85	17.10	13.38
Price/Sales (P/S)	6.44	14.15	2.69	4.12	4.72	3.95
Earnings Yield	2.96%	-15.43%	5.20%	9.22%	5.85%	7.47%
Debt/Equity	0.01	0.02	0.71	1.37	0.40	0.55
Cash Flow ($/share)	1.52	-1.07	6.92	5.63	7.80	3.86
Growth Score	D	-	-	A	C	F
Hist. EPS Growth (3-5 yrs)	219.12%	16.51%	10.85%	20.53%	0.76%	8.48%
Proj. EPS Growth (F1/F0)	-36.94%	7.05%	7.17%	29.80%	9.08%	-6.44%
Curr. Cash Flow Growth	180.36%	19.01%	8.56%	28.20%	4.27%	-12.32%
Hist. Cash Flow Growth (3-5 yrs)	31.20%	7.72%	8.36%	20.89%	7.11%	1.24%
Current Ratio	6.89	5.09	1.23	3.83	1.04	0.90
Debt/Capital	1.46%	3.97%	42.91%	57.87%	28.42%	35.53%
Net Margin	64.05%	-209.62%	11.81%	13.15%	24.73%	31.44%
Return on Equity	25.55%	-64.11%	16.86%	48.97%	23.39%	27.23%
Sales/Assets	0.60	0.20	0.54	0.53	0.39	0.32
Proj. Sales Growth (F1/F0)	-3.19%	16.39%	3.85%	59.81%	6.74%	-10.93%
Momentum Score	F	-	-	B	C	A
Daily Price Chg	0.75%	-0.26%	0.00%	-1.37%	-1.25%	-2.15%
1 Week Price Chg	10.58%	1.53%	2.47%	5.24%	1.40%	2.18%
4 Week Price Chg	-0.93%	-2.69%	0.56%	-1.05%	2.81%	-9.06%
12 Week Price Chg	23.85%	13.36%	6.96%	16.24%	8.00%	-2.15%
52 Week Price Chg	-9.19%	-7.74%	16.68%	30.00%	9.83%	-12.01%
20 Day Average Volume	3,116,880	195,889	2,020,569	12,950,735	2,169,082	25,314,646
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.78%	0.35%	0.00%
(F1) EPS Est 4 week change	-14.96%	0.00%	-0.05%	1.03%	0.81%	5.34%
(F1) EPS Est 12 week change	-22.50%	0.00%	-0.17%	13.69%	-0.80%	6.91%
(Q1) EPS Est Mthly Chg	-11.32%	0.00%	-0.24%	-0.22%	NA	NA

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	C
Growth Score	D
Momentum Score	F
VGM Score	D

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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