Momentum: F



Exelixis, Inc.(EXEL) \$18.59 (As of 02/28/20) Price Target (6-12 Months): \$20.00 Short Term: 1-3 Months Long Term: 6-12 Months (Since: 10/03/19) Prior Recommendation: Outperform Zacks Rank: (1-5) Zacks Style Scores: VGM:D

Summary

Exelixis' earnings beat estimates in the fourth quarter, while sales fell short of the same by a whisker. Its 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



Value: C

Growth: C

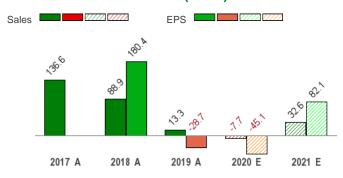
Data Overview

P/S TTM

\$25.31 - \$15.02
3,485,554
\$5.7 B
5.5%
1.93
\$0.00 / 0.0%
Medical - Biomedical and Genetics
Top 38% (96 out of 254)

Last EPS Surprise 46.7% Last Sales Surprise -0.2% EPS F1 Est- 4 week change -4.7% Expected Report Date NA Earnings ESP -13.3% P/E TTM 17.7 P/E F1 33.2 PEG F1 0.7		
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P/E TTM 17.7 P/E F1 33.2	Expected Report Date	NA
P/E F1 33.2	Earnings ESP	-13.3%
P/E F1 33.2		
.,	P/E TTM	17.7
PEG F1 0.7	P/E F1	33.2
	PEG F1	0.7

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	295 E	304 E	321 E	332 E	1,184 E
2020	218 E	229 E	234 E	250 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 02/28/2020. The reports text is as of 03/02/2020.

5.9

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.

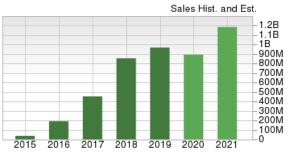
The company has four approved drugs in its portfolio. Of these, two are derived from cabozantinib, the company's flagship molecule, which an inhibitor of multiple tyrosine kinases, including MET, AXL, VEGF receptors and RET. The approved drugs are Cabometyx (cabozantinib) tablets approved for advanced 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, nonsteroidal, 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.

EPS Hist. and Est.

1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
-0.2
-0.4
-0.6
2015 2016 2017 2018 2019 2020 2021



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 antiangiogenic 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. In October 2019, Exelixis' partner 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 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. 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 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.

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)	1.02

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 lb 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

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 carringma

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 lb 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 5.5% in the year-to-date period but down 17.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 4.5% and 8.2% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 11.5% and 4.9%.

The S&P 500 index is down 8.3% in the year-to-date period but up 4.9% in the past year.

The stock is currently trading at 6.07X trailing 12-month sales per share, which compares to 2.99X for the Zacks sub-industry, 2.57X for the Zacks sector and 3.12X 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 10.81X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$20 price target reflects 6.53X 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
	Current	6.07	2.99	2.57	3.12
P/S F12M	5-Year High	24.16	2.99	3.84	3.43
	5-Year Low	4.45	2.03	2.45	2.54
	5-Year Median	10.81	2.57	2.97	3.01
	Current	4.21	3.69	4.21	3.96
P/B TTM	5-Year High	5.05	5.8	5.05	4.54
	5-Year Low	3.44	2.44	3.44	2.85
	5-Year Median	4.32	3.28	4.32	3.62

As of 02/28/2020

Industry Analysis Zacks Industry Rank: Top 38% (96 out of 254)

■ Industry Price Industry ■ Price 16 30 14 25 12 -20 10 15 8 10 6 2020 0 2016 2018 2017 2019

Top Peers

Pfizer Inc. (PFE)	Outperform
AVEO Pharmaceuticals, Inc. (AVEO)	Neutral
Bayer Aktiengesellschaft (BAYRY)	Neutral
Bristol-Myers Squibb Company (BMY)	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 Neutral	NVS Neutral	PFE Outperform
VGM Score	D	-	-	В	В	G
Market Cap	5.68 B	184.62 M	21.48 B	96.23 B	192.42 B	184.95
# of Analysts	4	3	13	5	5	
Dividend Yield	0.00%	0.00%	2.07%	3.05%	2.19%	4.55%
Value Score	С	-	-	В	В	В
Cash/Price	0.12	0.21	0.04	0.30	0.05	0.0
EV/EBITDA	10.69	-3.13	12.57	16.21	13.03	11.6
PEG Ratio	0.73	1.71	1.84	1.14	1.72	2.6
Price/Book (P/B)	3.37	3.68	2.88	1.86	3.46	2.83
Price/Cash Flow (P/CF)	17.15	12.02	11.58	9.84	10.76	8.6
P/E (F1)	33.48	32.67	16.87	9.63	14.63	11.9
Price/Sales (P/S)	5.87	13.67	2.34	3.68	4.06	3.5
Earnings Yield	3.01%	-16.34%	5.91%	10.38%	6.84%	8.38%
Debt/Equity	0.00	0.02	0.70	0.84	0.40	0.5
Cash Flow (\$/share)	1.08	-1.08	6.94	6.00	7.80	3.8
Growth Score	С	-	-	В	С	F
Hist. EPS Growth (3-5 yrs)	219.12%	18.80%	10.85%	20.53%	0.76%	8.48%
Proj. EPS Growth (F1/F0)	-45.10%	5.24%	6.79%	30.79%	9.54%	-5.17%
Curr. Cash Flow Growth	-27.41%	13.73%	5.92%	36.74%	4.27%	-12.32%
Hist. Cash Flow Growth (3-5 yrs)	31.20%	8.23%	8.38%	20.89%	7.11%	1.24%
Current Ratio	7.08	4.93	1.23	1.60	1.04	0.9
Debt/Capital	0.00%	4.19%	42.53%	45.63%	28.42%	35.53%
Net Margin	33.17%	-226.92%	11.57%	13.15%	24.73%	31.449
Return on Equity	20.83%	-66.46%	16.80%	31.85%	23.39%	27.23%
Sales/Assets	0.56	0.20	0.54	0.38	0.39	0.3
Proj. Sales Growth (F1/F0)	-5.38%	15.54%	4.07%	59.81%	6.74%	-10.93%
Momentum Score	F	-	-	С	C	D
Daily Price Chg	0.92%	0.00%	-1.44%	-0.87%	-2.39%	-1.99%
1 Week Price Chg	1.54%	0.69%	-0.94%	-1.13%	-0.89%	-2.16%
4 Week Price Chg	8.08%	-6.31%	-10.98%	-7.44%	-12.47%	-9.85%
12 Week Price Chg	8.40%	0.00%	-7.84%	-0.71%	-8.38%	-12.12%
52 Week Price Chg	-16.97%	-18.12%	1.20%	14.32%	-7.97%	-22.91%
20 Day Average Volume	3,485,554	189,577	2,169,477	11,925,315	2,384,555	26,315,67
(F1) EPS Est 1 week change	-4.69%	0.00%	0.00%	-0.31%	0.00%	0.00%
(F1) EPS Est 4 week change	-4.69%	0.00%	-0.09%	1.30%	1.20%	2.35%
(F1) EPS Est 12 week change	-26.14%	0.00%	-0.24%	2.76%	0.31%	8.15%
(Q1) EPS Est Mthly Chg	-2.98%	0.00%	-0.72%	-2.33%	NA	N.

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	С
Growth Score	C
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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