

Vertex Pharmaceuticals (VRTX)

\$234.15 (As of 01/15/20)

Price Target (6-12 Months): **\$246.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 12/20/19)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:B

Value: C

Growth: B

Momentum: B

Summary

Consistent approval for Vertex's cystic fibrosis (CF) drugs to treat younger patients is driving sales growth. The rapid approval of its triple combo CF regimen, Trikafta, was a big boost for Vertex. The regimen is crucial for long-term growth as it has the potential to treat up to 90% of CF patients. Also, reimbursement approval in England and France for Vertex's CF drugs removes a key overhang for the stock. Meanwhile, Vertex's non-CF pipeline is progressing rapidly with data in multiple diseases expected in 2020. However, competitive pressure is rising in the CF market. Also, Vertex's dependence on just the CF franchise for growth is a concern. Stock has outperformed the industry in the past year. Estimates have gone up slightly ahead of Q4 earnings. Vertex has a positive record of earnings surprises in the recent quarters.

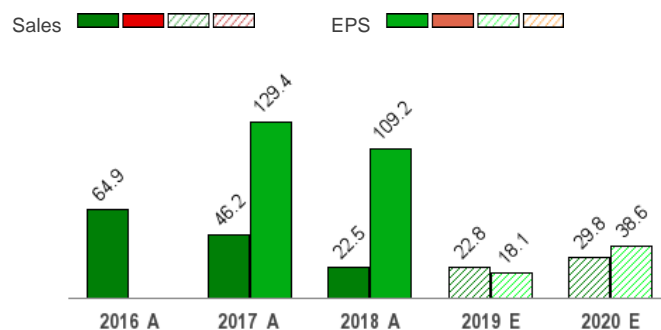
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$235.78 - \$163.68
20 Day Average Volume (sh)	1,118,162
Market Cap	\$60.2 B
YTD Price Change	6.9%
Beta	1.47
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Biomedical and Genetics
Zacks Industry Rank	Top 34% (87 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	7.9%
Last Sales Surprise	-0.3%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	02/04/2020
Earnings ESP	-3.0%
P/E TTM	47.5
P/E F1	35.1
PEG F1	1.2
P/S TTM	16.6

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2020	1,086 E	1,227 E	1,331 E	1,428 E	4,860 E
2019	858 A	941 A	950 A	996 E	3,744 E
2018	641 A	752 A	785 A	870 A	3,048 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	\$1.34 E	\$1.61 E	\$1.82 E	\$2.00 E	\$6.68 E
2019	\$1.14 A	\$1.26 A	\$1.23 A	\$1.20 E	\$4.82 E
2018	\$0.76 A	\$0.94 A	\$1.09 A	\$1.30 A	\$4.08 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 01/15/2020. The reports text is as of 01/16/2020.

Overview

Boston, MA-based Vertex Pharmaceuticals Incorporated is focused on the discovery, development, and commercialization of small molecule drugs targeting serious diseases. The company's main area of focus is cystic fibrosis (CF).

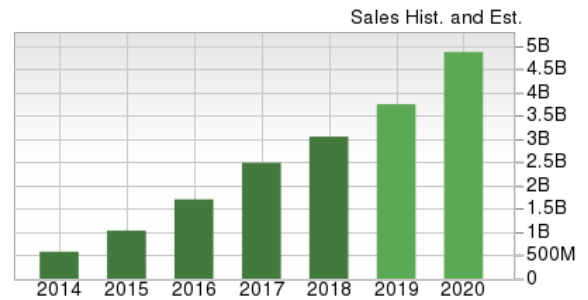
The company's lead marketed products are Symdeko/Symkevi (tezacaftor in combination with ivacaftor), Orkambi (lumacaftor in combination with ivacaftor) and Kalydeco (ivacaftor), which are collectively approved to treat around 50% of the 75,000 CF patients in North America, Europe and Australia. Symdeko was approved by the FDA in February 2018 and Symkevi (brand name of Symdeko in EU) was approved in the European Union in November 2018.

Vertex's CF pipeline is quite strong. Vertex evaluated two next-generation CFTR correctors (VX-659 and VX-445) in phase III studies as part of a triple combination with tezacaftor and ivacaftor. It chose VX-445 triple combination regimen for regulatory submissions and filed a new drug application (NDA) for the same in July 2019. The triple-combo regimen (elexacaftor/tezacaftor/ivacaftor and ivacaftor) was approved by the FDA in October 2019 for the treatment of CF in people aged 12 years and older who have at least one F508del mutation and will be marketed by the trade name of Trikafta. With approval of Trikafta, Vertex can address a significantly larger CF patient population — almost 90% of patients with CF — in the future.

While CF remains the main area of focus, Vertex is also developing treatments for sickle cell disease, thalassemia and pain management.

Pimodivir/VX-787, for the treatment of influenza, was out-licensed to Janssen in 2014 while oncology candidates VX-970, VX-984 and VX-803 were divested to Merck KGaA in 2017.

The company recorded total revenues of \$3.05 billion in 2018, up 22.5%. While Orkambi accounted for around 41% of the company's total revenues, Kalydeco accounted for 33% and Symdeko accounted for 25%.



Reasons To Buy:

▲ **Shares Outperforming Industry:** In the past one year, Vertex's shares have gained 25.7% against a decrease of 1.3% for the industry.

▲ **Consistent Rise in CF Product Sales:** Consistent positive regulatory approvals have led to an increase in the eligible patient population for Vertex's approved medicines in the past 2-3 years. In 2019 alone, Vertex received nine new regulatory approvals or label expansions for its CF medicines globally. With consistent expansion in patient population and additional ex-U.S. reimbursement arrangements, Vertex's CF product revenues rose 29% in 2017, 40% in 2018 and 26% in the first nine months of 2019. With the approval of Trikafta, approximately 45,000 patients worldwide are now eligible to be treated with one of Vertex's four CF medicines. Vertex believes that revenue growth in 2020 will be primarily driven by the uptake of Trikafta.

The rapid approval of Vertex's triple combo CF pill, Trikafta, was a big boost. Reimbursement approval in England for its CF drugs removed a key overhang.

▲ **Strong CF Portfolio:** The CF market represents huge commercial potential. It is a rare, life-threatening disease estimated to affect about 75,000 people in North America, Europe and Australia. Vertex enjoys a strong position in this market, being the first company to successfully develop a drug (Kalydeco) that treats the underlying cause of CF.

Kalydeco's sales rose 11% in 2016, 20% in 2017 and 19% in 2018. Vertex is looking to get Kalydeco approved in additional patient populations and is studying it in combination with other CF candidates.

In July 2015, Vertex gained approval for its second CF treatment – Orkambi for the treatment of the underlying cause of CF in patients with two copies of the F508del mutation. This is the most common form of the disease. Orkambi gained EU approval in November 2015.

Vertex gained FDA approval for its third medicine to treat the underlying cause of CF, Symdeko, which is a combination of tezacaftor and ivacaftor in February 2018. Symdeko, in a very short time, has become the primary driver of CF revenues. In June 2019, Vertex gained FDA approval for Symdeko in eligible patients as young as six years of age. This label expansion coupled with launch of Symkevi in additional European countries further boosted sales in the third quarter of 2019 with the positive trend expected to continue into the fourth quarter.

Vertex expects to consistently expand the number of eligible patients with several ongoing label expansion studies.

▲ **Strong CF Pipeline:** The company is developing many new combination regimens with CFTR modulators. The CF correctors could bring in multi-billion dollar sales for Vertex.

Vertex evaluated two next-generation CFTR correctors (VX-659 and VX-445) in phase III studies as part of a triple combination with tezacaftor and ivacaftor. Vertex evaluated both the combinations in two separate studies for F508del/Min and F508del homozygous patients.

Phase III studies on both VX-659 and VX-445 (elexacaftor) combination regimens met the primary endpoint showing significant improvements in lung function. However, Vertex chose the VX-445 triple combination regimen for regulatory submission based on detailed analysis of multiple factors, which showed that the regimen will be beneficial for a larger patient population compared to the VX-665 combo.

The VX-445 combination regimen called Trikafta was approved by the FDA five months ahead of the scheduled PDUFA date in March 2020. In the EU, a regulatory application for the VX-445 combination regimen is under review. With the approval of the triple-combo regime, Vertex can address a significantly larger CF patient population — almost 90% of patients with CF — in the future. Meanwhile, phase III studies are also ongoing to evaluate VX-445 triple combination regimens in children with CF ages 6 through 11 for F508del/Min as well as F508del homozygous patients.

In 2017, Vertex bought Concert Pharmaceuticals' CF pipeline candidate, VX-561 (previously CTP-656). A phase II dose ranging study is ongoing to evaluate VX-561 to support potential phase III development of VX-561 in a once-daily triple combination regimen. Vertex has initiated another phase II study evaluating the next-generation corrector, VX-121, in triple combination with VX-561 and tezacaftor as a potential once-daily triple combination regimen.

▲ **Upside Potential from Non-CF Pipeline:** While Vertex's main focus is on the development and strengthening of its CF franchise, the company also has a rapidly advancing early-stage portfolio in five other specialty disease areas like pain, alpha-1 antitrypsin deficiency (AAT), sickle cell disease, beta-thalassemia and APOL1-mediated kidney diseases.

In pain, Vertex demonstrated proof-of-concept across multiple phase II studies of Nav1.8 inhibitor, VX-150, in acute, neuropathic and musculoskeletal pain conditions. Vertex advanced another molecule (VX-961) to phase I study for various pain indications in 2019.

Vertex is also co-developing a gene editing treatment, CTX001 in partnership with CRISPR Therapeutics in two devastating diseases — sickle cell disease and thalassemia. Phase I/II studies of CTX001 in adult transfusion-dependent b-thalassemia in Europe and sickle cell disease in the United States are ongoing. First safety and efficacy data from the studies were positive. In June, Vertex announced expansion of its collaboration with CRISPR Therapeutics and acquisition of privately held Exonics Therapeutics to boost its gene editing capabilities to develop novel therapies for Duchenne muscular dystrophy ("DMD") and Myotonic dystrophy type 1 (DM1).

Also, Vertex moved the first oral small molecule corrector, VX-814, for the treatment of AAT in a phase I study in December 2018 while a second molecule, VX-864 entered clinical development in 2019. Both VX-814 and VX-864 have received Fast-Track Designation from the FDA. Vertex is conducting a phase I study on VX-147, its first oral small molecule medicine for kidney diseases that are APOL1-mediated like focal segmental glomerulosclerosis (FSGS). Data from the study is expected in 2020.

Vertex is also looking for early stage companies and products or intellectual property acquisitions that could help it broaden its pipeline beyond CF.

▲ **Collaborations Broadening Pipeline:** Vertex's success in CF has given it the financial strength to invest in both internal and external

innovation. Vertex has entered into multiple agreements in the past couple of years to provide it with access to new external scientific technologies, programs and expertise in multiple diseases to complement its internal pipeline. It has such collaborations with CRISPR Therapeutics, Arbor Biotechnologies, Moderna Therapeutics, Merck KGaA, Genomics Plc and X-Chem. Vertex also owns equity investments in CRISPR and Moderna. Vertex plans to pursue more business development transactions to bolster its pipeline for serious diseases with multiple modalities and technologies.

In October 2019, Vertex acquired Semma Therapeutics to develop a cellular therapy that both alone and in combination with an implantable device has the potential to cure type I diabetes. In 2019, Vertex invested approximately \$1.5 billion in cash in external innovation through new acquisitions and collaborations.

Reasons To Sell:

- ▼ **Trikafta Launch May Cannibalize Sales of Other Drugs:** On third-quarter conference call, management said that a large proportion of patients currently on Kalydeco, Orkambi or Symdeko will switch to Trikafta over time. We expect that once Trikafta is fully launched in the United States and EU and gains necessary reimbursement approvals in EU, there will be a rapid erosion of existing combinations.
- ▼ **Competing Therapies in Development:** Several companies like AbbVie, Elox Pharmaceuticals, ProQR Therapeutics and Proteostasis Therapeutics are developing medicines to treat CF. Among these, AbbVie and Proteostasis Therapeutics are developing triple CFTR combinations for CF, which can pose competition to Vertex's triple combos.

Even though Vertex enjoys a strong position in this market, the entry of additional competition would cut into revenues.

- ▼ **Banking on CF Franchise:** Although we are positive on Vertex's decision to focus on the CF franchise, we remain concerned about the company's dependence on just this franchise for growth. While the company does have other pipeline candidates targeting other therapeutic areas, it is too early to get excited about them.
- ▼ **Pipeline/Regulatory Setbacks:** Vertex has several studies ongoing with its CF product candidates and any negative development on the pipeline/regulatory front will have an adverse impact on shares. In October 2017, Vertex announced that it will not file regulatory applications for VX-661 - ivacaftor combination in CF patients with one copy of the F508del mutation and one copy of a gating mutation, as a phase III study evaluating VX-661 — ivacaftor use in such patients failed to meet the primary endpoint.

In October 2018, Vertex discontinued development of VX-210 (acute cervical spinal cord injuries) due to futility.

Vertex's dependence on just the CF franchise for growth is concerning. Moreover, several other companies are working on bringing their CF products to market.

Last Earnings Report

Vertex Q3 Earnings Beat, Revenues Lag Estimates

Vertex's third-quarter 2019 earnings per share of \$1.23 beat the Zacks Consensus Estimate of \$1.14. Moreover, earnings rose 13% year over year driven by higher product sales, which made up for higher costs and taxes.

Revenues of \$949.2 million missed the Zacks Consensus Estimate of \$952 million. Sales increased 21.1% year over year, primarily driven by higher CF product sales helped by global patient growth for its medicines. Meanwhile, expansion into pediatric patient populations for Orkambi and Symdeko also contributed to revenue growth.

Quarter Ending **09/2019**

Report Date	Oct 30, 2019
Sales Surprise	-0.25%
EPS Surprise	7.89%
Quarterly EPS	1.23
Annual EPS (TTM)	4.93

CF Franchise Sales Strong

Vertex's third-quarter revenues comprised only CF product revenues. The company did not record any collaborative and royalty revenues during the reported quarter.

Symdeko/Symkevi generated sales of \$404 million in the reported quarter, reflecting an increase of 58.4% year over year due to patient growth in both the United States and EU and the drug's U.S. label expansion approval to treat pediatric CF patients. In ex-U.S. markets, Symkevi sales were \$55 million in the quarter compared with \$46.1 million in the second quarter.

Kalydeco generated sales of \$249 million in the quarter, reflecting an increase of 1.2% year over year.

Orkambi generated sales of \$297 million in the quarter, reflecting an increase of 5.3% year over year. The company entered into new reimbursement agreements for Orkambi and Symkevi in England, Spain, Australia, and Scotland in September/October 2019, which should drive outside U.S. revenue growth in future quarters.

On third-quarter conference call, management stated that the first patients were already prescribed Trikafta by the physicians. The company said that a large proportion of patients currently on Kalydeco, Orkambi or Symdeko will switch to Trikafta over time.

Costs Rise

Adjusted operating income rose 37% to \$403 million in the quarter driven by higher revenues and disciplined spending, which was partially offset by increased income taxes.

Adjusted research and development (R&D) expenses rose 5.8% to \$290 million in the third quarter due to expansion of CF and non-CF pipeline. Adjusted selling, general and administrative (SG&A) expenses escalated 20.9% to \$127 million in the reported quarter due to investments made in supporting CF patients' treatment, globally.

2019 Revenue Guidance

Vertex maintained its 2019 outlook for sales from CF products and the combined operating costs.

The company expects total revenues for CF products in the range of \$3.70-3.75 billion, unchanged from prior expectations. The midpoint of the revenue guidance reflects 23% growth over 2018 revenues.

On FDA approval of Trikafta on Oct 21, the company raised its CF revenue guidance to \$3.70-3.75 billion from \$3.60-3.70 billion issued during the second quarter of 2019. In the fourth quarter of 2019, product revenues are expected to be higher due to the U.S. approval of Trikafta.

Moreover, combined adjusted research and development (R&D) plus selling, general and administrative (SG&A) expenses in 2019 are anticipated in the band of \$1.65-\$1.70 billion, unchanged from the previous view.

Initial 2020 Outlook

In 2020, Vertex expects significant revenue growth, driven primarily by the launch of Trikafta in the United States. Meanwhile, rate of growth of operating expenses will be somewhat higher than Vertex's normal range of 10% to 14% per year as it increases investments behind the pipeline.

Recent News

Amendment to Reimbursement Deal in Ireland – Dec 13

Vertex announced that it has negotiated an agreement with the Republic of Ireland to expand the existing long-term CF reimbursement agreement to include the triple combination regimen (elexacaftor, tezacaftor and ivacaftor). The triple combo regimen is under review and pending approval by the European Medicines Agency.

Kalydeco Gets EU Approval in Infants – Dec 10

Vertex announced that the European Commission has granted marketing authorization to Kalydeco for expanded use in infants aged from six to less than 12 months with at least one of specified nine mutations in the CFTR gene. The approval was based on data from an ongoing open-label phase III study, ARRIVAL, which evaluated children aged less than 24 months with a CFTR gating mutation

Gets French Reimbursement for CF Drug Orkambi – Nov 20

Vertex announced an agreement with the French Authorities for national reimbursement of Orkambi to treat patients aged above 2 years with two copies of the F508del mutation. Management stated that once the agreement gets published in the French Official Journal, Orkambi will be available for all eligible patients. The French reimbursement for Orkambi removes a key overhang from the stock as France was among the last nations with large CF patient populations not getting a formalized reimbursement for Orkambi.

Valuation

Vertex's shares are up 25.7% in the trailing 12-month period. While stocks in the Zacks sub-industry are down 1.3%, those in the sector are up 5.2% over the past year. The S&P 500 Index is up 24.5% in the past year.

The stock is currently trading at 16.85X trailing 12-month sales per share, which compares to 2.84X for the Zacks sub-industry, 3.14X for the Zacks sector and 3.55X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 55.11X and as low as 10.62X, with a 5-year median of 16.12X. Our Neutral recommendation indicates that the stock will perform in-line the market. Our \$246 price target reflects 17.7X forward 12-month sales per share.

Valuation Multiples - VRTX					
		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	16.85	2.84	3.14	3.55
	5-Year High	55.11	4.96	4.14	3.65
	5-Year Low	10.62	2.1	2.69	2.51
	5-Year Median	16.12	2.64	3.26	3.15
P/B TTM	Current	11.46	3.9	4.54	4.49
	5-Year High	33.17	5.71	5.02	4.49
	5-Year Low	8.16	2.41	3.42	2.85
	5-Year Median	17.97	3.24	4.28	3.61

As of 1/15/2020

Industry Analysis Zacks Industry Rank: Top 34% (87 out of 254)



Top Peers

Pfizer Inc. (PFE)	Outperform
Proteostasis Therapeutics, Inc. (PTI)	Outperform
AbbVie Inc. (ABBV)	Neutral
Senesco Technologies Inc. (ELOX)	Neutral
Merck & Co., Inc. (MRK)	Neutral
Novartis AG (NVS)	Neutral
ProQR Therapeutics N.V. (PRQR)	Neutral
Translate Bio, Inc. (TBIO)	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	VRTX Neutral	X Industry	S&P 500	ABBV Neutral	PRQR Neutral	PTI Outperform
VGM Score	B	-	-	A	F	F
Market Cap	60.21 B	190.68 M	24.22 B	132.00 B	410.73 M	95.61 M
# of Analysts	12	3	13	3	3	3
Dividend Yield	0.00%	0.00%	1.75%	5.29%	0.00%	0.00%
Value Score	C	-	-	B	F	F
Cash/Price	0.07	0.23	0.04	0.08	0.19	0.80
EV/EBITDA	80.39	-3.61	14.11	19.06	-7.96	-0.50
PEG Ratio	1.22	1.67	2.06	2.11	NA	NA
Price/Book (P/B)	11.46	3.91	3.34	NA	6.22	1.36
Price/Cash Flow (P/CF)	74.22	13.41	13.57	9.56	NA	NA
P/E (F1)	35.18	27.74	18.90	9.49	NA	NA
Price/Sales (P/S)	16.63	13.62	2.65	4.02	NA	NA
Earnings Yield	2.85%	-15.82%	5.29%	10.53%	-19.23%	-68.45%
Debt/Equity	0.12	0.02	0.72	-4.03	0.18	0.18
Cash Flow (\$/share)	3.15	-1.08	6.94	9.34	-1.10	-1.19
Growth Score	B	-	-	A	D	D
Hist. EPS Growth (3-5 yrs)	250.63%	16.50%	10.56%	21.99%	NA	NA
Proj. EPS Growth (F1/F0)	38.49%	7.27%	7.59%	5.12%	-2.99%	-6.94%
Curr. Cash Flow Growth	203.97%	20.28%	14.73%	33.63%	-11.84%	4.56%
Hist. Cash Flow Growth (3-5 yrs)	37.20%	8.03%	9.00%	18.69%	NA	NA
Current Ratio	3.44	5.15	1.24	1.15	7.01	6.89
Debt/Capital	10.32%	3.92%	42.99%	NA	15.03%	14.97%
Net Margin	59.24%	-197.98%	11.14%	9.90%	NA	NA
Return on Equity	20.33%	-64.11%	17.16%	-155.96%	-66.35%	-69.86%
Sales/Assets	0.53	0.20	0.55	0.56	NA	NA
Proj. Sales Growth (F1/F0)	29.82%	16.39%	4.23%	8.32%	31.92%	10.00%
Momentum Score	B	-	-	A	A	B
Daily Price Chg	1.92%	0.22%	0.27%	1.20%	-2.46%	-3.61%
1 Week Price Chg	5.03%	1.74%	0.39%	0.41%	-4.44%	-18.18%
4 Week Price Chg	6.75%	5.60%	2.17%	-0.08%	-13.15%	21.43%
12 Week Price Chg	22.91%	15.84%	6.65%	14.80%	7.22%	139.77%
52 Week Price Chg	25.79%	-4.05%	22.43%	4.34%	-45.26%	-41.01%
20 Day Average Volume	1,118,162	226,262	1,545,017	6,391,124	216,415	6,917,944
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	0.00%	0.00%	0.00%	5.64%
(F1) EPS Est 12 week change	45.43%	0.75%	-0.41%	0.48%	7.59%	18.00%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	NA	NA	0.00%

Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	C
Growth Score	B
Momentum Score	B
VGM Score	B

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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