BioMarin Pharma (BMRN)

$111.21 (As of 06/03/20)

Price Target (6-12 Months): **$117.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 01/15/20) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:C
	Value: D | Growth: C | Momentum: B	

Summary

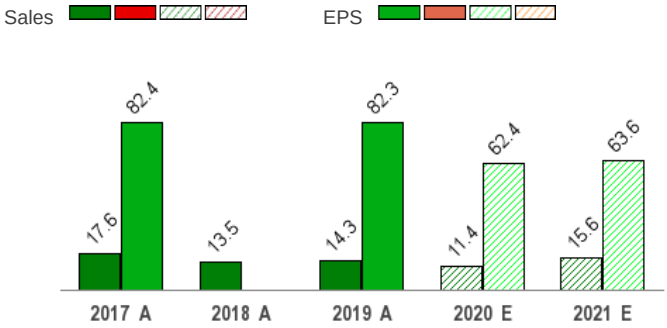
Sales of BioMarin's key orphan disease drugs — Vimizim and Kuvan — are being driven by strong demand trends. Its newest product, Palynziq is witnessing strong commercial uptake in the United States. BioMarin's rare disease pipeline is progressing well with multiple catalysts in 2020. Growing pipeline focus on gene therapy agents is encouraging. Regulatory applications for valrox, a gene therapy for hemophilia A, are under review while the same for another key candidate vosoritide are expected to be filed this year. Valrox is anticipated to be transformational, if approved this year. However, any regulatory setbacks related to valrox and vosoritide can hurt the stock. Moreover, Kuvan is expected to face generic competition in the fourth quarter of 2020, which can hurt sales. The stock has outperformed the industry this year so far.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$112.57 - $62.88**
20 Day Average Volume (sh)	**1,714,515**
Market Cap	**$20.1 B**
YTD Price Change	**31.5%**
Beta	**1.04**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Biomedical and Genetics**
Zacks Industry Rank	**Top 9% (24 out of 253)**
Last EPS Surprise	**90.9%**
Last Sales Surprise	**6.7%**
EPS F1 Est- 4 week change	**0.7%**
Expected Report Date	**08/06/2020**
Earnings ESP	**-23.9%**
P/E TTM	**79.4**
P/E F1	**73.7**
PEG F1	**1.4**
P/S TTM	**11.1**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021	517 E	519 E	543 E	570 E	2,195 E
2020	502 A	417 E	465 E	510 E	1,899 E
2019	401 A	388 A	461 A	454 A	1,704 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	$0.52 E	$0.50 E	$0.56 E	$0.64 E	$2.47 E
2020	$0.63 A	$0.18 E	$0.30 E	$0.36 E	$1.51 E
2019	$0.14 A	$0.09 A	$0.43 A	$0.25 A	$0.93 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 06/03/2020. The reports text is as of 06/04/2020.

Overview

San Rafael, CA-based BioMarin Pharmaceutical Inc. focuses on the development and commercialization of treatments for serious life threatening medical conditions, mostly for children. The company's portfolio comprises seven marketed products namely Aldurazyme (mucopolysaccharidosis type I (MPS I)), Naglazyme (MPS VI), Kuvan (phenylketonuria (PKU) – a rare genetic enzyme deficiency disorder), Vimizim (MPS IVA or Morquio syndrome type A), Brineura (CLN2– a form of Batten disease) and Palynziq (PKU). BioMarin has a collaboration agreement with Sanofi for Aldurazyme. BioMarin receives royalties on Aldurazyme sales from Genzyme

Interesting candidates in BioMarin's pipeline include Roctavian/valoctocogene roxaparvovec/valrox (hemophilia A) and vosoritide (achondroplasia) among others.

In Jan 2015, BioMarin acquired a Dutch biotech company Prosensa, in an all-cash transaction valued at $751.5 million, to boost its rare disease pipeline. Moreover, the company acquired all global rights to Kuvan, excluding Japan, and Palynziq (pegvaliase) from Merck Serono in Jan 2016, for cash payments of $374.5 million plus certain milestone payments.

BioMarin generated total sales of $1.7 billion in 2019, up 14%.

Reasons To Buy:

> BioMarin's key drugs, Vimizim and Kuvan, enjoy strong demand trends. It has an impressive rare disease pipeline with a growing focus towards gene therapy agents.

- **Share Price Outperforming Industry:** BioMarin's share price movement shows that the stock has outperformed the industry this year so far. The stock has risen 31.6% during this period, outperforming 9.2% increase for the industry.

- **Key Products Continue to Drive Growth:** Vimizim is doing well, surpassing the company's expectations. Vimizim's sales rose 17% in 2018 and 13% in 2019. Other products like Kuvan are also performing well. Kuvan's North American sales continue to be propelled by growth in new patients and high levels of adherence. Internationally, uptake has been solid and the acquisition of the drug's global rights has opened a stream of orders directly from the majority of the top markets to the company. Kuvan's sales rose 7% in 2019.

  Brineura was approved for the treatment of children with CLN2 disease – a form of Batten disease – both in the United States and the EU in 2017. Brineura sales were $72 million in 2019 and are expected to be much higher, in the range of $85-$115 million, in 2020.

  Meanwhile, Palynziq (pegvaliase) injection, developed to reduce blood phenylalanine (Phe) levels in PKU patients, gained FDA approval in May 2018 and was launched in July 2018. In the EU, a marketing application was approved in May 2019 with meaningful revenue contributions from this region expected in 2020. Palynziq is witnessing strong commercial uptake in the United States. BioMarin believes the injection has peak commercial opportunity of roughly $1 billion as it demonstrated dramatic Phe reductions in PKU patients in pivotal studies. BioMarin is optimistic that pegvaliase will be the approved treatment of choice for adults, complementing Kuvan, which is a popular treatment choice for children. Palynziq sales were $87 million in 2019 and are expected to be much higher, in the range of $160-$190 million, in 2020.

- **Promising Pipeline:** We are pleased with BioMarin's efforts to build its orphan disease-focused pipeline. The company has a robust rare disease pipeline with several data readouts lined up in the coming quarters.

  BioMarin's regulatory applications for Roctavian/valoctocogene roxaparvovec (valrox), a gene therapy for severe hemophilia A, are under review in the United States (PDUFA Date: Aug 21) and Europe with potential approval and launch in the United States in the second half of 2020. BioMarin conducted two separate phase III studies — GENEr8–1 (6e13 vg/kg dose) and GENEr8–2 (4e13 vg/kg dose) — on valrox for the treatment of patients without the pre-existing AAV5 antibodies. The interim phase III data from the GENEr8-1 study and updated three-year data from a long-term phase I/II study on valrox formed the basis of the regulatory submissions. Valrox is anticipated to be transformational, if approved, as it has the potential to dramatically change the treatment paradigm.

  Another important candidate in its pipeline is vosoritide, which is in a phase II study in children aged 5 to 14 with achondroplasia, the most common form of dwarfism. BioMarin estimates that around 25,000 children suffer from this disorder in its commercial territories, which represents decent sales growth opportunity. Data from this ongoing study has shown 9 centimeters of cumulative additional height gained at 54 months.

  Meanwhile a 52-week phase III pivotal study (n~110) evaluated vosoritide in children (ages 5-14) with achondroplasia. Top-line data from this study showed that patients treated with the candidate achieved placebo-adjusted change from baseline in growth velocity of 1.6 cm/year after treatment duration of one year. The company is planning to file regulatory applications for vosoritide in United States and EU in the third quarter of 2020 based on data from the above pivotal study as well as long-term safety and efficacy data from the phase II study and ongoing extension studies.

  In addition, BioMarin initiated a separate phase II study in 2018 to evaluate the effect of vosoritide in infants and young children (less than 60 months old). We note that vosoritide has Orphan Drug status in both the United States and the EU. Also, BioMarin plans to begin phase I/II study on vosoritide for a second indication — dominantly inherited short stature (DISS) — in the second half of 2020, as part of a research collaboration with Children's National Hospital.

  A third PKU treatment option in BioMarin's PKU franchise is its gene therapy candidate, BMN 307. Phase I/II study on BMN 307 is expected to begin dosing in the second half of 2020.

  Successful development and commercialization of these candidates will help drive long-term growth at BioMarin.

- **Deals to Boost Portfolio and Strengthen Pipeline**: In January 2016, BioMarin acquired all global rights to Kuvan and pegvaliase (now marketed as Palynziq) from Merck Serono. Previously, the company had exclusive rights to Kuvan in the U.S. and Canada and to pegvaliase in the U.S. and Japan. With this transaction, BioMarin has gained exclusive worldwide rights to Kuvan and pegvaliase with the exception of Kuvan in Japan. The acquisition of PKU rights in these markets represents significant opportunity for BioMarin to establish commercial leadership for the treatment of PKU, first with Kuvan, and then with pegvaliase.

- **Favorable Debt Profile:** As of Mar 31, 2020, BioMarin had $853 million in total debt (long-term debt plus current debt) on its balance sheet. Cash and cash equivalents totaled approximately $858 million. Its cash position is sound and the company is capable of paying the debt in case of insolvency. Its debt/capital ratio was 20.8 at the end of March 2020, lower than 21.4 at the end of December 2019. A lower ratio indicates lower financial risk.

Reasons To Sell:

- **Pipeline Setbacks:** While we believe that BioMarin has an impressive pipeline, delayed approvals or development setbacks would have a negative impact on the stock. In 2016, BioMarin discontinued clinical and regulatory development of Kyndrisa for the treatment of Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping. The decision followed the company's discussions with the European Medicines Agency's Committee for Medicinal Products for Human Use, which hinted at the issuance of a negative opinion. The FDA had also issued a complete response letter in January 2016 for Kyndrisa stating that the standard of substantial evidence of Kyndrisa effectiveness was not met.

  BioMarin has also discontinued the development of the three follow-on products of Kyndrisa – BMN 044, BMN 045, and BMN 053 – that were being evaluated in phase II studies for specific forms of DMD. BioMarin terminated internal development of the reveglucosidase alfa program (for the treatment of patients with late-onset Pompe disease). Also, BioMarin halted further development of BMN-195 for a type of muscle disease following disappointing results from an early-stage study.

> Generic challenges for Kuvan are concerning. Additional setbacks on the development/regulatory front could pull down the stock significantly.

- **Kuvan Faces Generic Threat:** BioMarin is facing generic threat for Kuvan, one of its most promising drugs, which has been performing well since its launch. Per settlements with Dr Reddy's and Par Pharmaceuticals, Kuvan generics are expected to enter the U.S. market beginning October 2020.

- **Prosensa Acquisition Failed to Deliver:** The Jan 2015 acquisition of Prosensa worth a million dollars was assumed to be a strategic move. The acquisition added a late-stage DMD candidate Kyndrisa, which was considered to be a synergistic fit for BioMarin's rare disease pipeline. However, BioMarin failed to clear regulatory hurdles related to Kyndrisa and ultimately decided to drop development of the candidate. DMD, a devastating and debilitating disease, is estimated to affect nearly 1 in every 3,500 boys born across the world. Kyndrisa, had it been developed successfully, would have captured a major share of this orphan disease market.

Last Earnings Report

BioMarin Beats on Q1 Earnings, Lowers Sales View

Quarter Ending	03/2020
Report Date	Apr 29, 2020
Sales Surprise	6.73%
EPS Surprise	90.91%
Quarterly EPS	0.63
Annual EPS (TTM)	1.40

BioMarin's adjusted earnings of 63 cents per share beat the Zacks Consensus Estimate of 33 cents. Earnings were significantly better than the year-ago earnings of 14 cents per share due to higher revenues and lower R&D costs.

Total revenues were $502.1 million in the reported quarter, up 25% from the year-ago period, driven by higher product revenues. Sales beat the Zacks Consensus Estimate of $470 million.

In the quarter, the company experienced minimal business interruptions due to COVID-19. However, it expects more meaningful impact in the future quarters of 2020 due to disruptions of day-to-day operations of clinics and hospitals.

Quarterly Details

Product revenues (including Aldurazyme) were $489.0 million in the quarter, reflecting a 24% increase year over year. Product revenues from BioMarin's marketed brands (excluding Aldurazyme) grew 24% year over year to $433.3 million. Royalty and other revenues were $13.03 million in the quarter, higher than $6.3 million a year ago.

Kuvan revenues rose 14% to $122 million driven by patient growth in North America.

Palynziq injection sales grossed $34.6 million in the quarter compared with $31.7 million in the previous quarter, driven by new patients initiating therapy as well as the growing number of U.S. patients who have now achieved maintenance dosing. The majority of Palynziq sales came from the United States. In the quarter, however, BioMarin experienced a seasonal slowing of new patient enrollments and patient starts for Palynziq

In the EU, Palynziq injection was approved in May 2019. BioMarin said that multiple clinics across Germany were now treating patients and early uptake trends were encouraging. The company is working to get reimbursement approvals in other European countries and expects meaningful contribution from European sales of Palynziq in 2020.

Naglazyme sales rose 32% to $114.3 million mainly due to orders from Brazil and Russia.

Vimizim contributed $137.2 million to total revenues, up 9% year over year owing to orders from Brazil.

Naglazyme and Vimzim revenues vary on a quarterly basis, primarily due to the timing of central government orders from some countries, mainly Brazil.

Brineura generated sales of $24.0 million in the first quarter, lower than $25.2 million reported in the previous quarter due to a modest year-end inventory build in the EMEA region in the fourth quarter.

BioMarin received Aldurazyme royalties totaling $55.7 million from Genzyme in the quarter, up 23% year over year.

R&D expenses declined 22.9% year over year to $123.8 million due to lower costs for development of Roctavian/valoctocogene roxaparvovec/valrox. Marketing expenses associated with Palynziq commercial efforts and launch preparations for Roctavian resulted in 16% increase in SG&A expenses to $153.7 million.

As of Mar 31, 2020, BioMarin had $1.15 billion in cash, cash equivalents and investments, compared with $1.17 billion at the end of Dec 31, 2019.

2020 Guidance

BioMarin lowered its total revenue guidance by 5% due to the uncertainty surrounding the coronavirus outbreak and its potential impact on its business. It expects the pandemic to cause demand interruptions such as missed patient infusions and disruption to new patient starts However, BioMarin expects the demand patterns to return to normal levels in the second half of the year.

Total revenue guidance was lowered from a range of $1.95-$2.05 billion to $1.85-$1.95 billion.

Vimizim sales are expected in the range of $530-$570 million, lower than $560-$610 million expected previously. Kuvan sales guidance was maintained in the range of $430-$480 million. Naglazyme sales are predicted in the band of $360-$400 million, lower than $380-$420 million expected previously. Brineura sales are expected within $85-$115 million (maintained). Palynziq sales are forecast in the $160-$190 million range compared with the previous expectation of $180-$210 million.

The guidance for costs was maintained. R&D costs are expected to be within $675-$725 million. SG&A expenses are anticipated in the range of $780-$830 million.

The company still expects adjusted net income in the range of $260-$310 million, the midpoint of which indicates growth of more than 70%.

Pipeline Update

In February, the FDA accepted and granted priority review to its biologics license application (BLA), seeking approval for valrox, its investigational gene therapy for severe hemophilia A. On the conference call, the company announced valrox's brand name to be Roctavian.

With the FDA granting priority review to the application, a decision is expected on Aug 21. Per the company, if the BLA is approved, valrox will be the first gene therapy in the United States to be approved to treat any type of hemophilia. Meanwhile, the Health Products Regulatory Authority of

Ireland, on behalf of EMA, conducted a pre-approval inspection of its gene therapy manufacturing facility for the production of valrox, and issued a cGMP certification.

Meanwhile, the EMA also validated the marketing application for the product. BioMarin earlier said that the EMA's review process commenced in January under accelerated assessment. However, along with the earnings release, the company said that the review process in EU may be extended by at least three months or the application may go back to the standard review process due to the COVID-19 delay. As such, an opinion from the CHMP is expected in late 2020/early 2021.

Meanwhile, initial dosing for PKU gene therapy candidate, BMN 307 is now expected to happen in the second half of 2020, delayed by COVID-19.

Recent News

Four Years Data from Phase I/II Study on Valrox – May 31

BioMarin presented four-year update for the 6e13 vg/kg and three-year update for the 4e13 vg/kg cohorts of the ongoing phase I/II study on valrox. Data from both the cohorts showed that all participants remain off prophylactic Factor VIII treatment since receiving their single dose of valrox. The data also showed that the cumulative mean annualized bleed rates (ABR) remain less than one (1) in both cohorts and below pre-treatment baseline levels.

Proposal to Offer Senior Notes – May 11

BioMarin announced its intention to offer $500.0 million aggregate principal amount of senior subordinated convertible notes due 2027 in a private placement to qualified institutional buyers

New Gene Therapy Collaboration – May 3

BioMarin announced that it has signed a preclinical collaboration and license agreement with DiNAQOR to develop gene therapies for rare genetic cardiomyopathies.

Valuation

BioMarin's shares are up 31.6% in the year-to-date period and 33.1% over the trailing 12-month period. While stocks in the Zacks sub-industry are up 9.2%, those in the sector are down 0.7% in the year-to-date period. Over the past year, stocks in the Zacks sub-industry and sector are up 15.6% and 4.4%, respectively.

The S&P 500 Index is down 4.4% in the year-to-date period but up 9.1% in the past year.

The stock is currently trading at 11.53X trailing 12-month sales per share, which compares to 3.54X for the Zacks sub-industry, 3.1 X for the Zacks sector and 3.31X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 27.85X and as low as 7.46X, with a 5-year median of 12.34X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $117 price target reflects 12.1X trailing 12-month sales per share.

The table below shows summary valuation data for BMRN

Valuation Multiples - BMRN

		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	11.53	3.54	3.1	3.31
	5-Year High	27.85	4.69	4.09	3.68
	5-Year Low	7.46	2.16	2.29	2.43
	5-Year Median	12.34	2.67	3.21	3.19
P/B TTM	Current	6.21	4.35	4.25	4.21
	5-Year High	10.15	5.46	5.07	4.56
	5-Year Low	3.76	2.45	2.93	2.83
	5-Year Median	5.61	3.33	4.29	3.66

As of 6/03/2020

Industry Analysis **Zacks Industry Rank:** Top 9% (24 out of 253)

Top Peers

Company (Ticker)	Rec	Rank
Ascendis Pharma AS **(ASND)**	Neutral	3
Editas Medicine, Inc. **(EDIT)**	Neutral	3
Senesco Technologies Inc. **(ELOX)**	Neutral	3
Amicus Therapeutics, Inc. **(FOLD)**	Neutral	3
Ultragenyx Pharmaceutical Inc. **(RARE)**	Neutral	3
Reata Pharmaceuticals, Inc. **(RETA)**	Neutral	2
REGENXBIO Inc. **(RGNX)**	Neutral	3
Sangamo Therapeutics, Inc. **(SGMO)**	Neutral	3

Industry Comparison Industry: Medical - Biomedical And Genetics

Industry Peers

	BMRN	X Industry	S&P 500	ASND	ELOX	RETA
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	2
VGM Score	C	-	-	F	D	D
Market Cap	20.11 B	236.46 M	22.50 B	7.01 B	136.03 M	4.50 B
# of Analysts	8	3	14	7	3	5
Dividend Yield	0.00%	0.00%	1.88%	0.00%	0.00%	0.00%
Value Score	D	-	-	F	D	D
Cash/Price	0.04	0.23	0.06	0.08	0.32	0.13
EV/EBITDA	617.83	-3.94	12.98	-27.38	-2.03	-14.01
PEG Ratio	1.37	1.88	3.05	NA	NA	NA
Price/Book (P/B)	6.21	4.32	3.11	11.57	5.18	19.68
Price/Cash Flow (P/CF)	174.54	14.21	12.18	NA	NA	NA
P/E (F1)	72.36	29.51	22.19	NA	NA	NA
Price/Sales (P/S)	11.14	16.30	2.40	618.18	NA	223.93
Earnings Yield	1.36%	-13.35%	4.31%	-4.11%	-30.38%	-6.25%
Debt/Equity	0.15	0.02	0.76	0.06	0.37	0.68
Cash Flow ($/share)	0.64	-1.05	7.01	-5.62	-1.25	-8.67
Growth Score	C	-	-	F	D	F
Hist. EPS Growth (3-5 yrs)	NA%	16.29%	10.87%	NA	NA	NA
Proj. EPS Growth (F1/F0)	62.51%	8.29%	-10.74%	-14.20%	23.38%	11.19%
Curr. Cash Flow Growth	200.25%	13.58%	5.48%	55.11%	6.63%	268.02%
Hist. Cash Flow Growth (3-5 yrs)	27.84%	7.77%	8.55%	NA	NA	NA
Current Ratio	2.58	5.17	1.29	13.19	4.14	3.25
Debt/Capital	13.06%	4.34%	44.75%	5.31%	26.98%	40.48%
Net Margin	6.31%	-203.29%	10.59%	-2,231.94%	NA	-1,542.06%
Return on Equity	3.62%	-63.33%	16.29%	-36.56%	-129.89%	-322.36%
Sales/Assets	0.39	0.20	0.55	0.01	NA	0.04
Proj. Sales Growth (F1/F0)	11.44%	0.00%	-2.65%	-18.41%	NA	-80.54%
Momentum Score	B	-	-	F	A	B
Daily Price Chg	2.66%	-0.87%	2.42%	0.01%	5.61%	-3.50%
1 Week Price Chg	9.27%	0.00%	4.60%	-0.72%	-3.14%	-9.18%
4 Week Price Chg	17.06%	9.07%	13.40%	4.70%	32.94%	-15.60%
12 Week Price Chg	27.98%	21.03%	12.78%	23.18%	17.71%	-14.22%
52 Week Price Chg	33.04%	1.08%	0.89%	14.75%	-61.61%	54.13%
20 Day Average Volume	1,714,515	296,067	2,528,787	222,830	107,502	262,335
(F1) EPS Est 1 week change	0.69%	0.00%	0.00%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	0.69%	0.00%	-0.14%	-1.30%	-0.33%	-2.65%
(F1) EPS Est 12 week change	-39.25%	0.28%	-16.00%	-20.50%	12.00%	-0.02%
(Q1) EPS Est Mthly Chg	1.47%	0.00%	-0.02%	0.75%	10.67%	0.23%

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	D
Growth Score	C
Momentum Score	B
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.

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