Jazz Pharmaceuticals (JAZZ)

$150.47 (As of 01/22/20)

Price Target (6-12 Months): **$158.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 11/07/19) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:A
	Value: A | Growth: B | Momentum: C	

Summary

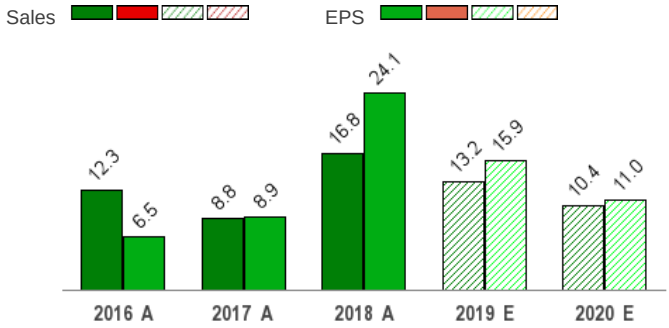
Jazz's key drug, Xyrem, continues to witness improved volume trends in 2019 on the back of awareness efforts and label expansion in pediatric patients. Management expects Xyrem's volume growth to continue in the fourth quarter. Sunosi's launch in July 2019 complements the sleep franchise and its successful commercialization may offset a decline in Xyrem's sales following patent expiry in 2023. Jazz's leukemia drug, Vyxeos, has also witnessed strong growth so far in 2019. Shares of Jazz have outperformed the industry so far this year. However, Jazz's leukemia drug, Erwinaze, has been facing supply crunch due to constrained manufacturing capacity, which is likely to continue in 2020. Defitelio sales also vary every quarter.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$154.24 - $116.52**
20 Day Average Volume (sh)	**404,111**
Market Cap	**$8.5 B**
YTD Price Change	**0.8%**
Beta	**1.13**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Drugs**
Zacks Industry Rank	**Top 40% (103 out of 255)**
Last EPS Surprise	**14.2%**
Last Sales Surprise	**2.9%**
EPS F1 Est- 4 week change	**0.0%**
Expected Report Date	**02/25/2020**
Earnings ESP	**-0.1%**
P/E TTM	**9.7**
P/E F1	**8.5**
PEG F1	**1.0**
P/S TTM	**4.1**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	548 E	589 E	605 E	620 E	2,363 E
2019	508 A	534 A	538 A	557 E	2,140 E
2018	445 A	500 A	469 A	476 A	1,891 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	$3.93 E	$4.47 E	$4.61 E	$4.71 E	$17.62 E
2019	$3.67 A	$4.05 A	$4.10 A	$4.07 E	$15.88 E
2018	$2.98 A	$3.49 A	$3.58 A	$3.64 A	$13.70 A

*Quarterly figures may not add up to annual.

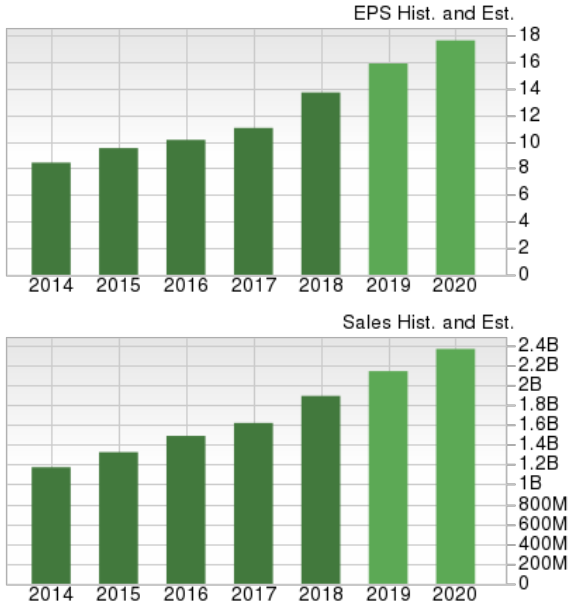
The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 01/22/2020. The reports text is as of 01/23/2020.

Overview

Dublin, Ireland-based Jazz Pharmaceuticals is a specialty biopharmaceutical company with a focus in the areas of sleep and hematology/oncology. Key drugs include Xyrem for cataplexy and excessive daytime sleepiness (EDS) in narcolepsy patients, Erwinaze for acute lymphoblastic leukemia (ALL) patients who have developed hypersensitivity to E.coli-derived asparaginase,Defitelio for the treatment of patients with hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT) and Vyxeos for the treatment of adults with two types of Acute Myeloid Leukemia (AML). Sunosi (solriamfetol) was approved for excessive sleepiness in narcolepsy & obstructive sleep apnea (OSA) in March 2019.

Jazz has bolstered its commercial portfolio and pipeline through acquisitions. These include addition of marketed drugs – Defitelio, Vyxeos and Erwinaze. Jazz also added solriamfetol, through one of these acquisitions.

In September 2018, the company sold all rights to pain drug, Prialt to TerSera. The company generates the majority of its revenues from Xyrem sales. The drug registered sales of $1.41 billion, up 18% and almost 74% of total revenues, in 2018.



Reasons To Buy:

▲ **Xyrem has Strong Commercial Potential:** Xyrem has immense commercial potential considering that it is the only FDA approved product for both cataplexy and EDS. Sales reps continue to educate healthcare providers on narcolepsy and the use of Xyrem with a focus on physicians with high narcolepsy potential and low Xyrem utilization. Volume trends for Xyrem improved in 2018 and the trend continues so far in 2019 supported by the company's disease awareness education efforts, which led to increased diagnosis rate of new narcolepsy patients. Management seems confident of generating volume growth in the rest of 2019.

> Jazz's sleep franchise should continue to perform well. The company is looking to broaden Xyrem's label by expanding the targeted patient population.

The company is also striving to expand Xyrem's label. In October 2018, the FDA granted approval to the sNDA for Xyrem to include the pediatric patients with cataplexy or EDS. Jazz launched the drug for pediatric patients in March 2019, which is bringing in additional sales. Moreover, settlement of all patent litigation related to generic version removes an overhang. There is no generic competition expected till 2022 as of now.

▲ **Strong Sleep Disorder Portfolio:** Jazz's sleep disorder portfolio looks strong with the launch of Sunosi and several ongoing and planned development activities in the sleep therapeutic area.

In March 2019, Sunosi (solriamfetol), received approval in the United States for excessive sleepiness in narcolepsy & OSA and was launched in the United States in July 2019. The drug is under review in Europe for a similar indication with a decision expected by early 2020. In November 2019, the CHMP recommended the approval of the drug in Europe. According to Jazz, there is significant unmet need in narcolepsy and OSA with about 175-300K patients having an inadequate response to current wake-promoting therapies. The company plans to develop Sunosi as a potential treatment for EDS in other sleep or central nervous system disorders, including major depressive disorder.

Other than Sunosi, Jazz is also studying JZP-258 (a low sodium formulation of Xyrem) in phase III studies for EDS and cataplexy in narcolepsy patients. The filed an NDA in January 2020 based on phase III study data. JZP-258 is also being studied for Idiopathic hypersomnia, or IH in a phase III study.

▲ **Hematology/Oncology Drugs Add Strong Growth and Diversification:** Defitelio is currently available in the EU and the United States for the treatment of severe hepatic VOD. Meanwhile, Jazz is presently conducting a phase III study and a phase II study to evaluate Defitelio for the prevention of VOD in high-risk patients and prevention of acute graft versus host disease, respectively. An exploratory phase II study is evaluating the drug for the prevention of CAR T-cell associated neurotoxicity in patients with relapsed or refractory DLBCL. These label expansion studies represent long-term growth opportunities for Defitelio. The company is also looking to launch Defitelio in new countries. In June 2019, the drug was approved for VOD in Japan.

With the Celator acquisition, Jazz added Vyxeos to its pipeline. In August 2017, Vyxeos was approved and launched in the United States for the treatment of acute myeloid leukemia (AML). Jazz is increasing its dedicated AML sales team for reaching out to a wider physician community and also for promotion of the recent inclusion in the guidelines of the National Comprehensive Cancer Network (NCCN). Sales of the drug improved in the past couple of quarters following the company's efforts.

Meanwhile, Jazz is also evaluating Vyxeos in other AML patient populations, such as pediatric patients and adults with standard or intermediate risk AML, in combination with targeted AML treatments and in new populations (MDS). If approved for these additional patient segments, sales of the drug can pick up. The company is also developing JZP-458, a recombinant crisantaspase, in acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL). The company initiated a pivotal phase II/III study in December 2019.

▲ **Regular Acquisitions/Collaborations to Boost Portfolio:** Jazz has added several drugs to its marketed portfolio and clinical-stage candidates to its pipeline through acquisitions or collaborations. In December 2019, the company acquired U.S. rights to a late-stage small cell lung cancer candidate, lurbinectedin, from Ireland-based PharmaMar. In August 2019, the company acquired private biotech Cavion adding a mid-stage movement disorder candidate (CX-8998). In July 2019, the company acquired Redx Pharma's pan-RAF inhibitor program for developing treatment for RAF and RAS mutant tumors. In January 2019, Jazz collaborated with Codiak BioSciences, to develop and commercialize exosome therapeutics to treat cancer. It also includes an exclusive license for five targets to be developed using Codiak's exosome platform. Other deals include the acquisition of biopharma company Gentium in December 2013, which added Defitelio to its portfolio. The company also acquired worldwide development, manufacturing and commercial rights to Sunosi (solriamfetol) from Aerial BioPharma in January 2014. In July 2016, Jazz acquired Celator, which added Vyxeos to its pipeline.

Earlier deals include the EUSA Pharma Inc. acquisition in June 2012 and the Jazz-Azur Pharma merger in January 2012. Both acquisitions added a number of products (FazaClo LD, FazaClo HD, Prialt and Erwinaze) to Jazz's portfolio.

Reasons To Sell:

- **Regulation on Xyrem and Competition:** Xyrem is a controlled substance with a highly restricted distribution channel subject to a risk evaluation and mitigation strategy (REMS). In February 2015, the FDA approved Jazz's Xyrem REMS requiring distribution through a single pharmacy. Single pharmacy can put pressure on patient access as well as the overall healthcare delivery system. Moreover, the FDA plans to evaluate the Xyrem REMS on an ongoing basis and reserves the rights to make modifications if required, which can either lower entry barriers for companies looking to market generic versions of Xyrem or make it more expensive or difficult to market the drug.

> The earlier-than-expected entry of Xyrem generics and any pipeline setback would weigh heavily on the stock.

Jazz had been involved in patent infringement lawsuits with generic drug makers for Xyrem. Several generic versions of Xyrem may hit the market in 2023. Launch of Xyrem's generic will unfavorably impact sales of the company's major drug. With nearly three-fourth of sales coming from Xyrem this will severely impact the company's top-line and weigh on share price. Moreover, the market for EDS in patients with narcolepsy is highly competitive, given the presence of Teva's Nuvigil and generic versions of Provigil, among others. Moreover, other companies are also developing treatments for similar indication including Avadel Pharmaceuticals' sodium oxybate formulation, FT-218.

- **Erwinaze Supply Constraints:** Jazz has been facing challenges in building sufficient inventory levels for Erwinaze due to constrained manufacturing capacity. This resulted in supply disruptions and hurt sales of Erwinaze in 2017, 2018 and 2019.The company anticipates the supply challenges to continue in in 2020 as well. Moreover, in February 2019, Jazz received termination notice from Porton Biopharma related to license and supply of Erwinaze which is set to expire by 2020 end. Without renewing the agreement, Jazz will not be able to sell Erwinaze beginning 2021, except for certain Erwinaze inventory for 12 months post termination of the agreement.

- **Pipeline Setbacks:** Jazz has had its share of pipeline setbacks. Although solriamfetol achieved improvement in patients in a phase II study evaluating it in EDS and Parkinson's disease, the company discontinued further development in May 2019. In June 2019, Jazz's partner, ImmunoGen, discontinued development of its anti-body drug conjugate candidate, IMGN779, for which Jazz possessed opt-in rights. In January 2016, the company terminated a phase II pivotal study on JZP-416 due to the occurrence of hypersensitivity-like reactions in patients suffering from ALL who are hypersensitive to pegylated E. coli-derived asparaginase. In addition to this, the company terminated a study evaluating Erwinaze in patients (18 to 39 years) suffering from ALL who are hypersensitive to E. coli-derived asparaginase due to its inability to enroll patients. Moreover, the company along with its partner Concert Pharmaceuticals decided not to move sleep disorder candidate, JZP-386, into the next stage of development following phase I study results.

  Jazz decided to discontinue the late-stage development of Leukotac after the candidate failed in a clinical study as a treatment for patients who developed steroid-refractory acute graft-versus-host disease post allogeneic hematopoietic stem cell transplant. Discontinuation of development of important candidates could affect the company's growth prospects significantly.

Last Earnings Report

Jazz Pharmaceuticals Q3 Earnings and Sales Beat Estimates

Quarter Ending	09/2019
Report Date	**Nov 05, 2019**
Sales Surprise	**2.87%**
EPS Surprise	**14.21%**
Quarterly EPS	**4.10**
Annual EPS (TTM)	**15.46**

Jazz Pharmaceuticals delivered adjusted earnings of $4.10 per share for the third quarter of 2019, which surpassed the Zacks Consensus Estimate of $3.59. Earnings rose 15% from the year-ago figure driven by higher sales, which made up for higher operating expense.

Total revenues in the reported quarter rose 15% year over year to $537.7 million and also beat the Zacks Consensus Estimate of $523.0 million. This can be attributed to higher sales of Xyrem.

Quarter in Detail

Net product sales in the reported quarter increased 14.4% from the year-ago quarter to $532.3 million. Royalties and contract revenues rose 28.9% to $5.38 million in the quarter.

Sales of Xyrem rose 19% year over year to $425.6 million. Sales were driven by a 6.5% rise in bottle volume growth. The average number of active Xyrem patients increased 5% in the quarter.

Volume trends for Xyrem improved supported by the company's disease awareness education efforts, which led to increased diagnosis rate of new narcolepsy patients.

Erwinaze/Erwinase revenues were $34.0 million, down 17% year over year due to ongoing supply and manufacturing issues at its sole manufacturer, PDL. Defitelio sales rose 4% year over year to $37.6 million in the quarter. However, Defitelio's sales declined sequentially. Defitelio product sales vary from quarter to quarter in both the United States and EU because Defitelio treats an ultra-rare acute condition — hepatic veno-occlusive disease.

Acute myeloid leukemia drug,Vyxeos generated sales of $29.6 million, up 41% from the year-ago period, primarily due to the ongoing launch in EU. However, Vyxeos' sales declined sequentially.

Sunosi recorded sales of $1 million in the quarter. Other product sales declined 53.3% to $4.5 million.

Adjusted selling, general and administrative (SG&A) expenses rose 12.8% to $158.4 million driven by higher expenses for business expansion and costs to support the launch of Sunosi in the United States.

Adjusted research and development (R&D) expenses increased 57.6% to $73.4 million, primarily due to escalating expenses related to development of the company's pipeline and partnered programs.

2019 Guidance

The company raised its previously issued guidance for total revenues as well as earnings. However, the guidance includes only minimal net sales contribution from Sunosi in the United States.

It expects earnings in the range of $15.50 - $16.15 in 2019 versus the prior expectation of $14.30-$15.00 per share. Total revenues are expected to be higher in the range of $2.10-$2.18 billion compared with the previous range of $2.07-$2.15 billion. The 2019 sales and earnings ranges represent growth of 11-15% and 13-18%, respectively over 2018 levels.

Total product sales are predicted in the range of $2.08-$2.16 billion (previously $2.055-$2.125 billion) for 2019. The company raised the guidance for Xyrem sales to the range of $1.60-$1.64 billion from $1.55-$1.59 billion. Erwinaze/Erwinase sales forecast was maintained in the band of $160-$195 million.

Jazz raised the lower end of its guidance range for Defitelio from $155-$180 million to $160 -$180 million. It lowered the higher end of its guidance range for Vyxeos from $120-$150 million to $120-$135 million.

While adjusted SG&A expenses are anticipated in the range of $630 million to $650 million (previously $620 million to $650 million), adjusted R&D expenses are expected to be in the band of $245 million to $265 million (previously $235 million to $265 million).

Recent News

Files NDA for JZP-258 – Jan 22

Jazz announced that it has submitted a NDA seeking approval for JZP-258 as a treatment for cataplexy and EDS associated with narcolepsy in patients seven years or younger. The company has redeemed a priority review voucher for the NDA submission.

Sunosi Gets Approval in Europe – Jan 20

Jazz announced that the European Commission approved Sunosi. The drug will be available in Europe as a treatment to improve wakefulness and reduce EDS in adults with narcolepsy (with or without cataplexy) or OSA, whose EDS has not been satisfactorily treated by primary OSA therapy.

Enrolls First Patient in Phase II/III Leukemia Study – Dec 30

Jazz announced that it has enrolled the first patient in the pivotal phase II/III study evaluating JZP-258 in pediatric and adult patients with ALL or LBLwho are hypersensitive to E. coli-derived asparaginases.

This single-arm, open-label dose confirmation and confirmatory study is being conducted in collaboration with Children's Oncology Group.

Per the company, the study will assess the safety, tolerability and efficacy of JZP-458 in patients with ALL/LBL who have silent inactivation or an allergic reaction to E. coli-derived asparaginases having received no prior asparaginase Erwinia chrysanthemi.

The primary objective of the study is to determine the efficacy of JZP-458 measured by asparaginase activity.

Valuation

Jazz's shares are up 19.6% over the trailing 12-month period. Over the past year, the Zacks sub-industry and the Zacks sector are up 1.1% and 6.5%, respectively.

The S&P 500 Index is up 25% in the past year.

The stock is currently trading at 4.2X trailing12-month sales per share, which compares to 3.3X for the Zacks sub-industry, 3.19X for the Zacks sector and 3.59X for the S&P 500 index.

Over the past five years, the stock has traded as high as 10.13X and as low as 3.31X, with a 5-year median of 5.71X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our $158.00 price target reflects 4.41X trailing 12-month sales per share.

The table below shows summary valuation data for JAZZ

Valuation Multiples - JAZZ

		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	4.2	3.3	3.19	3.59
	5-Year High	10.13	4.13	4.14	3.64
	5-Year Low	3.31	1.98	2.75	2.56
	5-Year Median	5.71	2.6	3.26	3.15
P/B TTM	Current	2.79	1.56	4.61	4.54
	5-Year High	8.93	12.47	5.02	4.55
	5-Year Low	2.25	0.96	3.48	2.9
	5-Year Median	3.99	2.5	4.28	3.62

As of 01/22/2020

Industry Analysis **Zacks Industry Rank:** Top 40% (103 out of 255)

Top Peers

Alexion Pharmaceuticals, Inc. **(ALXN)**	Outperform
Alkermes plc **(ALKS)**	Neutral
Avadel Pharmaceuticals PLC. **(AVDL)**	Neutral
BioMarin Pharmaceutical Inc. **(BMRN)**	Neutral
Endo International plc **(ENDP)**	Neutral
Horizon Therapeutics Public Limited Company **(HZNP)**	Neutral
Incyte Corporation **(INCY)**	Neutral
Ionis Pharmaceuticals, Inc. **(IONS)**	Neutral

Industry Comparison Industry: Medical - Drugs

Industry Peers

	JAZZ Neutral	X Industry	S&P 500	ALKS Neutral	ALXN Outperform	BMRN Neutral
VGM Score	A	-	-	B	B	B
Market Cap	8.51 B	121.78 M	24.65 B	2.93 B	24.65 B	15.73 B
# of Analysts	11	2	13	8	14	10
Dividend Yield	0.00%	0.00%	1.77%	0.00%	0.00%	0.00%
Value Score	A	-	-	C	C	D
Cash/Price	0.13	0.26	0.04	0.19	0.09	0.05
EV/EBITDA	10.57	-2.22	13.98	-332.20	33.54	-5,264.34
PEG Ratio	0.93	1.18	2.05	1.61	0.67	NA
Price/Book (P/B)	2.79	3.30	3.38	2.74	2.38	5.12
Price/Cash Flow (P/CF)	8.98	10.98	13.60	30.03	12.32	409.15
P/E (F1)	8.43	14.97	19.07	33.51	9.84	49.28
Price/Sales (P/S)	4.14	5.80	2.69	2.73	5.21	9.82
Earnings Yield	11.70%	-14.33%	5.24%	2.96%	10.16%	2.03%
Debt/Equity	0.56	0.03	0.72	0.26	0.25	0.27
Cash Flow ($/share)	16.75	-0.62	6.94	0.62	9.04	0.21
Growth Score	B	-	-	B	B	A
Hist. EPS Growth (3-5 yrs)	14.93%	8.54%	10.60%	NA	17.67%	NA
Proj. EPS Growth (F1/F0)	10.90%	18.23%	7.53%	5.11%	8.65%	98.14%
Curr. Cash Flow Growth	29.40%	13.49%	13.90%	126.78%	20.32%	-246.03%
Hist. Cash Flow Growth (3-5 yrs)	18.61%	8.38%	9.00%	-9.18%	26.87%	21.12%
Current Ratio	3.89	3.65	1.22	2.69	3.98	3.77
Debt/Capital	36.08%	8.10%	42.99%	20.46%	19.89%	21.53%
Net Margin	29.61%	-110.57%	11.21%	-18.71%	31.05%	-2.65%
Return on Equity	27.99%	-67.50%	17.16%	-6.08%	21.21%	-1.35%
Sales/Assets	0.38	0.29	0.55	0.61	0.33	0.36
Proj. Sales Growth (F1/F0)	10.42%	8.86%	4.08%	-8.43%	14.48%	15.20%
Momentum Score	C	-	-	A	B	A
Daily Price Chg	0.08%	0.00%	-0.04%	0.30%	-1.42%	0.05%
1 Week Price Chg	2.98%	1.10%	2.29%	-1.43%	3.46%	-3.11%
4 Week Price Chg	-2.12%	2.50%	2.05%	-12.81%	1.02%	1.41%
12 Week Price Chg	19.20%	5.98%	6.92%	-6.96%	4.85%	19.12%
52 Week Price Chg	17.55%	-16.95%	21.50%	-42.73%	-4.79%	-6.40%
20 Day Average Volume	404,111	192,590	1,518,423	1,184,301	1,451,722	1,152,761
(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%	1.35%	0.00%
(F1) EPS Est 12 week change	0.00%	2.20%	-0.23%	73.53%	2.19%	3.80%
(Q1) EPS Est Mthly Chg	NA%	0.00%	0.00%	0.00%	3.43%	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	A
Growth Score	B
Momentum Score	C
VGM Score	A

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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