

Incyte Corporation (INCY)

\$87.75 (As of 04/08/20)

Price Target (6-12 Months): **\$93.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 04/02/20)

Prior Recommendation: Underperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

4-Sell

Zacks Style Scores:

VGM:D

Value: F

Growth: C

Momentum: B

Summary

Incyte's lead drug, Jakafi, maintains momentum, propelled by increasing demand in all three approved indications (polycythemia vera, myelofibrosis and the recent label expansion in acute GVHD). The company's efforts to further expand the drug's label should boost sales. Moreover, its efforts to diversify the revenue base and develop the pipeline are impressive. However, pipeline failures are concerning. GRAVITAS-301, the phase III study of itacitinib as a treatment for patients with newly-diagnosed acute GVHD, did not meet the primary endpoint. Moreover, the company is highly dependent on Jakafi for a major chunk of revenues. The recently-approved therapies will pose stiff competition to Jakafi and sales might take a hit. Shares have outperformed the industry in the past one year.

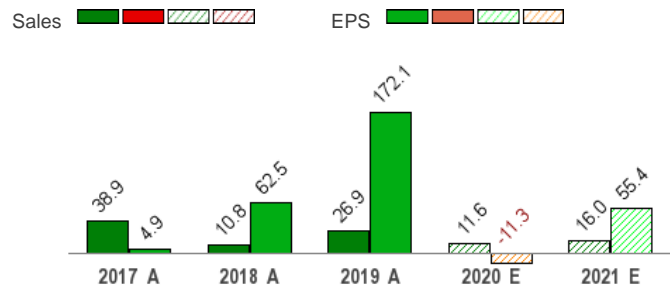
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$96.79 - \$62.48
20 Day Average Volume (sh)	2,569,882
Market Cap	\$19.0 B
YTD Price Change	0.5%
Beta	0.80
Dividend / Div Yld	\$0.00 / 0.0%
Industry	<u>Medical - Biomedical and Genetics</u>
Zacks Industry Rank	Top 9% (24 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	12.1%
Last Sales Surprise	1.6%
EPS F1 Est- 4 week change	-8.0%
Expected Report Date	05/05/2020
Earnings ESP	-602.6%

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	609 E	673 E	701 E	766 E	2,794 E
2020	537 E	577 E	626 E	657 E	2,409 E
2019	498 A	530 A	552 A	579 A	2,159 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.83 E	\$1.02 E	\$1.11 E	\$1.24 E	\$3.90 E
2020	\$0.11 E	\$0.73 E	\$0.81 E	\$0.89 E	\$2.51 E
2019	\$0.62 A	\$0.75 A	\$0.82 A	\$0.65 A	\$2.83 A

*Quarterly figures may not add up to annual.

P/E TTM	30.9
P/E F1	35.0
PEG F1	1.1
P/S TTM	8.8

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 04/08/2020. The reports text is as of 04/09/2020.

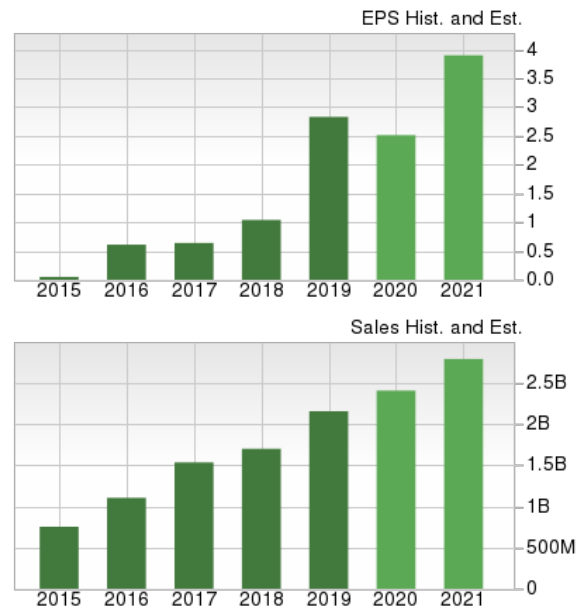
Overview

Wilmington, DE-based Incyte Corporation is a biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. The company conducts its European clinical development operations in Geneva, Switzerland.

Incyte's lead drug, Jakafi (ruxolitinib), is a first-in-class JAK1/JAK2 inhibitor, approved in the United States for the treatment of patients with polycythemia vera ("PV"), who have had an inadequate response to or are intolerant to hydroxyurea. It is also approved for the treatment of patients with intermediate or high-risk myelofibrosis (MF), including primary MF, post-PV MF, and post-essential thrombocythemia MF. In May 2019, Jakafi obtained FDA approval for the treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients aged 12 years or older. While Incyte markets the drug in the United States, it is marketed by Novartis as Jakavi outside the country. Jakafi sales came in at \$1.7 billion in 2019, thereby contributing 78% to total revenues.

The company's second JAK1 and JAK2 inhibitor, Olumiant (baricitinib, JAK1/JAK2 inhibitor) was approved in the EU in Feb 2017 for rheumatoid arthritis (RA). Incyte is co-developing Olumiant with Eli Lilly. In June 2018, the FDA approved the 2mg dose of baricitinib as Olumiant for the treatment of adults with RA. The approval brings another source of income for Incyte as royalties.

In Jun 2016, Incyte entered into a share purchase agreement with ARIAD under which it gained the latter's European business and the rights to Iclusig in the EU and 22 other countries including Switzerland, Norway, Turkey, Israel and Russia. Revenues for 2019 came in at \$2.2 billion, up from \$1.9 billion in 2018.



Reasons To Buy:

▲ **Share Price Performance:** Incyte's stock has outperformed the industry in the past one year.

▲ **Jakafi Driving Growth:** Jakafi continues to drive growth for the company on label expansions. It became the first FDA-approved JAK inhibitor for any indication, and the first and only product to be approved by the FDA for the treatment of MF and PV — rare blood cancers. Jakafi is the only treatment to provide consistent hematocrit control, spleen volume reduction and complete hematological remission by targeting the overactive JAK pathway. Its label has been updated several times since approval, which has boosted Incyte's sales. It was updated in June 2013 to include information on a new recommended dosing guidance for patients with low platelet count. In 2014, the FDA approved a supplemental labeling for Jakafi to include Kaplan Meier overall survival (OS) curves as well as additional safety and dosing information. Further, in March 2016, the FDA approved supplemental labeling for Jakafi to include additional safety data and efficacy analyses from the RESPONSE study that assessed the durability of response in Jakafi-treated patients after 80 weeks. We note that Jakafi enjoys Orphan Drug status in the United States for MF, PV and essential thrombocythemia. The drug also has long patent life that runs until late 2027.

Key growth driver, Jakafi, has been performing well. Incyte's efforts to develop its pipeline are also encouraging.

In order to expand the patient population and increase the commercial potential of the drug, the company is working on expanding the drug's label further. In October 2017, the FDA approved a label update of the drug to include the addition of new patient-reported outcome (PRO) data from the COMFORT-I study, as well as updating the warning related to progressive multifocal leukoencephalopathy. The FDA recently approved Jakafi for the treatment of steroid-refractory acute GVHD in adult and pediatric patients aged 12 years or older. This is the third indication, for which the drug has been approved in the United States. The label expansion of the drug will further boost sales. Meanwhile, REACH2 and REACH3, evaluating steroid-refractory acute and steroid-refractory chronic graft-versus-host disease, respectively, are ongoing in collaboration with Novartis. REACH2, the phase III study evaluating Jakafi in patients with steroid-refractory acute GVHD, met its primary endpoint of superior overall response. An Independent Data Monitoring Committee (IDMC) recommended that the phase III REACH3 trial should continue without modification following an interim efficacy and safety analysis.

Moreover, the cream formulation is currently in phase III development for the treatment of patients with mild to moderate atopic dermatitis (TRuE-AD). It is also being evaluated for the treatment of adolescents and adults with vitiligo (TRuE-V).

Incyte announced that it is working with the FDA to initiate a phase III study, RUXCOVID, to evaluate the efficacy and safety of Jakafi plus standard-of-care (SoC) compared to SoC therapy alone in patients with COVID-19-associated cytokine storm.

▲ **Pipeline Holds Promise:** Incyte's pipeline is highly encouraging. The company has several candidates in early-to mid-stage development in its pipeline, including both targeted therapies and immune therapies that are being developed in oncology and outside oncology. Interesting targeted therapies include pemigatinib (phase II for bladder cancer and cholangiocarcinoma), capmatinib and baricitinib in atopic dermatitis, among others. Incyte submitted an NDA to the FDA for pemigatinib seeking approval as a second-line treatment for patients with FGFR2 translocated cholangiocarcinoma under Breakthrough Therapy designation. The FDA has accepted the same. With the FDA granting priority review to the NDA, a decision from the regulatory body is expected on May 30, 2020. The Marketing Authorization Application (MAA) seeking approval in Europe for pemigatinib as a second-line treatment for cholangiocarcinoma patients with FGFR2 fusions or rearrangements was validated by the EMA.

GRAVITAS-309, a phase III study of itacitinib as a treatment for patients with newly-diagnosed chronic GVHD, was initiated in January and results are expected in 2021. Capmatinib was discovered by Incyte and was included in the 2009 license agreement with Novartis. Capmatinib is an oral reversible inhibitor of the MET receptor tyrosine kinase and it has shown both high selectivity for MET and is extremely potent against MET exon-14 skipping mutations compared to all other MET inhibitors in development. In June 2019, the FDA granted Breakthrough Therapy designation to capmatinib as a treatment for patients with metastatic NSCLC harboring MET exon-14 skipping mutation with disease progression on or after platinum-based chemotherapy. If approved, Incyte will be eligible for 12-14% royalties on global net sales by Novartis and could receive more than \$500 million in potential milestones over time. This February, Incyte and Novartis announced that the NDA for capmatinib was accepted for Priority Review by the FDA, seeking approval in patients with NSCLC and MET exon 14 skipping mutations.

▲ **Encouraging Collaborations:** Incyte has two major agreements with Novartis and Lilly. The 2009 agreement with Novartis includes Jakafi (excluding topical formulations). Per the agreement, Incyte is marketing Jakafi in the United States while Novartis is responsible for the same outside the United States. The deal with Eli Lilly gives the latter exclusive worldwide development and commercialization rights to Olumiant. The FDA approval of Olumiant has triggered a \$100 million milestone payment from Lilly. However, Incyte has elected to not participate in the development of baricitinib in order to reallocate capital, over time, to other promising internal projects. Nevertheless, it will continue to receive royalties on global net sales of Olumiant, pursuant to the terms of its agreement with Lilly. Incyte also entered into a strategic collaboration agreement with China-based Innovent Biologics, Inc. Both the companies have entered into an agreement, through their respective subsidiaries, for the development of three clinical-stage product candidates - pemigatinib (FGFR1/2/3 inhibitor), itacitinib (JAK1 inhibitor) and piasclisib.

Reasons To Sell:

- ▼ **Overdependence on Jakafi for Growth:** Incyte's dependence on a single product, Jakafi for growth is concerning. Lower-than-expected sales would be a huge setback for the company. While we are positive on the company's efforts to expand Jakafi's label, any development/regulatory setback could pull down the stock significantly.
- ▼ **Pipeline Setbacks:** Though we are pleased with Incyte's broad pipeline, the candidates still have to go a long way before hitting the market. Any hiccup in the development process or adverse study results may weigh heavily on the stock and hamper the company's growth progress.
- ▼ The phase III GRAVITAS-301, evaluating itacitinib in combination with corticosteroids in patients with treatment-naïve (first-line) acute GVHD, did not meet the primary endpoint of overall response rate (ORR) at day 28 compared to placebo plus corticosteroids (74.0% vs. 66.4%, p=0.08, respectively). Incyte earlier suffered a setback with epacadostat. The external Data Monitoring Committee (eDMC) review of the pivotal phase III study, ECHO-301, evaluating epacadostat in combination with Keytruda in patients with unresectable or metastatic melanoma determined that the study did not meet the primary endpoint of improving progression-free survival in the overall population compared to pembrolizumab monotherapy. Consequently, based on the disappointing data and the recommendation of the eDMC, Incyte stopped the study to enable patients and their physicians to consider alternative therapeutic options.
- ▼ **Stiff Competition:** The FDA recently approved Inrebic for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. This will increase competition for Jakafi. Additionally, Jakafi is likely to face competition from generics. Also, Iclusig faces intense competition. Meanwhile, the oncology market is attracting a lot of attention, with several companies inking deals to tap into this high revenue-potential market.

Overdependence on Jakafi is concerning. Also, most of its pipeline candidates are in early-to-mid stages of development, which translates into a long way to approval.

Last Earnings Report

Incyte Q4 Earnings Top Estimates on Solid Jakafi Sales

The company reported earnings of 65 cents per share, which easily surpassed the Zacks Consensus Estimate of 58 cents but declined from 66 cents in the year-ago quarter.

Including milestones and contracts, revenues came in at \$579.4 million, which grew 10% year over year and beat the Zacks Consensus Estimate of \$570.1 million.

Quarter in Detail

Total product-related revenues came in at \$490.8 million, up 22.9% from the year-ago quarter.

Jakafi revenues came in at \$466.5 million, increasing 23% from the year-ago quarter and beating the Zacks Consensus Estimate of \$454 million. Robust demand for Jakafi in all three approved indications drove revenues.

Net product revenues of Iclusig amounted to \$24.3 million, up from \$19.1 million in the year-ago quarter.

Jakavi (name outside the United States) royalty revenues from Novartis AG or commercialization in ex-U.S. markets grew 17% to \$65 million. Olumiant's product royalty revenues from Eli Lilly came in at \$23.6 million.

R&D expenses were \$312.9 million, up from \$304 million in the year-ago quarter. SG&A expenses amounted to \$136.2 million, up from \$108.4 million in the prior-year quarter.

2019 Results

Revenues in 2019 came in at \$2.16 billion, up 15% from 2018. Earnings per share came in at \$2.83 in 2019, up from \$1.63 in 2018.

2020 Outlook

The company expects Jakafi revenues of \$1,880 - \$1,950 million for 2020. Iclusig revenues are projected around \$100-\$105 million.

Pipeline Update

REACH2, the phase III study in patients with steroid-refractory acute graft-versus-host disease (GVHD), met its primary endpoint of superior overall response rate at day 28 with Jakafi treatment compared with best available therapy. The REACH2 and REACH3 trials, evaluating steroid-refractory acute and steroid-refractory chronic GVHD, respectively, are being conducted in collaboration with Novartis.

However, GRAVITAS-301, the phase III study of itacitinib as a treatment for patients with newly-diagnosed acute GVHD, did not meet the primary endpoint.

In November 2019, the FDA accepted Incyte's new drug application (NDA) for its investigational FGFR inhibitor pemigatinib as a second-line treatment for locally advanced or metastatic cholangiocarcinoma, also known as bile-duct cancer. With the FDA granting priority review to the NDA, a decision from the regulatory body is expected on May 30, 2020.

The Marketing Authorization Application (MAA) seeking approval in Europe for pemigatinib as a second-line treatment for cholangiocarcinoma patients with FGFR2 fusions or rearrangements was validated by the EMA.

TRuE-AD2, the first of the two phase III studies in the TRuE-AD development program of ruxolitinib cream in patients with mild-to-moderate atopic dermatitis, met its primary endpoint.

Incyte expects the results of TRuE-AD1, the second of the two phase III studies required for regulatory submission, to be available in the first quarter of 2020.

Incyte entered into a global collaboration with MorphoSys for the development and commercialization of tafasitamab, an anti-CD19 monoclonal antibody. Pending clearance by antitrust authorities, the collaboration agreement is expected to become effective in the first half of 2020.

Quarter Ending **12/2019**

Report Date	Feb 13, 2020
Sales Surprise	1.64%
EPS Surprise	12.07%
Quarterly EPS	0.65
Annual EPS (TTM)	2.84

Recent News

Evaluate Lead Drug Jakafi for COVID-19 Infection – Apr 2

Incyte announced that it is working with the FDA to initiate a phase III study, RUXCOVID, to evaluate the efficacy and safety of Jakafi plus standard-of-care (SoC) compared to SoC therapy alone in patients with COVID-19-associated cytokine storm.

The Jakafi study will be sponsored by Incyte in the United States and Novartis outside of the country. Moreover, Incyte plans to initiate a separate open-label emergency Expanded Access Program (EAP) in the United States. Under this protocol, eligible patients with severe COVID-19 associated cytokine storm are allowed to receive Jakafi while it is being evaluated for this indication.

The RUXCOVID and EAP studies are awaiting potential FDA approvals.

Breakthrough Therapy Designation for Baricitinib for the Treatment of Alopecia Areata - Mar 16

Incyte and partner Eli Lilly announced today that the FDA has granted Breakthrough Therapy designation to Olumiant (baricitinib) for the treatment of alopecia areata (AA), an autoimmune disorder that can cause unpredictable hair loss on the scalp, face and other areas of the body.

Incyte & MorphoSys Get Antitrust Clearance – Mar 3

Incyte and MorphoSys AG announced that their collaboration and license agreement for the further development and global commercialization of the latter's investigational candidate, tafasitamab (MOR208), has received antitrust clearance. This triggers a \$750-million upfront payment to be received by MorphoSys from Incyte. Additionally, Incyte will make an equity investment of \$150 million in new American Depositary Shares (ADS) in MorphoSys within the defined timelines. The FDA recently accepted MorphoSys' Biologics License Application (BLA) for tafasitamab in combination with lenalidomide for the treatment of patients with relapsed or refractory diffuse large B-cell lymphoma (r/r DLBCL) and granted Priority Review.

Positive Topline Results From Phase 3 TRuE-AD Program – Feb 19

Incyte announced that the second randomized, vehicle-controlled, pivotal phase III study from the TRuE-AD clinical trial program has met its primary endpoint.

The results of TRuE-AD1 showed that significantly more patients treated with ruxolitinib cream 0.75% or 1.5% achieved Investigator's Global Assessment Treatment Success (IGA-TS) — defined as an IGA score of 0 (clear) or 1 (almost clear) with at least a two-point improvement from baseline at Week 8 as compared to patients treated with vehicle control (non-medicated cream). The overall efficacy and safety profile of ruxolitinib cream was consistent with previous data, and no new safety signals were observed.

Capmatinib NDA Gets Priority Review From FDA – Feb 11

Incyte announced that the FDA accepted and granted Priority Review to the new drug application (NDA) for capmatinib, which is an investigational, oral selective MET inhibitor. The company is seeking approval of capmatinib for the treatment of first-line and previously treated patients with locally advanced or metastatic MET exon 14 skipping (METex14) mutated non-small cell lung cancer (NSCLC) — a type of lung cancer with a particularly poor prognosis. If approved, the candidate will be the first therapy to specifically target METex14 mutated advanced lung cancer.

Valuation

Incyte's shares are up 0.5% in the year-to-date period and 5.2% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 7.1% and 10.4% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 11.1% while the sector is down 8.3%.

The S&P 500 index is down 17.3% in the year-to-date period and 8.1% in the past year.

The stock is currently trading at 7.57X forward 12-month sales per share which compares to 2.94X for the Zacks sub-industry, 2.51X for the Zacks sector and 3.04X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 27.64X and as low as 5.35X, with a 5-year median of 11.76X. Our Neutral recommendation indicates that the stock will perform in-line with the the market. Our \$93 price target reflects 7.95X forward 12-month sales per share.

The table below shows summary valuation data for INCY

Valuation Multiples - INCY					
		Stock	Sub-Industry	Sector	S&P 500
P/S F12M	Current	7.57	2.94	2.51	3.04
	5-Year High	27.64	3.2	3.84	3.44
	5-Year Low	5.35	2.05	2.26	2.54
	5-Year Median	11.76	2.62	2.96	3.01

P/B TTM	5-Year Median	11.19	2.92	2.50	3.01
	Current	7.32	3.62	3.46	3.66
	5-Year High	426.7	5.46	5.05	4.55
	5-Year Low	N/A	2.45	2.9	2.84
	5-Year Median	11.86	3.34	4.3	3.63

As of 04/08/2020

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



Top Peers

Alkermes plc (ALKS)	Neutral
SWEDISH ORP BIO (BIOVF)	Neutral
BioMarin Pharmaceutical Inc. (BMRN)	Neutral
Bristol-Myers Squibb Company (BMY)	Neutral
Emergent Biosolutions Inc. (EBS)	Neutral
Horizon Therapeutics Public Limited Company (HZNP)	Neutral
QIAGEN N.V. (QGEN)	Neutral
SINO PHARMACEUT (SBMFF)	Neutral

Industry Comparison Industry: Medical - Biomedical And Genetics				Industry Peers		
	INCY Neutral	X Industry	S&P 500	BMRN Neutral	BMY Neutral	QGEN Neutral
VGM Score	D	-	-	B	B	C
Market Cap	19.02 B	161.87 M	19.05 B	14.32 B	131.50 B	8.99 B
# of Analysts	7	3	13	11	5	4
Dividend Yield	0.00%	0.00%	2.23%	0.00%	3.09%	0.00%
Value Score	F	-	-	D	B	D
Cash/Price	0.12	0.31	0.06	0.05	0.12	0.09
EV/EBITDA	31.18	-2.13	11.47	439.90	23.73	35.54
PEG Ratio	1.08	1.72	2.00	NA	1.29	2.95
Price/Book (P/B)	7.27	3.03	2.56	4.58	2.51	3.55
Price/Cash Flow (P/CF)	35.07	13.87	10.14	124.93	13.27	14.86
P/E (F1)	34.51	28.40	16.97	49.78	9.54	28.72
Price/Sales (P/S)	8.81	12.55	2.01	8.40	5.03	5.89
Earnings Yield	2.86%	-19.78%	5.81%	2.01%	10.49%	3.49%
Debt/Equity	0.01	0.02	0.70	0.16	0.84	0.56
Cash Flow (\$/share)	2.50	-1.03	7.01	0.64	4.39	2.66
Growth Score	C	-	-	A	B	B
Hist. EPS Growth (3-5 yrs)	52.48%	18.12%	10.92%	NA	20.53%	7.82%
Proj. EPS Growth (F1/F0)	-11.20%	5.73%	-0.64%	71.95%	30.19%	-3.85%
Curr. Cash Flow Growth	132.41%	13.26%	5.93%	200.25%	36.74%	9.25%
Hist. Cash Flow Growth (3-5 yrs)	140.30%	8.18%	8.55%	27.84%	22.46%	5.76%
Current Ratio	4.83	4.82	1.24	2.08	1.60	1.65
Debt/Capital	1.21%	4.33%	42.36%	13.47%	45.63%	35.91%
Net Margin	20.70%	-229.34%	11.64%	-1.40%	13.15%	-2.72%
Return on Equity	20.05%	-65.95%	16.74%	0.81%	31.85%	13.00%
Sales/Assets	0.70	0.20	0.54	0.38	0.38	0.29
Proj. Sales Growth (F1/F0)	11.60%	8.07%	0.61%	16.33%	58.79%	0.81%
Momentum Score	B	-	-	A	D	C
Daily Price Chg	1.26%	2.69%	4.33%	-0.29%	2.37%	-1.79%
1 Week Price Chg	13.96%	-3.64%	-4.40%	5.91%	5.19%	-0.45%
4 Week Price Chg	22.05%	-3.76%	-1.70%	-8.40%	3.08%	-3.92%
12 Week Price Chg	8.95%	-25.90%	-20.64%	-10.43%	-12.51%	16.25%
52 Week Price Chg	5.20%	-33.49%	-12.97%	-13.76%	26.93%	-4.59%
20 Day Average Volume	2,569,882	254,972	4,016,075	1,932,940	19,585,412	1,948,795
(F1) EPS Est 1 week change	0.00%	0.00%	-0.26%	0.00%	-0.41%	-5.66%
(F1) EPS Est 4 week change	-7.98%	0.00%	-5.64%	0.00%	-0.38%	-9.54%
(F1) EPS Est 12 week change	-21.36%	-1.79%	-7.49%	-29.85%	0.16%	-7.00%
(Q1) EPS Est Mthly Chg	-10.53%	0.00%	-9.90%	0.00%	-2.27%	-38.67%

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	F
Growth Score	C
Momentum Score	B
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.

Disclosures

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