United Therapeutics (UTHR)

$88.08 (As of 01/01/20)

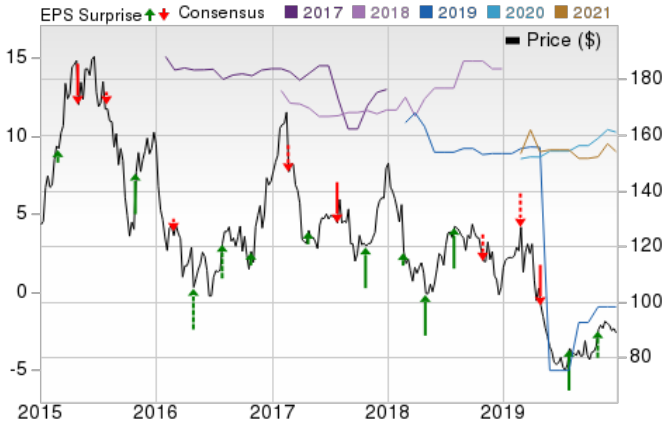
Price Target (6-12 Months): **$93.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 12/30/19) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**4-Sell**
	Zacks Style Scores:	VGM:A
	Value: A | Growth: B | Momentum: A	

Summary

Demand for United Therapeutics' treprostinil medicines, namely Remodulin, Tyvaso and Orenitram is consistently growing despite generic concerns and competitive pressure. The company is working on new delivery mechanisms for Remodulin and extended indications for Orenitram and Tyvaso, which might boost long-term growth. Some improved Remodulin delivery devices are expected to be launched in the next 12 months, which can expand its market. Moreover, the company acquired several new product candidates to strengthen its pipeline. However, competition in the PAH market is on the rise. Also, two of its biggest products like Remodulin and Adcirca lost exclusivity in 2018. Generic versions of both drugs have been launched, which should substantially erode the drugs' sales. The stock has underperformed the industry in the past year.

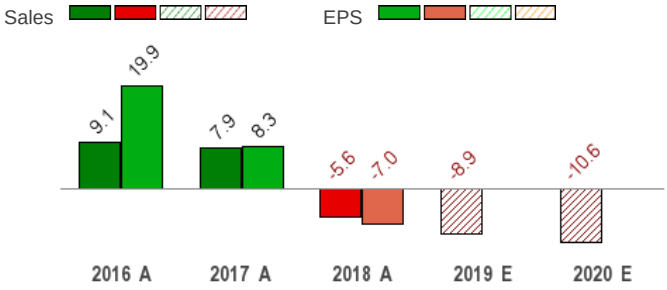
Price, Consensus & Surprise



Data Overview

52 Week High-Low	**$128.94 - $74.31**
20 Day Average Volume (sh)	**366,221**
Market Cap	**$3.9 B**
YTD Price Change	**-19.1%**
Beta	**0.95**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Drugs**
Zacks Industry Rank	**Top 23% (59 out of 253)**
Last EPS Surprise	**28.6%**
Last Sales Surprise	**19.9%**
EPS F1 Est- 4 week change	**0.0%**
Expected Report Date	**02/26/2020**
Earnings ESP	**0.0%**
P/E TTM	**6.5**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**2.5**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	323 E	318 E	313 E	313 E	1,326 E
2019	363 A	374 A	402 A	345 E	1,483 E
2018	389 A	445 A	413 A	381 A	1,628 A

EPS Estimates

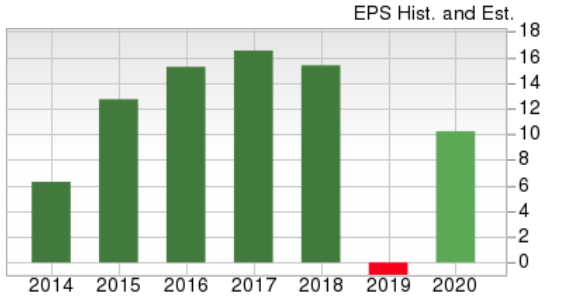
	Q1	Q2	Q3	Q4	Annual*
2020	$2.40 E	$2.13 E	$1.81 E	$1.58 E	$10.23 E
2019	$3.58 A	$3.63 A	$3.01 A	$2.41 E	-$0.96 E
2018	$3.76 A	$4.36 A	$3.98 A	$3.34 A	$15.36 A

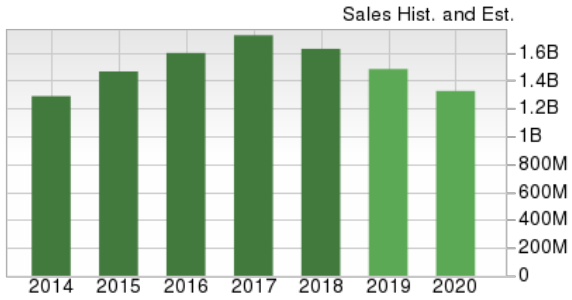
*Quarterly figures may not add up to annual.

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 01/01/2020. The reports text is as of 01/02/2020.

Overview

Silver Spring, MD-based United Therapeutics Corporation engages in the development and commercialization of therapeutic products for patients with chronic and life-threatening diseases. The company markets four medicines in the United States to treat pulmonary arterial hypertension (PAH): Remodulin, an injectable formulation of treprostinil, Orenitram, an oral version of treprostinil, Tyvaso, an inhaled version of treprostinil, and Adcirca (tadalafil; also sold by Eli Lilly as Cialis for erectile dysfunction) tablets. Remodulin is approved for both subcutaneous (SC) and intravenous (IV) use.





The company licensed certain exclusive rights to Adcirca from Lilly in November 2008. The company paid upfront fees of $150 million to Lilly for the exclusive rights to commercialize Adcirca for the treatment of PAH in the United States.

In 2015, the company gained approval for Unituxin for the treatment of pediatric patients with high-risk neuroblastoma. The antibody has been developed under an agreement with the National Cancer Institute (NCI) of the United States National Institutes of Health (NIH).

In August, United Therapeutics acquired SteadyMed, adding its drug device pipeline product Trevyent for PAH to its portfolio. In January 2019, United Therapeutics acquired the worldwide rights to manufacture and develop/commercialize Arena Pharmaceuticals' oral, potent, once-daily IP receptor agonist, ralinepag. Ralinepag is being developed in late-stage studies for PAH.

The company reported total revenues of $1.63 billion in 2018, down 5.7%. Around 75% of its revenues in 2018 were derived from Remodulin, Tyvaso and Orenitram.

Reasons To Buy:

United Therapeutics is working on new delivery mechanisms for Remodulin and expanded indications for its other marketed products like Orenitram and Tyvaso, which might drive long-term growth.

- **Strong Position in PAH Market:** United Therapeutics holds a strong position in the PAH market with four approved products targeting this indication. Lead product, Remodulin, is available in both the IV and SC forms. Patients usually start on a SC dose and move on to an IV dose of the drug once subcutaneous administration is either no longer tolerated or sufficient to control the symptoms. Meanwhile, the company has three more PAH products in its portfolio – Adcirca, Tyvaso and Orenitram. With these products, United Therapeutics has a varied range of therapies targeting the PAH market.

- **New Delivery Mechanisms for Remodulin:** The company is working on bringing multiple second generation Remodulin drug delivery systems to drive Romudulin sales growth. In July, United Therapeutics gained FDA approval for Remodulin Injection in the Implantable System for Remodulin (ISR). United Therapeutics had developed this implantable pump for delivering Remodulin intravenously in collaboration with Medtronic. United Therapeutics and Medtronic pursued parallel regulatory filings related to the device and the drug. The system has been developed to eliminate two biggest problems with Remodulin, subcutaneous pain and the life-threatening sepsis risk. The company expects to launch ISR in 2020. United Therapeutics has also developed a pre-filled, semi-disposable pump system for subcutaneous delivery of Remodulin (RemUnity) in partnership with DEKA. In February 2018, DEKA filed RemUnity with the FDA (510(k) filing) that was cleared by the FDA in May 2019. United Therapeutics intends to launch the product after it gets an FDA clearance for a special 510(k) filing, which DEKA plans to submit to the FDA shortly. RemoPro, a pain-free subcutaneous Remodulin prodrug, is in phase I studies.

- **PAH Market Represents Significant Opportunity:** The PAH market is highly attractive given the low diagnosis rate, the low penetration of existing therapies, and the significant unmet medical need. The incidence of PAH is growing rapidly, especially in patients with associated diseases such as HIV, sickle cell anemia, systemic sclerosis, and chronic obstructive pulmonary disease (COPD). However, many of the associated PAH cases develop from idiopathic origins. As PAH is a progressive disease without a cure, many patients continue to deteriorate on currently approved therapies. Although the majority of PAH patients start out on oral endothelin receptor antagonist (ETRA) treatments like J&J's Tracleer (bosentan) or Gilead's Letairis (ambrisentan), PAH progression often moves fast and patients typically begin to fail oral first-line monotherapy within two years. The next progression is usually to SC/IV prostacyclin agents such as Glaxo's Flolan (epoprostenol) or Remodulin. We note that phosphodiesterase type-IV (PDE-5) agents, like Pfizer's Revatio, have gained significant front-line use thanks to their oral administration and vasodilating properties. This presents market growth opportunities for Remodulin, Tyvaso and Adcirca as viable alternatives or complementary treatments to existing therapies. Furthermore, the market should continue to expand as more patients are diagnosed with PAH each year. United Therapeutics is, therefore, well-positioned to gain additional share in the PAH market.

- **Expanding Pipeline:** United Therapeutics is working on expanded indications for some of its marketed products like Orenitram and Tyvaso. A phase III FREEDOM-EV study evaluated an oral combination therapy of Orenitram — OreniPlus. In October 2019, United Therapeutics gained an FDA approval to get FREEDOM-EV data included in the label of Orenitram. With this label update, United Therapeutics is optimistic that it will be able to double the number of patients treated with Orenitram over the next two to three years.

  Other phase III programs include Tyvaso-ILD (Tyvaso being evaluated in patients with PAH associated with idiopathic pulmonary fibrosis – phase III INCREASE study), OreniLeft, gene therapy (Aurora-GT) for PAH (phase II/III SAPPHIRE study), Treprostinil Technosphere (PAH — phase III BREEZE study), Tyvaso in PAH patients who have COPD (phase III PERFECT study) and Ralinepag (PAH — phase III ADVANCE studies). Success in these studies may open up attractive market opportunities and address significant unmet clinical needs.

  Finally, the company is also developing dinutuximab, the active ingredient in Unituxin, for small cell lung cancer (phase II/III DISTINCT study). United Therapeutics also has four different kinds of organ manufacturing products in clinical and preclinical development. These include xenotransplantation, three-dimensional organ printing, regenerative medicine and ex-vivo lung perfusion.

- **Regular In-Licensing Deals Expands Product Portfolio:** In 2018, United Therapeutics signed four major agreements to acquire new product candidates.

  With the August merger with SteadyMed, United Therapeutics added SteadyMed's drug device pipeline product Trevyent for PAH to its portfolio, which could have posed competition to ISR. Trevyent is a single-use, pre-filled pump that has been developed by SteadyMed to deliver a two-day supply of treprostinil subcutaneously using SteadyMed's PatchPump technology to treat PAH. Trevyent is under review with the FDA (PDUFA Date: April 27, 2020). RemUnity and Trevyent, if approved, will provide two expanded options for patients on subcutaneous Remodulin.

  In October, United Therapeutics in-licensed MannKind's phase III-ready investigational drug-device combination product, Treprostinil Technosphere. The product combines MannKind's dry inhalation technology with treprostinil for the treatment of PAH. In September, United Therapeutics in-licensed the U.S. and Canadian rights to Samumed's SM04646, a phase I development-stage oral Wnt pathway inhibitor, to treat idiopathic pulmonary fibrosis. In January 2019, United Therapeutics acquired the worldwide rights to manufacture and develop/commercialize Arena Pharmaceuticals oral, potent, once-daily IP receptor agonist ralinepag. Ralinepag is being developed in late-stage studies for PAH. We believe that with the deal United Therapeutics has added a quality PAH asset to its portfolio. Further, the purchase of ralinepag removes potential competition for United Therapeutics' PAH products.

Reasons To Sell:

- **Shares Underperforming Industry:** Shares of United Therapeutics have declined 17.8% in the past year versus its industry's 14.6% increase.

- **Intense Competition:** Even though United Therapeutics has four products for the treatment of PAH, competition in this market is intense. The majority of PAH patients start out on oral ETRA treatments that include Gilead's Letairis and Acelion's Tracleer. PDE-5 agents including Pfizer's Revatio (sildenafil, sold as Viagra for erectile dysfunction) have gained significant front-line use, thanks to their oral administration and vasodilating properties. Meanwhile, Actelion's (now a part of J&J) Uptravi was approved by the FDA in December 2015, 0which competes with Orenitram. We believe competition will continue to increase with several companies working on bringing additional therapies to the market.

Competition in the PAH market is increasing. Moreover, two of its biggest products — Remodulin and Adcirca — lost exclusivity in 2018 and generics have been launched which may hurt sales.

Moreover, competition in the market has increased with the entry of generic versions of Revatio, Letairis and Tracleer. A generic version of Gilead's Letairis was launched in May 2019 while that of Actelion's Tracleer was launched in June, both by Teva in the United States.

- **Dependence on Remodulin, Generic Competition:** We are concerned about the company's dependence on Remodulin for revenues. Remodulin, which accounted for almost 37% of total sales in 2018, lost exclusivity in June 2018. A generic version was launched by Novartis' Sandoz in March 2019. Par Sterile Products and Teva received FDA approval for their Remodulin generics in September and October 2019, respectively, and may launch the same in the United States soon. More generics may be unveiled in Europe and the United Sates, which may reduce revenues from this product in the future quarters.

  Adcirca lost patent exclusivity in May 2018 and a generic formulation was launched by Mylan last August and by additional companies in February 2019. This has significantly lowered Adcirca sales in the first nine months of 2019 with the same expected to persist in the upcoming quarters.

  Moreover, with the launch of Orenitram, there has been some cannibalization of Tyvaso and Remodulin sales.

  Importantly, though United Therapeutics is a leader in PAH, a lack of product as well as pipeline diversification beyond PAH is a concern.

- **Setback for Remodulin Life Cycle Management Plans:** The company's life cycle management plans for Remodulin faced a setback with the FDA issuing a response letter to partner Medtronic for its premarket approval application (PMA) for the catheter for ISR, saying that the PMA is not approvable. The agency noted various measures that Medtronic needs to take for approval of the PMA. United Therapeutics also received a complete response letter for its NDA requesting FDA approval for the use of Remodulin with ISR. The CRL indicated that the FDA cannot approve the NDA before Medtronic's PMA is approved. Both the NDA and PMA have to be approved in order to launch ISR in the U.S.

  Though United Therapeutics already obtained an FDA approval, a final Medtronic nod is awaited before the product can be commercially launched. A launch is not expected before 2020.

Last Earnings Report

United Therapeutics Q3 Earnings & Sales Top

Quarter Ending	09/2019
Report Date	**Oct 30, 2019**
Sales Surprise	**19.94%**
EPS Surprise	**28.63%**
Quarterly EPS	**3.01**
Annual EPS (TTM)	**13.56**

United Therapeutics reported earnings of $3.01 per share for the third quarter of 2019, which beat the Zacks Consensus Estimate of $2.34. Earnings also rose 24% year over year, driven by lower costs.

The earnings include the impact of share-based compensation expenses, impairment charges, unrealized gains/losses on equity securities and other items. Excluding these items, adjusted earnings were $3.83 per share, down 4% year over year.

Revenues for the reported quarter were $401.5 million, which surpassed the Zacks Consensus Estimate of $335 million. Revenues, however, fell 3% year over year due to loss of exclusivity for Adcirca.

Quarter in Detail

Adcirca sales were $30.3 million, down 59% year over year as generic competition resulted in lower volumes in the quarter. Orenitram sales amounted to $62 million, up 15% year over year owing to an increase in the number of patients being treated with the drug and price hikes. Tyvaso sales totaled $110 million, up 3% year over year, driven by price rise implemented in January. Remodulin sales were $168.3 million, up 10% year over year as higher volumes of sales to international distributors and U.S. patient growth were partially offset by price reductions.

Unituxin's (for the treatment of pediatric patients with high-risk neuroblastoma) sales of $30.1 million were up 31% year over year on increased number of vials sold and price surges.

Research and development (R&D) expenses were $85.7 million in the quarter, down 15% year over year owing to some upfront payments made in the third quarter of 2018, which were absent in third-quarter 2019. Total selling, general and administrative expense declined 10% year over year to $99.4 million.

Outlook

In 2019, revenues are expected to be lower than the 2018-level as the generic version of Adcirca will be available for the whole year compared to the only four-month period of 2018. Meanwhile, erosion from generic launches, both in the United States and EU, may hurt Remodulin sales in the fourth quarter and create further top-line pressure.

Recent News

Gets FDA Nod to Include FREEDOM-EV Data on Orenitram's Label — Oct 21

United Therapeutics announced that the FDA has approved inclusion of data from the FREEDOM-EV study on the label of Orenitram.

With the inclusion of FREEDOM-EV, Orenitram can now be prescribed to delay disease progression when used in conjunction with an approved oral background PAH therapy. The label now indicates that treatment with Orenitram led to a significant increase in the time to first clinical worsening event compared to placebo, which was associated with a reduction in the risk of an event.

Trevyent NDA Accepted by FDA — Sep 11

United Therapeutics' new drug application for its drug-device combination product, Trevyent, was accepted for review by the FDA. The FDA is expected to give its decision on Trevyent NDA on Apr 27, 2020.

In 2017, SteadyMed received a refuse-to-file letter from the FDA for Trevyent NDA for want of further information. United Therapeutics resubmitted the NDA in June 2019.

Valuation

United Therapeutics' shares are down 17.8% in the trailing 12-month period. Stocks in the Zacks sub-industry and sector are up 14.6% and 11.9%, respectively, over the past year. The S&P 500 Index is up 30.7% in the past year.

The stock is currently trading at 2.61X forward 12-month sales per share which compares to 2.5X for the Zacks sub-industry, 2.94X for the Zacks sector and 3.51X for the S&P 500 index.

Over the past five years, the stock has traded as high as 5.47X and as low as 2.53X, with a 5-year median of 3.74X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $93 price target reflects 2.76X forward 12-month sales per share.

The table below shows summary valuation data for UTHR

Valuation Multiples - UTHR

		Stock	Sub-Industry	Sector	S&P 500
P/S F12M	Current	2.61	2.5	2.94	3.51
	5-Year High	5.47	3.69	3.8	3.51
	5-Year Low	2.53	2.29	2.42	2.54
	5-Year Median	3.74	2.79	2.94	3
P/B TTM	Current	1.42	1.65	4.59	4.41
	5-Year High	7.99	12.89	5.01	4.42
	5-Year Low	1.27	0.95	3.42	2.85
	5-Year Median	2.81	2.49	4.27	3.6

As of 12/31/2019

Industry Analysis **Zacks Industry Rank:** Top 23% (59 out of 253)

Top Peers

Pfizer Inc. **(PFE)**	Outperform
Bayer Aktiengesellschaft **(BAYRY)**	Neutral
Gilead Sciences, Inc. **(GILD)**	Neutral
GlaxoSmithKline plc **(GSK)**	Neutral
Insmed, Inc. **(INSM)**	Neutral
Johnson & Johnson **(JNJ)**	Neutral
Reata Pharmaceuticals, Inc. **(RETA)**	Neutral
Teva Pharmaceutical Industries Ltd. **(TEVA)**	Neutral

Industry Comparison Industry: Medical - Drugs

Industry Peers

	UTHR Neutral	X Industry	S&P 500	GILD Neutral	JNJ Neutral	PFE Outperform
VGM Score	A	-	-	B	B	D
Market Cap	3.87 B	108.12 M	23.93 B	82.21 B	383.91 B	216.83 B
# of Analysts	4	2	13	13	8	4
Dividend Yield	0.00%	0.00%	1.78%	3.88%	2.61%	3.68%
Value Score	A	-	-	A	B	B
Cash/Price	0.40	0.27	0.04	0.27	0.05	0.04
EV/EBITDA	3.77	-1.94	13.95	7.99	15.15	13.35
PEG Ratio	NA	1.44	2.12	3.79	2.46	3.48
Price/Book (P/B)	1.42	3.26	3.33	3.96	6.60	3.31
Price/Cash Flow (P/CF)	6.14	10.59	13.67	8.87	13.38	9.30
P/E (F1)	NA	16.76	19.66	9.27	16.84	13.23
Price/Sales (P/S)	2.54	5.80	2.69	3.68	4.70	4.09
Earnings Yield	-1.09%	-18.66%	5.08%	10.79%	5.94%	7.55%
Debt/Equity	0.28	0.03	0.72	1.11	0.46	0.55
Cash Flow ($/share)	14.34	-0.56	6.94	7.33	10.90	4.21
Growth Score	B	-	-	C	C	F
Hist. EPS Growth (3-5 yrs)	29.17%	8.54%	10.56%	-12.33%	9.06%	8.42%
Proj. EPS Growth (F1/F0)	-106.34%	0.00%	0.00%	1.49%	6.16%	-1.09%
Curr. Cash Flow Growth	20.23%	13.56%	14.83%	-24.62%	13.87%	8.89%
Hist. Cash Flow Growth (3-5 yrs)	22.90%	8.03%	9.00%	21.29%	7.92%	2.30%
Current Ratio	4.11	3.65	1.23	2.96	1.26	0.90
Debt/Capital	21.64%	8.33%	42.92%	52.58%	31.62%	35.53%
Net Margin	-6.04%	-118.66%	11.08%	12.04%	21.09%	30.57%
Return on Equity	-3.54%	-67.23%	17.10%	37.50%	39.81%	28.10%
Sales/Assets	0.40	0.29	0.55	0.36	0.53	0.33
Proj. Sales Growth (F1/F0)	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Momentum Score	A	-	-	C	C	B
Daily Price Chg	1.35%	0.22%	0.33%	0.08%	0.39%	0.69%
1 Week Price Chg	-1.73%	1.47%	0.13%	-1.35%	-0.21%	0.23%
4 Week Price Chg	-1.28%	3.33%	3.67%	-1.65%	6.35%	2.97%
12 Week Price Chg	11.90%	5.44%	10.64%	5.33%	10.64%	10.58%
52 Week Price Chg	-19.12%	-9.43%	27.46%	3.88%	13.03%	-10.24%
20 Day Average Volume	366,221	212,883	1,693,267	6,902,463	5,889,424	16,710,056
(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%	-0.10%	0.01%	0.00%
(F1) EPS Est 12 week change	51.08%	3.46%	0.14%	-0.37%	0.75%	5.49%
(Q1) EPS Est Mthly Chg	0.00%	0.00%	0.00%	-0.08%	0.00%	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	A
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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