

United Therapeutics (UTHR)

\$117.20 (As of 07/17/20)

Price Target (6-12 Months): **\$124.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 06/26/20)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:C

Value: D

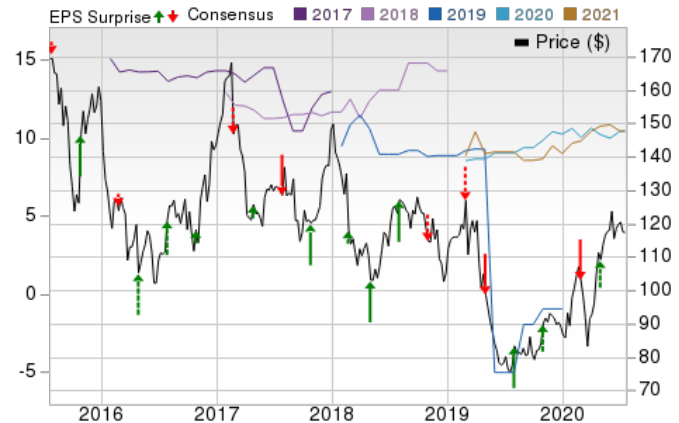
Growth: C

Momentum: A

Summary

Demand for United Therapeutics' treprostinil medicines like Remodulin, Tyvaso and Orenitram is strong despite generic concerns and competitive pressure. It is working on new delivery mechanisms for Remodulin and expanded indications for Orenitram and Tyvaso, which might drive long-term growth. Some improved Remodulin delivery devices are expected to be launched in the next 18 months, which can widen its market. The stock has outperformed the industry this year so far. However, competition in the PAH market is increasing. Importantly, though United Therapeutics is a leader in PAH, lack of product as well as pipeline diversification beyond PAH is a concern. The company expects a reduction in new patient starts in Q2 due to coronavirus.

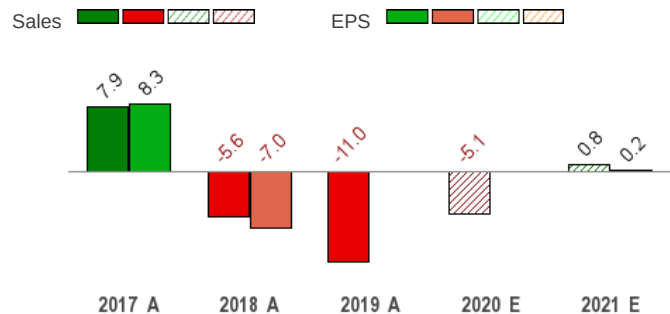
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$127.79 - \$74.31
20 Day Average Volume (sh)	537,646
Market Cap	\$5.2 B
YTD Price Change	33.1%
Beta	0.86
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Drugs
Zacks Industry Rank	Top 41% (104 out of 251)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	28.4%
Last Sales Surprise	2.5%
EPS F1 Est- 4 week change	4.4%
Expected Report Date	07/29/2020
Earnings ESP	9.1%
P/E TTM	10.7
P/E F1	11.3
PEG F1	NA
P/S TTM	3.6

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021					1,386 E
2020	356 A	341 E	341 E	337 E	1,375 E
2019	363 A	374 A	402 A	311 A	1,449 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$3.52 E	\$2.31 E	\$1.70 E	\$1.92 E	\$10.42 E
2020	\$3.12 A	\$2.41 E	\$2.27 E	\$2.01 E	\$10.40 E
2019	\$3.58 A	\$3.63 A	\$3.01 A	\$1.20 A	-\$2.39 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 07/17/2020. The reports text is as of 07/20/2020.

Overview

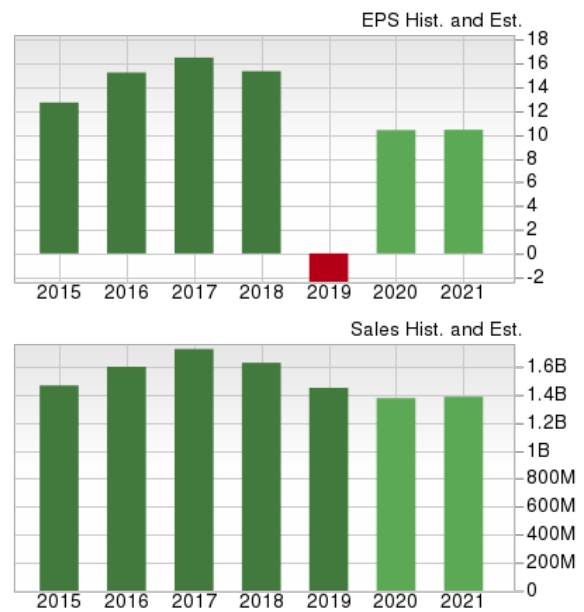
Silver Spring, MD-based United Therapeutics Corporation markets four medicines in the United States to treat pulmonary arterial hypertension (PAH): Remodulin, an injectable formulation of treprostinil, Orenitram, an oral version of treprostinil, Tyvaso, an inhaled version of treprostinil, and Adcirca (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 Trevynta 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 \$1.44 billion in 2019, down 11% year over year. Around 85% of its revenues in 2019 were derived from Remodulin, Tyvaso and Orenitram.



Reasons To Buy:

▲ **Shares Outperforming Industry:** United Therapeutics' share price has risen 33.1% this year so far, against the industry's decrease of 5.3%.

▲ **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 – Addircra, 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 sales growth. Some improved Remodulin delivery devices, which can widen its market, are expected to be launched in the next 18 months. In July 2018, United Therapeutics gained FDA approval for the use of 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 2021. 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. In February 2020, United Therapeutics gained an FDA clearance for a special 510(k) filing and expects to launch the pharmacy-filled version of the product in July. RemoPro, a pain-free subcutaneous Remodulin prodrug, is in phase I studies.

Also, United Therapeutics expects to resubmit the NDA for Trevyent disposable treprostinil pump system in 2020. RemUnity and Trevyent, if approved, will provide two expanded options for patients on subcutaneous Remodulin.

▲ **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.

In February 2020, United Therapeutics announced that the pivotal phase III INCREASE study evaluating Tyvaso in patients with PAH associated with interstitial lung disease met its primary efficacy endpoint of demonstrating improvement in six-minute walk distance. The study also met its key secondary endpoints. The company plans to submit a supplemental new drug application to expand the Tyvaso label to include INCREASE study data by mid-2020. If approved, the label update will increase Tyvaso's eligible U.S. population by more than 30,000 patients.

Other phase III programs include autologous cell therapy (PAH - phase II/III SAPPHIRE study), Treprostinil Technosphere dry powder inhaler (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 Unituxin in relapsed/refractory neuroblastoma in a late-stage 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.

▲ **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 Addircra 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.

▲ **Favorable Debt Profile:** As of Mar 31, 2020, United Therapeutics had \$800 million in long-term debt on its balance sheet. Cash and cash equivalents totaled approximately \$1.55 billion. Its cash position is sound and the company is more than capable of paying the debt in case of insolvency. Its debt/capital ratio was 21.3 at the end of March 2020, lower than 23.4 at the end of December 2019. A lower ratio indicates lower financial risk. Meanwhile, its times interest earned ratio stands at 16, higher than 0.8 for the industry. A higher ratio indicates that the company is capable of meeting its interest obligations from operating earnings.

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.

Reasons To Sell:

▼ **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 Acetelion's Tracleer. PDE-5 agents including Pfizer's Revatio (sildenafil, sold as Viagra for erectile dysfunction) also gained significant front-line use, thanks to their oral administration and vasodilating properties. Meanwhile, Actelion's (now a part of J&J) Uptravi competes directly with Orenitram.

Moreover, competition in the market has increased with the entry of generic versions of Revatio, Letairis and Tracleer.

We believe competition will continue to increase with several companies working on bringing additional therapies to the market. Several investigational PAH therapies are in the later stages of development. LIQ861, a dry powder inhalation formulation of treprostinil, developed by Liquidia Technologies is under review with the FDA with a decision expected in November 2020.

▼ **Dependence on Remodulin, Upcoming Generic Competition:** We are concerned about the company's dependence on Remodulin for revenues. Remodulin, which accounted for 40% of total sales in 2019, 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 2019 and may launch the same in the United States soon. More generics may be unveiled in Europe and the United States, 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 in August 2018 and by additional companies in February 2019. This significantly lowered Adcirca sales in 2019 with the trend expected to persist in 2020.

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 Medtronic's pre-market approval for the ISR device was given approval by the FDA in December 2017, the launch is pending on the satisfaction of further regulatory requirements by Medtronic which are not expected to be fulfilled in 2020. Launch of the ISR is not expected before 2021.

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.

Last Earnings Report

United Therapeutics Q1 Earnings & Sales Beat

United Therapeutics reported earnings of \$3.12 per share for the first quarter of 2020 against a loss of \$11.32 per share in the year-ago quarter. The Zacks Consensus Estimate was pegged at \$2.43.

The above-mentioned earnings included the impact of share-based compensation expenses, impairments of investments, unrealized gains/losses on equity securities/privately held company and other items. Excluding these items, adjusted earnings were \$3.61 per share, up 1% year over year.

Revenues for the reported quarter were \$356.3 million, which beat the Zacks Consensus Estimate of \$348 million. However, revenues fell 2% year over year due to generic competition for Adcirca.

The company clarified that new patient starts for Remodulin, Tyvaso, and Orenitram were not impacted by coronavirus outbreak in the quarter. However, most prescriptions in the quarter for new patients were issued before the outbreak in the United States. Importantly, the company said it noticed a decline in new prescriptions and new patients starts for the three products in the month of April as patients were unable to visit their doctors. As such the company expects a reduction in new patient starts in the future quarters. The company said that due to challenges posed by the pandemic, it cannot predict whether its revenues will grow year over year in 2020 as there is lack of visibility regarding its prospects and product development plans.

However, in April, the company recorded a larger order from a specialty pharmacy which may offset the softening in new patient starts in future quarters.

The company said that its inventory of Remodulin, Tyvaso, and Orenitram was sufficient to supply the market for two years and that they have three years' worth of API in hand.

Quarter in Detail

Adcirca sales were \$12.5 million, down 38% year over year as generic competition resulted in lower volumes in the quarter.

Orenitram sales amounted to \$69 million in the reported quarter, up 18% year over year due to new patient growth and price hike. The expanded Orenitram label reflecting the FREEDOM-EV results also contributed to revenue growth. Tyvaso sales totaled \$102.9 million, down 1% year over year due to higher gross-to-net revenue deductions and lower volumes which offset the impact of price increase. Remodulin sales were \$145.3 million, down 7% year over year due to lower volumes and price reductions. Remodulin lost exclusivity in June 2018 and generic versions have been launched. However, the company specified that despite generic availability, U.S. patients' demand for Remodulin remained stable. Lower international sales hurt Remodulin sales in the quarter.

At the call, the company said that transition of patients to generic Remodulin was negligible in the quarter, with approximately 15% of those transitioned to generic earlier having returned to Remodulin.

Unituxin's (for the treatment of pediatric patients with high-risk neuroblastoma) sales of \$26.6 million were up 7% year over year as price increases offset the impact of decrease in the number of vials sold.

Research and development ("R&D") expenses were \$68.6 million in the quarter, down 92% year over year as last year's R&D costs included an \$800 million upfront payment to Arena and \$12.5 million to MannKind per collaboration deals signed last year. General and administrative expenses rose 2% to \$55 million in the quarter while sales and marketing costs declined 4% to \$13 million.

Pipeline Update

Along with the earnings release, the company said that the INCREASE filing remains on track by mid-2020 despite the coronavirus pandemic. Regarding its other clinical studies, the company said that the patients already enrolled in studies continue to receive the study drug. However, it has stopped new patient enrollment in most ongoing studies and said that completion and data readouts for several ongoing and planned studies will be delayed.

Meanwhile, though the company is on track to launch RemUnity in July, it warned that COVID-19 may delay this timeline and could slow the launch.

United Therapeutics' Trevyent disposable treprostinil pump system is under review with the FDA. In April, however, the FDA issued a complete response letter ("CRL") to the NDA indicating that some of the issues previously raised by the FDA have not yet been addressed to its satisfaction.

Quarter Ending **03/2020**

Report Date	Apr 29, 2020
Sales Surprise	2.50%
EPS Surprise	28.40%
Quarterly EPS	3.12
Annual EPS (TTM)	10.96

Recent News

Files Patent Infringement Lawsuit against Liquidia Technologies – Jun 5

United Therapeutics announced that it has filed a lawsuit in the district court of Delaware against Liquidia Technologies for infringement of two patents on Tyvaso, the '901 and '066 patents. Both the patents expire in December 2028. Liquidia has filed a new drug application seeking approval of LIQ861, a dry powder inhalation formulation of treprostinil. In March 2020, Liquidia filed petitions for inter partes review seeking to invalidate the '901 and '066 patents. United Therapeutics has filed the lawsuit within 45 days of receiving notice of filing the NDA. The company claims that FDA is automatically precluded from approving Liquidia's NDA for up to 30 months or until the resolution of the litigation, whichever occurs first.

Additional Data from FREEDOM-EV Study – Apr 23

United Therapeutics announced additional data from the FREEDOM-EV study in presentations in recent healthcare conferences. The data showed that Orenitram demonstrated improvement in hemodynamic parameters and risk status which are important indicators of long-term outcomes in PAH patients

Valuation

United Therapeutics' shares rose 33.1% in the year-to-date period and 56.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 5.3% and up 2.2%, respectively, in the year-to-date period. Over the past year, Zacks sub-industry and sector are down 1.9% and up 8.8%, respectively.

The S&P 500 index is up 0.3% in the year-to-date period and up 8.8% in the past year.

The stock is currently trading at 3.58X trailing 12-month sales per share which compares to 2.19X for the Zacks sub-industry, 3.13X for the Zacks sector and 3.47X for the S&P 500 index.

Over the past five years, the stock has traded as high as 6.82X and as low as 2.08X, with a 5-year median of 3.34X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our \$124 price target reflects 3.78X trailing 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 TTM	Current	3.58	2.19	3.13	3.47
	5-Year High	6.82	4.3	4.08	3.68
	5-Year Low	2.08	1.7	2.29	2.43
	5-Year Median	3.34	2.59	3.19	3.21
P/B TTM	Current	1.75	1.59	4.47	4.41
	5-Year High	7.77	13.33	5.07	4.56
	5-Year Low	1.25	1.02	2.94	2.83
	5-Year Median	2.54	2.46	4.3	3.71

As of 07/17/2020

Industry Analysis Zacks Industry Rank: Top 41% (104 out of 251)



Top Peers

Company (Ticker)	Rec	Rank
Bayer Aktiengesellschaft (BAYRY)	Outperform	1
Gilead Sciences, Inc. (GILD)	Neutral	3
GlaxoSmithKline plc (GSK)	Neutral	3
Insmmed, Inc. (INSM)	Neutral	2
JohnsonJohnson (JNJ)	Neutral	3
Pfizer Inc. (PFE)	Neutral	3
Reata Pharmaceuticals, Inc. (RETA)	Neutral	4
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral	4

Industry Comparison Industry: Medical - Drugs				Industry Peers		
	UTHR	X Industry	S&P 500	GILD	JNJ	PFE
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	3
VGM Score	C	-	-	B	B	A
Market Cap	5.16 B	128.31 M	22.62 B	97.23 B	393.48 B	201.36 B
# of Analysts	4	3	14	13	9	4
Dividend Yield	0.00%	0.00%	1.82%	3.51%	2.71%	4.19%
Value Score	D	-	-	B	B	A
Cash/Price	0.30	0.27	0.07	0.22	0.05	0.06
EV/EBITDA	-58.93	-2.49	13.05	13.04	16.26	9.59
PEG Ratio	NA	1.11	2.99	3.33	3.21	2.83
Price/Book (P/B)	1.75	3.60	3.13	4.40	6.42	3.08
Price/Cash Flow (P/CF)	NA	11.01	12.20	10.62	12.96	8.82
P/E (F1)	11.24	16.92	22.02	11.52	19.14	12.59
Price/Sales (P/S)	3.58	6.67	2.34	4.28	4.89	3.97
Earnings Yield	8.87%	-14.76%	4.28%	8.68%	5.22%	7.94%
Debt/Equity	0.27	0.01	0.75	1.00	0.41	0.56
Cash Flow (\$/share)	-1.34	-0.52	6.94	7.30	11.52	4.11
Growth Score	C	-	-	D	D	B
Hist. EPS Growth (3-5 yrs)	13.75%	6.56%	10.85%	-16.32%	9.40%	8.07%
Proj. EPS Growth (F1/F0)	535.27%	13.44%	-9.37%	1.47%	-10.11%	-2.37%
Curr. Cash Flow Growth	-109.37%	2.43%	5.51%	-2.57%	3.68%	-6.57%
Hist. Cash Flow Growth (3-5 yrs)	NA%	6.05%	8.55%	-8.08%	7.62%	2.54%
Current Ratio	8.91	3.69	1.30	3.04	1.31	1.02
Debt/Capital	21.34%	6.01%	44.33%	49.91%	29.29%	35.70%
Net Margin	36.59%	-114.76%	10.59%	21.84%	22.69%	31.17%
Return on Equity	19.19%	-62.98%	15.74%	35.44%	35.70%	25.76%
Sales/Assets	0.36	0.30	0.54	0.37	0.52	0.31
Proj. Sales Growth (F1/F0)	-5.08%	0.00%	-2.44%	2.63%	-2.56%	-10.61%
Momentum Score	A	-	-	A	B	D
Daily Price Chg	1.07%	0.48%	0.36%	1.14%	0.07%	1.83%
1 Week Price Chg	-2.40%	-0.21%	-0.41%	-0.04%	0.99%	-1.97%
4 Week Price Chg	1.34%	0.00%	2.56%	4.69%	4.14%	9.06%
12 Week Price Chg	6.56%	14.38%	15.49%	-0.35%	-3.96%	-1.20%
52 Week Price Chg	53.71%	-9.33%	-3.93%	15.33%	13.08%	-15.82%
20 Day Average Volume	537,646	306,553	2,236,294	7,691,478	6,826,341	29,839,392
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	1.27%	1.67%	0.00%
(F1) EPS Est 4 week change	4.42%	0.00%	0.01%	5.08%	1.97%	0.00%
(F1) EPS Est 12 week change	-1.93%	0.00%	-5.24%	11.50%	1.75%	6.75%
(Q1) EPS Est Mthly Chg	8.79%	0.00%	0.00%	1.71%	0.39%	-0.46%

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	A
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.

Disclosures

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