United Therapeutics (UTHR)

$93.99 (As of 03/11/20)

Price Target (6-12 Months): **$108.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 02/13/20) Prior Recommendation: Neutral	**Outperform**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**2-Buy**
	Zacks Style Scores:	VGM:D
	Value: B | Growth: D | Momentum: F	

Summary

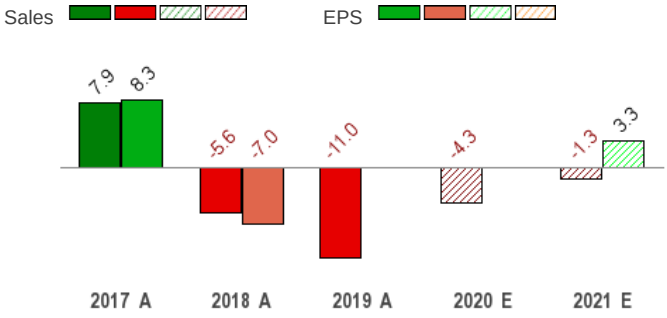
United Therapeutics missed estimates for both earnings and sales in Q4. It holds a strong position in the PAH market. Demand for its treprostinil medicines like Remodulin, Tyvaso and Orenitram is strong despite generic concerns and competitive pressure. It is working on new delivery mechanisms for Remodulin 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 in the past six months. 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.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$123.88 - $74.31**
20 Day Average Volume (sh)	**642,572**
Market Cap	**$4.1 B**
YTD Price Change	**6.7%**
Beta	**0.79**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Drugs**
Zacks Industry Rank	**Top 27% (68 out of 253)**
Last EPS Surprise	**-51.4%**
Last Sales Surprise	**-11.1%**
EPS F1 Est- 4 week change	**0.2%**
Expected Report Date	**05/06/2020**
Earnings ESP	**0.0%**
P/E TTM	**8.2**
P/E F1	**9.3**
PEG F1	**NA**
P/S TTM	**2.9**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021					1,369 E
2020	348 E	352 E	345 E	343 E	1,387 E
2019	363 A	374 A	402 A	311 A	1,449 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021					$10.40 E
2020	$2.50 E	$2.63 E	$2.31 E	$2.10 E	$10.07 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 03/11/2020. The reports text is as of 03/12/2020.

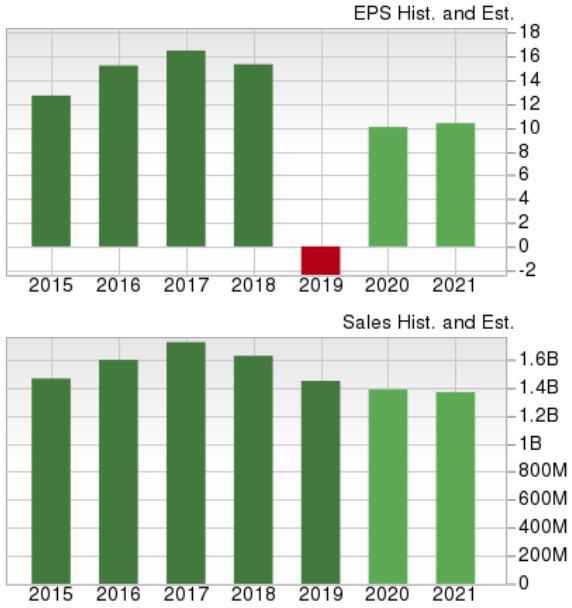
Overview

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 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 $1.44 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:

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.

- **Shares Up in the Past 6 Months:** United Therapeutics' share price has risen 16.5% in the past six months, outperforming the industry which has decreased 4.7%.

- **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 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 product in July. RemoPro, a pain-free subcutaneous Remodulin prodrug, is in phase I studies.

  Also, United Therapeutics' Trevyent disposable treprostinil pump system is under review with the FDA. A decision is expected 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 2019, 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. 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 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.

Risks

- **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) 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. 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.

  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 including LIQ861by Liquidia Technologies and Bardoxolone, an oral therapy being developed by Reata Pharmaceuticals.

- **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 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 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.

Last Earnings Report

United Therapeutics Q4 Earnings & Sales Miss

Quarter Ending	12/2019
Report Date	**Feb 26, 2020**
Sales Surprise	**-11.10%**
EPS Surprise	**-51.42%**
Quarterly EPS	**1.20**
Annual EPS (TTM)	**11.42**

United Therapeutics reported earnings of $1.20 per share for the fourth quarter of 2019, which declined 18.9% year over year. The Zacks Consensus Estimate was pegged at $2.47.

The abovementioned earnings include the impact of share-based compensation expenses, license-related fees, unrealized gains/losses on equity securities and other items. Excluding these items, adjusted earnings were $1.96 per share compared with $3.34 per share in the year-ago quarter.

Revenues for the reported quarter were $311.1 million, which missed the Zacks Consensus Estimate of $350 million. Revenues also fell 18.4% year over year.

In the quarter, sales of United Therapeutics' PAH products, Remodulin, Tyvaso and Orenitram, were hurt by inventory destocking by one distributor.

Quarter in Detail

Adcirca sales were $27.8 million, down 33% year over year as generic competition resulted in lower volumes in the quarter. Orenitram sales amounted to $50.9 million in the reported quarter, up 3% year over year due to an increase in the number of patients being treated with the drug and price hikes, which partially offset the negative impact of the distributor adjustment. Tyvaso sales totaled $91.4 million, down 14% year over year. Remodulin sales were $107.4 million, down 32% year over year due to the distributor adjustment and unfavorable patient mix as some higher dosage patients switched to generic treprostinil. However, the company specified that despite generic availability, U.S. patient demand for Remodulin remains stable. Lower international sales also hurt Remodulin sales in the fourth quarter.

Unituxin's (for the treatment of pediatric patients with high-risk neuroblastoma) sales of $33.6 million were up 39% year over year due to an increase in the number of vials sold and price increases.

Research and development (R&D) expenses were $109.6 million in the quarter, down 22% year over year as higher costs for pipeline development were offset by easy comparison with the fourth quarter of 2018, which included a one-time payment to MannKind under a licensing agreement. General and administrative expense rose 6% to $61.7 million in the quarter while sales and marketing costs went up by 10% to $18.6 million.

2019 Results

Full-year 2019 sales declined 11% to $1.44 billion, missing the Zacks Consensus Estimate of $1.49 billion. Adjusted earnings of $12.94 per share declined 15.8% year over year.

2020 Outlook

In 2020, United Therapeutics expects its revenues to grow above 2019 levels, primarily driven by expanded Orenitram label reflecting the FREEDOM-EV results and higher Remodulin revenues. United Therapeutics expects Remodulin U.S. sales growth in 2020 despite facing generic headwinds on continued new patient starts and patient growth following RemUnity launch

Pipeline Update

Along with the earnings release, United Therapeutics said it expects to launch ISR in 2021, delayed from the prior expectation of 2020.

Also, United Therapeutics' Trevyent disposable treprostinil pump system is under review with the FDA. However, along with the earnings release, the company said that the FDA's current action date of Apr 27, 2020 for Trevyent may be extended as the regulatory agency noticed some deficiencies in the NDA and asked for some information. Though the company has provided some information to address the deficiencies, it believes the action date may be extended or the FDA may issue a complete response letter if it is not satisfied with the company's response.

Recent News

Final FDA Clearance for RemUnity – Feb 24

United Therapeutics announced that it has received an FDA clearance for a special 510(k) filing for RemUnity which it has developed in partnership with DEKA. United Therapeutics expects to launch the product in July.

INCREASE Study on Tyvaso Meets Primary & Secondary Endpoints – Feb 24

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.

DISTINCT Study on Unituxin Fails to Meet Primary Endpoint – Feb 3

United Therapeutics announced disappointing top-line results from the phase II/III DISTINCT study, evaluating Unituxin (dinutuximab) injection added to irinotecan compared to irinotecan or topotecan alone in patients with relapsed or refractory small cell lung cancer. The study did not meet its primary efficacy objective of extending the overall survival with Unituxin and irinotecan versus irinotecan alone.

Valuation

United Therapeutics' shares rose 6.7% in the year-to-date period but declined 18.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 10.3% and 7% in the year-to-date period. Over the past year, the Zacks sub-industry and sector are down 15.7% and 7.5%, respectively.

The S&P 500 index is down 10.6% in the year-to-date period but up 1.5% in the past year.

The stock is currently trading at 2.85X trailing 12-month sales per share which compares to 3.03X for the Zacks sub-industry, 2.93X for the Zacks sector and 3.12X for the S&P 500 index.

Over the past five years, the stock has traded as high as 7.46X and as low as 2.08X, with a 5-year median of 3.42X. Our Outperform recommendation indicates that the stock will perform better than the market. Our $108 price target reflects 3.3X 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	2.85	3.03	2.93	3.12
	5-Year High	7.46	4.23	4.17	3.68
	5-Year Low	2.08	2.01	2.73	2.5
	5-Year Median	3.42	2.66	3.27	3.18
P/B TTM	Current	1.48	1.45	4.27	3.88
	5-Year High	7.99	13.16	5.05	4.56
	5-Year Low	1.27	0.98	3.44	2.85
	5-Year Median	2.7	2.53	4.32	3.63

As of 3/11/2020

Industry Analysis **Zacks Industry Rank:** Top 27% (68 out of 253)

Top Peers

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

Industry Comparison Industry: Medical - Drugs

Industry Peers

	UTHR Outperform	X Industry	S&P 500	GILD Underperform	JNJ Neutral	PFE Outperform
VGM Score	D	-	-	F	B	D
Market Cap	4.12 B	84.38 M	19.20 B	93.13 B	347.47 B	178.47 B
# of Analysts	5	2	13	12	9	4
Dividend Yield	0.00%	0.00%	2.31%	3.42%	2.88%	4.72%
Value Score	B	-	-	D	C	B
Cash/Price	0.34	0.30	0.05	0.24	0.05	0.05
EV/EBITDA	-43.24	-1.62	11.76	12.16	14.39	8.64
PEG Ratio	-1.56	0.57	1.73	5.20	2.20	2.59
Price/Book (P/B)	1.48	2.39	2.64	4.12	5.83	2.81
Price/Cash Flow (P/CF)	NA	12.24	10.55	10.10	11.44	7.83
P/E (F1)	9.33	14.67	15.66	11.39	14.60	11.50
Price/Sales (P/S)	2.85	5.11	2.06	4.15	4.23	3.45
Earnings Yield	10.71%	-18.30%	6.38%	8.78%	6.85%	8.70%
Debt/Equity	0.22	0.03	0.70	1.02	0.45	0.57
Cash Flow ($/share)	-1.34	-0.59	7.01	7.30	11.52	4.11
Growth Score	D	-	-	F	B	F
Hist. EPS Growth (3-5 yrs)	29.43%	3.93%	10.85%	-14.87%	9.27%	8.48%
Proj. EPS Growth (F1/F0)	521.17%	17.40%	6.02%	-2.41%	4.03%	-5.17%
Curr. Cash Flow Growth	-109.37%	6.36%	6.09%	-2.57%	3.68%	-6.57%
Hist. Cash Flow Growth (3-5 yrs)	NA%	6.77%	8.52%	-8.08%	7.62%	2.54%
Current Ratio	4.03	3.31	1.24	3.10	1.26	0.88
Debt/Capital	17.75%	6.72%	42.57%	50.49%	30.82%	36.17%
Net Margin	-7.21%	-114.24%	11.69%	23.99%	22.18%	31.44%
Return on Equity	-4.03%	-68.55%	16.74%	35.49%	39.27%	27.01%
Sales/Assets	0.37	0.32	0.54	0.36	0.53	0.32
Proj. Sales Growth (F1/F0)	-4.26%	5.54%	3.55%	-0.81%	4.68%	-10.93%
Momentum Score	F	-	-	C	C	C
Daily Price Chg	-6.47%	-4.16%	-5.37%	1.88%	-6.95%	-7.00%
1 Week Price Chg	-4.56%	0.00%	-0.67%	15.66%	5.61%	4.79%
4 Week Price Chg	-10.02%	-20.17%	-20.57%	10.08%	-12.77%	-14.76%
12 Week Price Chg	4.77%	-15.28%	-17.57%	12.21%	-7.95%	-17.28%
52 Week Price Chg	-18.67%	-38.78%	-8.21%	12.09%	-5.46%	-23.42%
20 Day Average Volume	642,572	192,914	2,882,511	24,758,066	10,350,478	35,843,980
(F1) EPS Est 1 week change	0.45%	0.00%	0.00%	-0.20%	0.00%	0.00%
(F1) EPS Est 4 week change	0.17%	0.00%	-0.23%	-0.59%	-0.04%	1.36%
(F1) EPS Est 12 week change	2.17%	0.00%	-0.60%	-10.52%	-0.44%	8.15%
(Q1) EPS Est Mthly Chg	1.36%	0.00%	-0.52%	0.00%	-0.36%	0.00%

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	B
Growth Score	D
Momentum Score	F
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.

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