United Therapeutics Corporation

NASDAQ: UTHR
Biotechnology / Specialty Pharmaceuticals

RESEARCH OVERVIEW

United Therapeutics Corporation (NASDAQ: UTHR) is a public benefit corporation focused on developing and commercializing therapies for chronic and life-threatening diseases. UTHR holds a dominant franchise in the pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) markets, built on its treprostinil-based product platform. The company is experiencing a transformative period defined by three parallel developments: (1) the successful completion of both TETON-1 and TETON-2 Phase 3 studies establishing Tyvaso as a potential first-in-class inhaled therapy for idiopathic pulmonary fibrosis (IPF); (2) exceptional Phase 3 data for ralinepag, potentially the first and only once-daily oral prostacyclin for PAH; and (3) pioneering xenotransplantation programs positioning the company at the frontier of organ manufacturing.

Shares rose approximately 15% on March 30, 2026, following the announcement that TETON-1 met its primary endpoint with a 130.1 mL improvement in forced vital capacity (FVC) over 52 weeks, exceeding the already impressive 95.6 mL benefit seen in TETON-2. Combined with a $2 billion share repurchase authorization already in execution and management guidance for double-digit revenue growth in 2026, the current market pricing may not fully capture the embedded optionality from the IPF indication, ralinepag commercialization, or the long-term xenotransplant opportunity. Multiple sell-side firms have recently raised estimates in response to recent catalysts: Leerink to $615, Jefferies to $668, Cantor Fitzgerald to $625, and RBC to $643, reflecting growing conviction in the pipeline's value creation potential. The sell-side consensus currently stands at approximately $550 on average with a median of $612.50, though this is expected to move higher as analysts formally incorporate the TETON-1 data.

COMPANY OVERVIEW

United Therapeutics, headquartered in Silver Spring, Maryland and Research Triangle Park, North Carolina, was founded by Dr. Martine Rothblatt and has built its commercial franchise around treprostinil, a prostacyclin analogue used to treat PAH and PH-ILD. The product portfolio includes Tyvaso DPI (dry powder inhaler), nebulized Tyvaso, Remodulin (subcutaneous/intravenous infusion), Orenitram (oral extended-release tablets), Unituxin (an oncology antibody for high-risk neuroblastoma), and Adcirca (a PDE-5 inhibitor). Products are distributed primarily through specialty pharmaceutical channels in the United States, with a growing international footprint through distributor partnerships. Beyond therapeutics, United Therapeutics is pursuing an ambitious organ manufacturing initiative across four technology platforms (xenotransplantation, regenerative medicine, 3D organ bioprinting, and bio-artificial organs) targeting hearts, kidneys, livers, and lungs. As a public benefit corporation, the company's charter balances expanding the supply of transplantable organs with creating long-term shareholder value. The company recently appointed Dr. Kevin J. Tracey to its Board of Directors in January 2026, adding further expertise in biomedical innovation.

FINANCIAL PERFORMANCE: FY2025 RESULTS

United Therapeutics delivered record financial results for fiscal year 2025, crossing the $3 billion revenue threshold for the first time. Full-year revenues reached $3.18 billion, reflecting 11% growth

over FY2024's $2.88 billion. Diluted EPS rose to $27.86, up from $24.64 in FY2024, a 13% year-over-year increase. Net income totaled $1.33 billion, with net margins of approximately 42%, underscoring exceptional profitability relative to specialty pharma peers. In Q4 2025, revenues of $790.2 million grew 7% year over year, while diluted EPS of $7.70 exceeded consensus estimates of $6.78 by $0.92. Revenue modestly missed Street expectations of approximately $815 million, primarily attributable to typical Q4 seasonal ordering patterns and weather-related disruptions impacting patient starts. Q4 operating margin was 45.1%, contracting 350 basis points year over year as the company increased investment in its pipeline and organ manufacturing infrastructure. Management guided to double-digit revenue growth for FY2026, driven by continued Tyvaso DPI adoption and Orenitram momentum.

FY2025 REVENUE BREAKDOWN ($ in millions)

Product	FY2025	FY2024	YoY Chg	% of Rev
Tyvaso DPI	$1,292.5	$1,033.6	+25%	40.6%
Nebulized Tyvaso	$585.7	$586.8	Flat	18.4%
Total Tyvaso	**$1,878.2**	**$1,620.4**	**+16%**	**59.0%**
Orenitram	$496.9	$434.3	+14%	15.6%
Remodulin	$526.8	$538.1	-2%	16.6%
Unituxin	$226.8	$238.7	-5%	7.1%
Other (Adcirca + misc.)	$54.0	$45.9	+18%	1.7%
Total Revenues	**$3,182.7**	**$2,877.4**	**+11%**	**100%**

Revenue Drivers: Product-Level Analysis

Tyvaso DPI remains the primary growth engine, with FY2025 sales of $1.29 billion (+25% YoY), driven by continued patient adoption, expanded utilization among PH-ILD patients, and the convenience advantage of the dry powder inhaler format over nebulized delivery. The launch of the 80-microgram cartridge further improved dosing flexibility. Q4 Tyvaso DPI revenue of $338.6 million grew 24% year over year, demonstrating durable momentum even in a seasonally soft quarter. Nebulized Tyvaso revenues were essentially flat at $585.7 million for the full year, as domestic volume cannibalization by DPI was offset by growing international sales and continued PH-ILD adoption. Orenitram delivered robust 14% growth to $496.9 million, partially aided by the Inflation Reduction Act's (IRA) Medicare Part D benefit redesign, which has meaningfully improved commercial utilization across the prostacyclin portfolio by reducing out-of-pocket costs for patients. Remodulin declined 2% to $526.8 million as patients continue to migrate to less invasive inhaled and oral formulations, a secular trend expected to persist. Unituxin declined 5% to $226.8 million on lower volumes.

Balance Sheet and Capital Allocation

The balance sheet remains a significant competitive advantage and is among the strongest in the biotech sector. As of Q3 2025, the company held approximately $1.34 billion in cash and $2.99 billion in marketable investments (current and non-current), totaling roughly $4.3 billion in liquid assets. Total assets stood at approximately $8.0 billion, with stockholders' equity of $7.0 billion and zero long-term debt, a rarity among biotech companies at this scale. Property, plant, and equipment grew to $1.56 billion from $1.22 billion at the end of FY2024, reflecting heavy investment in xenotransplantation facilities in Christiansburg, Virginia and Stewartville, Minnesota. On March 9, 2026, the Board authorized a $2 billion stock repurchase program, committing $1.5 billion immediately through an accelerated share repurchase (ASR) agreement, with an additional $500 million authorized over the following year. This represents a meaningful return of capital, equivalent to roughly 6–7% of the outstanding share count at recent prices. Shares outstanding declined from approximately 45.2 million in mid-2025 to 43.1 million by Q3, even before the new program commenced, reflecting the company's sustained commitment to buybacks.

PIPELINE CATALYSTS: A TRANSFORMATIVE PERIOD

Tyvaso in Idiopathic Pulmonary Fibrosis (TETON Program)

The March 30, 2026 announcement that TETON-1 met its primary endpoint represents a watershed moment. The study demonstrated a 130.1 mL improvement in FVC relative to placebo at 52 weeks across 598 patients in the U.S. and Canada, exceeding the 95.6 mL benefit observed in the ex-U.S. TETON-2 study (597 patients, results published in the New England Journal of Medicine). Integrated analyses across both trials confirmed consistent efficacy across all patient subgroups, reduced risk of clinical worsening, and no new safety signals. Notably, approximately 75% of TETON-2 patients were on background antifibrotic therapy, demonstrating additive benefit on top of existing standard of care. IPF affects roughly 100,000 patients in the United States, and current treatment options (nintedanib and pirfenidone) merely slow FVC decline without meaningfully improving lung function. Nebulized Tyvaso would represent the first inhaled anti-fibrotic with a multimodal mechanism targeting fibrotic, vascular, and inflammatory pathways simultaneously. The company plans to seek priority review of a supplemental NDA to be submitted to the FDA by the end of summer 2026. Based on the addressable patient population and existing PAH/PH-ILD pricing benchmarks, independent estimates suggest peak annual revenue potential for the IPF indication in the range of $1.5–$2.5 billion, which would represent a near-doubling of the current Tyvaso franchise. An ongoing third study, TETON PPF, is evaluating Tyvaso in progressive pulmonary fibrosis, a broader indication that could further expand the addressable market.

Ralinepag in Pulmonary Arterial Hypertension (ADVANCE OUTCOMES)

Announced March 2, 2026, the Phase 3 ADVANCE OUTCOMES study demonstrated ralinepag reduced the risk of clinical worsening in PAH patients by 55% versus placebo (HR 0.45, 95% CI 0.33–0.62, $p<0.0001$), an exceptional result in a predominantly pre-treated population: 80% of the 687 enrolled patients were on dual background therapy and 70% were WHO/NYHA Functional Class II at baseline. The study also met key secondary endpoints, including a 47% increase in the odds of clinical improvement at Week 28 ($p=0.015$), along with favorable trends in six-minute walk distance and NT-proBNP biomarker levels. The safety profile was consistent with known prostacyclin-related adverse events, with no new safety signals. Ralinepag is a highly selective, potent IP receptor agonist with continuous-exposure pharmacokinetics, offering the potential to be the first and only once-daily oral prostacyclin, a significant convenience improvement over existing oral (Orenitram, twice-daily) and inhaled (Tyvaso, four times daily) options. UTHR intends to file an NDA by H2 2026. Consensus estimates for ralinepag's peak sales potential range from $800 million to $1.2 billion, though this could prove conservative if oral convenience drives rapid adoption and post-launch label expansion into combination regimens.

Xenotransplantation: UKidney, UHeart, and UThymoKidney

United Therapeutics is the established leader in xenotransplantation. In February 2025, the FDA cleared the company's IND to initiate the EXPAND clinical trial of the UKidney, a xenokidney derived from a 10 gene-edited pig (six human genes added to facilitate immune acceptance, four porcine genes knocked out to reduce rejection and moderate organ growth). The first transplant in EXPAND was performed at NYU Langone Health in November 2025. The study uses a "phaseless" design (combined Phase 1/2/3) enrolling an initial cohort of six end-stage renal disease (ESRD) patients, expanding to up to 50, and is intended to support an eventual Biologics License Application. To date, 12 xenotransplantation procedures using the company's UHearts, UThymoKidneys, and UKidneys have been performed in both living and decedent recipients, including two living UHeart transplants (University of Maryland, 2022 and 2023), one living UThymoKidney transplant (NYU Langone, 2024), and one living UKidney transplant (2024). The company operates a clinical-scale pathogen-free facility in Virginia and is completing a second in Minnesota, each with capacity of approximately 125 organs per year, with additional sites planned. With over 557,000 ESRD patients on dialysis in the U.S. and chronic organ shortages across all organ types, the addressable market is vast. While commercial revenues are likely multiple years away, industry analysts view this as a multi-billion-dollar long-term opportunity that is currently ascribed minimal value in the stock.

VALUATION CONSIDERATIONS

At the March 30 closing price of approximately $600, UTHR trades at roughly 20.7x consensus FY2026E EPS of ~$29 and approximately 7.5x trailing twelve-month revenues. This represents a modest premium to large-cap biotech peers on a P/E basis but appears justified by the superior growth trajectory, debt-free balance sheet, and unprecedented pipeline optionality. Using a sum-of-the-parts framework, the base PAH/PH-ILD franchise can be valued at approximately 21x forward earnings, reflecting the durability and profitability of the treprostinil platform and the accretive impact of the ongoing $2 billion buyback. Layering in probability-adjusted values for the IPF indication (supported by two positive Phase 3 readouts and a planned sNDA filing) and ralinepag (backed by highly significant Phase 3 data with a clear NDA pathway) adds meaningful incremental value beyond the core business. The xenotransplantation platform, while early-stage, represents a call option on a potentially transformational

healthcare technology. The current sell-side consensus average of approximately $550 with a median of $612.50 appears likely to move higher as analysts formally incorporate TETON-1 data; several firms already have estimates above $640. UTHR's one-year total shareholder return of approximately 68% reflects the market's re-rating of the pipeline, but multiple catalysts remain ahead.

RISK FACTORS

Regulatory Risk: The IPF supplemental NDA and ralinepag NDA filings remain subject to FDA review timelines and potential requests for additional data. Any unexpected regulatory pushback, clinical hold, or advisory committee concerns could delay or prevent commercialization. The xenotransplantation regulatory pathway is novel and inherently uncertain, with no established precedent for commercial approval of xenograft organs.

Competitive and Intellectual Property Risk: Generic treprostinil challengers remain a persistent threat, although UTHR has successfully defended its IP to date. Competing PAH and IPF therapies under development at other firms could erode market share or pricing power. Emerging inhaled and oral competitors in the prostacyclin space warrant monitoring.

Revenue Concentration: The Tyvaso franchise represents approximately 59% of total revenues. Any safety signal, manufacturing disruption, formulary exclusion, or competitive displacement affecting Tyvaso would have a disproportionate impact on financial performance.

Pricing and Policy Risk: While the IRA's Medicare Part D redesign has been a near-term tailwind for patient utilization, expanding government drug price negotiation authority could introduce pricing headwinds over the medium to long term. Specialty pharmacy reimbursement changes and payer mix shifts represent additional variables.

Xenotransplantation Execution Risk: The organ manufacturing programs carry inherent clinical, manufacturing, ethical, and immunological uncertainties. Scaling from single-digit procedures to commercial-scale organ supply is unprecedented, and long-term graft survival, infection risk, and immune rejection management remain active areas of investigation.

CONCLUSION

United Therapeutics is at the most significant inflection point in its corporate history. The dual confirmation of Tyvaso efficacy in IPF across both TETON studies, combined with exceptional ralinepag data in PAH and the initiation of landmark xenotransplantation clinical trials, underpin a compelling multi-year growth trajectory. The company's financial profile is equally differentiated: record revenues exceeding $3 billion, 42% net margins, a debt-free balance sheet with $4.3 billion in liquid assets, and an active $2 billion buyback program. Multiple high-conviction catalysts over the next 12 to 18 months, including the IPF sNDA filing (summer 2026), ralinepag NDA filing (H2 2026), ongoing EXPAND trial data for UKidney, TETON PPF study progress, and potential priority review designations, could serve as meaningful events for the stock. The current sell-side consensus appears to lag the evolving fundamental picture, and the full impact of the TETON-1 readout and cumulative pipeline value have yet to be fully incorporated into analyst models.