Section 1: 8-K (FORM 8-K)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15 (d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **February 26, 2020**

United Therapeutics Corporation
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-26301**	**52-1984749**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1040 Spring Street **Silver Spring, MD**	**20910**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code:
(301) 608-9292

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.01 per share	UTHR	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 26, 2020, United Therapeutics Corporation issued a press release setting forth its earnings and business updates for the quarter and year ended December 31, 2019.

A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01. Exhibits.

This information shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated February 26, 2020
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

UNITED THERAPEUTICS CORPORATION

Dated: February 26, 2020

By: /s/ Paul A. Mahon
Name: Paul A. Mahon
Title: General Counsel

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Section 2: EX-99.1 (EXHIBIT 99.1)

Exhibit 99.1

For Immediate Release
Contact: Dewey Steadman
Phone: (202) 919-4097
Email: ir@unither.com

United Therapeutics Corporation Reports Fourth Quarter and Full Year 2019 Financial Results

~ Full year net revenue growth of 3% excluding Adcirca® ~

~ Company expects 2020 full year net revenue growth ~

~ INCREASE study of Tyvaso® in PH-ILD meets primary and secondary endpoints ~

~ Remunity™ system cleared by FDA for pharmacy-filled use; launch expected by July 2020 ~

Silver Spring, MD and Research Triangle Park, NC, February 26, 2020: United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the fourth quarter and year ended December 31, 2019. Full year net revenue decreased 11% to $1,449 million, largely due to the launch of generic versions of Adcirca® in late 2018. Full year net revenue excluding Adcirca increased 3% in 2019 as compared to 2018. Quarterly net revenue of $311 million decreased 18% from the prior year. The year-over-year quarterly revenue decline was largely due to an estimated $43.6 million decrease in purchases of our treprostinil-based products in the fourth quarter of 2019 by one U.S. distributor to adjust its inventory levels to correct for a mistake in the distributor's utilization calculations. The distributor adjustment is not reflective of a change in actual patient utilization or demand as there was no material change to treprostinil products dispensed by our distributors to patients during 2019.

"Following the positive results of the *INCREASE* study of Tyvaso® (treprostinil) Inhalation Solution in pulmonary hypertension associated with interstitial lung disease (ILD), we're looking forward to submitting a supplemental new drug application to expand the Tyvaso label mid-year that, if approved, could expand Tyvaso's addressable U.S. population by more than 30,000 patients and help patients with no available approved therapies control their pulmonary hypertension associated with ILD," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "After *INCREASE*, we're looking forward to continued progress on three new infusion systems for delivery of parenteral treprostinil over the next 18 months: the launch of the Remunity™ system by July of this year, FDA action on the Trevyent® system, and the potential launch of the Implantable System for Remodulin expected next year."

Michael Benkowitz, President and Chief Operating Officer of United Therapeutics, commented, "Overall, we are pleased with the growth in our treprostinil products in 2019, and in particular, the strength in Remodulin new patient starts and active patients on therapy, despite generic competition for most of the year. With 2020 representing the first full year of an expanded Orenitram® label reflecting the *FREEDOM-EV* results, and the anticipated near-term launch of Remunity, we're confident in our ability to grow our net revenue over 2019 levels."

FOURTH QUARTER AND FULL YEAR 2019 FINANCIAL RESULTS

Key financial highlights include (dollars in millions, except per share data):

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues	$ 311.1	$ 381.4	$ 1,448.8	$ 1,627.8
Net income (loss)	$ 52.6	$ 65.3	$ (104.5)	$ 589.2
Non-GAAP earnings[(1)]	$ 86.3	$ 147.1	$ 569.2	$ 676.0
Net income (loss), per basic share	$ 1.20	$ 1.50	$ (2.39)	$ 13.54
Net income (loss), per diluted share	$ 1.20	$ 1.48	$ (2.39)	$ 13.39
Non-GAAP earnings, per diluted share[(1)]	$ 1.96	$ 3.34	$ 12.94	$ 15.36

(1) See definition of non-GAAP earnings, a non-GAAP financial measure, and a reconciliation of net income (loss) to non-GAAP earnings below.

Revenues

The table below summarizes the components of total revenues (dollars in millions):

	Three Months Ended December 31,		Percentage Change	Year Ended December 31,		Percentage Change
	2019	2018		2019	2018	
Net product sales:						
Remodulin®	$ 107.4	$ 159.1	(32)%	$ 587.0	$ 599.0	(2)%
Tyvaso®	91.4	106.9	(14)%	415.6	415.2	—%
Orenitram®	50.9	49.6	3%	225.3	205.1	10%
Unituxin®	33.6	24.1	39%	113.7	84.8	34%
Adcirca®	27.8	41.7	(33)%	107.2	323.7	(67)%
Total revenues	$ 311.1	$ 381.4	(18)%	$ 1,448.8	$ 1,627.8	(11)%

Revenues for the quarter and year ended December 31, 2019, decreased by $70.3 million and $179.0 million, respectively, as compared to the same periods in 2018. The decrease in full year revenues was primarily due to a decrease in Adcirca sales as a result of the onset of generic competition for Adcirca in August 2018. Net revenues from our treprostinil-based products (Remodulin, Tyvaso and Orenitram) grew by $8.6 million in full year 2019, compared to 2018.

As we note in our Annual Report on Form 10-K for 2019, our distributors typically place monthly orders based on utilization trends and contractual minimum and maximum inventory requirements. As a result, sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand for our products. The information we have on patient demand, active patients on therapy and patients using these products for the first time is based upon our review of patient utilization data provided to us by our specialty pharmaceutical distributors.

U.S. patient demand for Remodulin remained strong across 2019. Despite the launch of generic versions of treprostinil, the number of new U.S. patients starting to use Remodulin in 2019 reached the highest level in the last ten years. A small percentage of higher dose Remodulin patients transitioned to generic treprostinil when the first generic version became available in 2019, but these transitions declined to a negligible amount in the fourth quarter of 2019. After these initial transitions to generic treprostinil, U.S. patient demand for Remodulin remained consistent across the second, third and fourth quarters. As new patients who started Remodulin in 2019 titrate to their effective dose, and assuming the rate of patient transitions from Remodulin to generic treprostinil does not materially change, we expect to see a corresponding increase in our U.S. Remodulin revenues in 2020.

Distributor Adjustment. During the fourth quarter of 2019, one of our U.S. distributors identified a mistake in its utilization data, which caused the distributor to order more product than normal, primarily in the third quarter of 2019. Specifically, we estimate that the distributor's excess orders of Remodulin, Tyvaso and Orenitram generated additional net sales for these products totaling $15.6 million, $10.6 million and $5.2 million, respectively, or $31.4 million in total, during the third quarter of 2019. Upon the distributor's correction of its utilization data in the fourth quarter of 2019, the distributor reduced its purchases of our products in order to normalize its inventory levels. We estimate that this correction reduced our net sales of Remodulin, Tyvaso and Orenitram during the fourth quarter of 2019 by $21.9 million, $14.4 million and $7.3 million, respectively, or $43.6 million in total. We believe this distributor's inventory levels have returned to normal, and anticipate more traditional ordering patterns going forward. While this inventory fluctuation had a significant impact on our net sales during the third and fourth quarters of 2019, the effect on full-year net revenues was negligible.

Remodulin net product sales for the quarter ended December 31, 2019 decreased by $51.7 million as compared to the quarter ended December 31, 2018. U.S. Remodulin net product sales decreased by $37.5 million, primarily due to: (1) the $21.9 million negative impact of a distributor reducing its purchases of Remodulin in order to normalize its inventory levels, as discussed above; and (2) a decrease in quantities sold of $13.4 million, primarily due to changes in patient mix that resulted from a limited number of existing higher dosage patients switching to generic treprostinil during the second quarter of 2019, and the fact that new patients start on lower dosages of Remodulin and then begin the process of titrating to their effective dose. International Remodulin net product sales decreased by $14.2 million, primarily due to: (1) lower quantities sold of $10.9 million; and (2) the $3.9 million impact of price reductions to certain international distributors.

Remodulin net product sales for the year ended December 31, 2019 decreased by $12.0 million as compared to 2018. U.S. Remodulin net product sales decreased by $37.5 million, primarily due to: (1) a decrease in quantities sold of $24.0 million, primarily due to changes in patient mix that resulted from a limited number of existing higher dosage patients switching to generic treprostinil, and the fact that new patients start on lower dosages of Remodulin and then begin the process of titrating to their effective dose; and (2) higher gross-to-net revenue deductions of $11.0 million. International Remodulin net product sales increased by $25.5 million, primarily due to higher quantities sold of $47.0 million, partially offset by the $21.5 million impact of price reductions to certain international distributors.

Tyvaso net product sales for the quarter ended December 31, 2019 decreased by $15.5 million as compared to the quarter ended December 31, 2018. The decrease was primarily due to: (1) higher gross-to-net revenue deductions of $17.1 million, which included the reversal in the fourth quarter of 2018 of an estimated $15.4 million liability for Medicaid rebates; and (2) the $14.4 million negative impact of a distributor reducing its purchases of Tyvaso in order to normalize its inventory levels, as discussed above. This decrease was partially offset by: (1) the impact of replacing $6.2 million of commercial Tyvaso in the fourth quarter of 2018 that a U.S. distributor previously used in connection with a clinical trial; and (2) the $4.8 million impact of a January 2019 price increase.

Tyvaso net product sales for the year ended December 31, 2019 increased by $0.4 million as compared to 2018. The increase was primarily due to: (1) the $21.6 million impact of a January 2019 price increase; and (2) the impact of replacing $6.2 million of commercial Tyvaso product in 2018 that a U.S. distributor previously used in connection with a clinical trial. This increase was partially offset by higher gross-to-net revenue deductions of $24.3 million, which included the reversal in 2018 of an estimated $15.4 million liability for Medicaid rebates.

Orenitram net product sales for the quarter and year ended December 31, 2019 increased by $1.3 million and $20.2 million, respectively, as compared to the same periods in 2018. For the quarter and year ended December 31, 2019, these increases resulted from: (1) $7.6 million and $16.4 million, respectively, due to growth in the number of patients being treated with Orenitram; and (2) $2.8 million and $12.3 million, respectively, due to a January 2019 price increase, partially offset by higher gross-to-net revenue deductions of $1.8 million and $8.5 million, respectively. In addition, the fourth quarter of 2019 included the $7.3 million negative impact of a distributor reducing its purchases of Orenitram in order to normalize its inventory levels, as discussed above.

Unituxin net product sales for the quarter and year ended December 31, 2019 increased by $9.5 million and $28.9 million, respectively, as compared to the same periods in 2018. For the quarter and year ended December 31, 2019, these increases resulted from: (1) a $6.5 million and $21.5 million, respectively, increase in the number of vials sold; and (2) $3.1 million and $8.3 million, respectively, due to an April 2019 price increase.

Adcirca net product sales for the quarter and year ended December 31, 2019 decreased by $13.9 million and $216.5 million, respectively, as compared to the same periods in 2018. These decreases were primarily due to a decrease in bottles sold following the onset of generic competition for Adcirca beginning in August 2018.

Expenses

Cost of product sales. The table below summarizes cost of product sales by major category (dollars in millions):

	Three Months Ended December 31,		Percentage	Year Ended December 31,		Percentage
	2019	2018	Change	2019	2018	Change
Category:						
Cost of product sales	$ 28.2	$ 32.2	(12)%	$ 117.4	$ 201.9	(42)%
Share-based compensation expense (benefit)[(1)]	0.6	(0.3)	300%	0.2	(3.2)	106%
Total cost of product sales	$ 28.8	$ 31.9	(10)%	$ 117.6	$ 198.7	(41)%

(1) Refer to *Share-based compensation* below for discussion.

Cost of product sales, excluding share-based compensation. The decrease in cost of product sales of $4.0 million for the quarter ended December 31, 2019, as compared to the same period in 2018, was primarily attributable to a decrease in royalty expense for Adcirca as fewer bottles were sold following the onset of generic competition for Adcirca beginning in August 2018.

The decrease in cost of product sales of $84.5 million for the year ended December 31, 2019, as compared to the same period in 2018, was primarily attributable to a $91.9 million decrease in royalty expense for Adcirca as fewer bottles were sold following the onset of generic competition for Adcirca beginning in August 2018.

Research and development expense. The table below summarizes research and development expense by major category (dollars in millions):

	Three Months Ended December 31,		Percentage	Year Ended December 31,		Percentage
	2019	2018	Change	2019	2018	Change
Category:						
Research and development projects	$ 109.6	$ 139.9	(22)%	$ 1,182.2	$ 370.0	220%
Share-based compensation expense (benefit)[(1)]	4.0	(1.1)	464%	0.4	(12.1)	103%
Total research and development expense	$ 113.6	$ 138.8	(18)%	$ 1,182.6	$ 357.9	230%

(1) Refer to *Share-based compensation* below for discussion.

Research and development expense, excluding share-based compensation. We continued to invest in our product pipeline during 2019, which includes products in multiple phase III clinical trials as well as programs in regenerative medicine and organ manufacturing. The decrease in research and development expense of $30.3 million for the quarter ended December 31, 2019, as compared to the same period in 2018, was primarily due to a decrease in one-time payments of $32.5 million under our licensing and research agreements with MannKind Corporation (MannKind).

The increase in research and development project expense of $812.2 million for the year ended December 31, 2019, as compared to 2018, was driven by the continued investment in our product pipeline, which includes multiple phase III clinical trials in cardiopulmonary diseases and oncology as well as programs in regenerative medicine and organ manufacturing. Research and development expense for the treatment of cardiopulmonary diseases increased by $804.4 million for the year ended December 31, 2019, as compared to the same period in 2018, due to: (1) an $800.0 million up-front payment in January 2019 to Arena Pharmaceuticals, Inc. under our licensing agreement related to ralinepag; and (2) $40.3 million of expenditures in 2019 associated with the phase III *ADVANCE* studies of ralinepag; partially offset by (3) a $30.0 million decrease in 2019 in spending related to one-time payments under our licensing and research agreements with MannKind. Research and development expense for organ manufacturing projects increased by $14.2 million for the year ended December 31, 2019, as compared to the same period in 2018, due to increased preclinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues. Research and development expense for cancer-related projects decreased by $10.9 million for the year ended December 31, 2019, as compared to 2018, due to a decrease in spending on the *DISTINCT* study once the study was fully enrolled in late 2018.

Selling, general and administrative expense. The table below summarizes selling, general and administrative expense by major category (dollars in millions):

	Three Months Ended December 31,		Percentage Change	Year Ended December 31,		Percentage Change
	2019	2018		2019	2018	
Category:						
General and administrative	$ 61.7	$ 58.1	6%	$ 230.7	$ 217.8	6%
Sales and marketing	18.6	16.9	10%	60.7	59.1	3%
Share-based compensation expense (benefit)[(1)]	24.9	4.2	493%	44.8	(11.1)	504%
Total selling, general and administrative expense	$ 105.2	$ 79.2	33%	$ 336.2	$ 265.8	26%

(1) Refer to *Share-based compensation* below for discussion.

General and administrative, excluding share-based compensation. The increase in general and administrative expenses of $12.9 million for the year ended December 31, 2019, as compared to the same period in 2018, primarily resulted from: (1) a $6.7 million increase in compensation due to an increase in staffing; and (2) a $5.6 million increase in consulting expenses.

Share-based compensation. The table below summarizes share-based compensation expense (benefit) by major category (dollars in millions):

	Three Months Ended December 31,		Percentage Change	Year Ended December 31,		Percentage Change
	2019	2018		2019	2018	
Category:						
Stock options	$ 18.3	$ 13.7	34%	$ 70.5	$ 58.5	21%
Restricted stock units	3.5	2.0	75%	13.3	7.3	82%
Share tracking awards plan (STAP)	7.3	(13.3)	155%	(39.7)	(93.4)	57%
Employee stock purchase plan	0.4	0.4	—%	1.3	1.2	8%
Total share-based compensation expense (benefit)	$ 29.5	$ 2.8	954%	$ 45.4	$ (26.4)	272%

The increases in share-based compensation expense of $26.7 million and $71.8 million, respectively, for the quarter and year ended December 31, 2019, were primarily due to an increase in STAP expense of $20.6 million and a decrease in STAP benefit of $53.7 million, respectively. The increase in STAP expense for the quarter ended December 31, 2019 was primarily driven by an increase in our stock price during the fourth quarter of 2019 as compared to a decrease in our stock price during the same period in 2018. The decrease in STAP benefit for the year ended December 31, 2019 was primarily driven by a more significant decrease in our stock price during 2018 as compared to 2019. The remaining increase in share-based compensation expense for the year ended December 31, 2019 was primarily due to an increase of $12.0 million in stock option expense due to additional awards of options granted and outstanding in 2019 and a $6.0 million increase in restricted stock unit expense due to additional awards of restricted stock units granted and outstanding in 2019.

Other Income (Expense), Net. The increase in other income (expense), net of $30.3 million for the year ended December 31, 2019 was primarily due to the recognition of $21.4 million net unrealized and realized gains on publicly-traded equity securities. The remaining increase in other income (expense), net for the year ended December 31, 2019 was primarily due to an increase of $4.8 million of net unrealized and realized foreign currency gains compared to the same period in 2018.

Impairments of Investment in a Privately-Held Company. We recorded no impairment charges for the quarter and year ended December 31, 2019, and we recorded $41.1 million and $53.5 million of impairment charges, respectively, for the quarter and year ended December 31, 2018 related to our investment in a privately-held company.

Income Taxes. The income tax benefit was $60.5 million for the year ended December 31, 2019, as compared to income tax expense of $169.7 million for the same period in 2018. For the years ended December 31, 2019 and 2018, the effective tax rates were approximately 37 percent and 22 percent, respectively. We recognized a loss before income taxes and a corresponding income tax benefit for the year ended December 31, 2019, as a result of the one-time $800.0 million payment to Arena in January 2019. As a result of this loss, our tax benefit and resulting effective tax rate for the year ended December 31, 2019 increased primarily due to our anticipated tax credits, compared to the year ended December 31, 2018.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income (loss), adjusted for: (1) share-based compensation expense (including expenses relating to stock options, restricted stock units, share tracking awards and our employee stock purchase plan); (2) impairments of investment in privately-held company; (3) impairment charges; (4) license-related fees; (5) impact of The Tax Cuts and Jobs Act (Tax Reform); (6) net unrealized and realized gains on equity securities; and (7) tax benefit on non-GAAP earnings adjustments.

A reconciliation of net income (loss) to non-GAAP earnings is presented below (in millions, except per share data):

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Net income (loss), as reported	$ 52.6	$ 65.3	$ (104.5)	$ 589.2
Adjusted for the following charges:				
Share-based compensation expense (benefit)	29.5	2.8	45.4	(26.4)
Impairments of investment in privately-held company	—	41.1	—	53.5
Impairment charges	—	—	17.2	—
License-related fees	12.5	51.0	825.0	71.0
Impact of Tax Reform	—	(1.8)	—	(1.8)
Net unrealized and realized gains on equity securities	(1.9)	—	(21.4)	—
Tax benefit	(6.4)	(11.3)	(192.5)	(9.5)
Non-GAAP earnings	$ 86.3	$ 147.1	$ 569.2	$ 676.0
Non-GAAP earnings per share:				
Basic	$ 1.97	$ 3.37	$ 13.00	$ 15.54
Diluted	$ 1.96	$ 3.34	$ 12.94	$ 15.36
Weighted average number of common shares outstanding:				
Basic	43.9	43.6	43.8	43.5
Diluted	44.0	44.0	44.0	44.0

PRODUCT COMMERCIALIZATION UPDATE

Over the next 18 months, we expect to launch three products for pulmonary arterial hypertension (PAH): the Remunity system, the Trevyent system and the Implantable System for Remodulin.

Remunity system for Remodulin. On February 24, 2020, we announced FDA clearance of the pharmacy-filled version of the Remunity system for Remodulin, developed in partnership with DEKA. We plan to make the Remunity system available to patients by July 2020. The Remunity system consists of a small, lightweight, ambulatory pump that is intended to have a service life of at least three years. The Remunity system uses disposable prefilled cassettes, which are connected to the pump. The system was initially cleared by the FDA in May 2019 with instructions for patient filling. This additional 510(k) clearance enables cassettes to be prefilled with Remodulin by contracted specialty pharmacy distributors in order to improve convenience for patients. We are also developing a version of the system that includes disposable components that are prefilled as part of the manufacturing process.

Trevyent®. We submitted a 505(b)(1) new drug application (NDA) to the FDA for our Trevyent disposable treprostinil pump system in June 2019. The FDA accepted the NDA for review with a Prescription Drug User Fee Act (PDUFA) target action date of April 27, 2020. However, recent interactions with the FDA have included a mid-cycle information request from the FDA noting several deficiencies in the Trevyent NDA. We have provided written responses to the FDA addressing these deficiencies in hopes of preserving the current PDUFA date; however, based on recent discussions with the FDA, we believe the PDUFA date could be extended beyond April 2020, and/or the FDA may issue a complete response letter if the FDA is not satisfied with our responses to the agency's comments.

Implantable System for Remodulin (ISR). Developed in partnership with Medtronic, the premarket approval application (PMA) for ISR was approved by the FDA in December 2017. However, our ability to launch the product is subject to our partner satisfying various conditions to its PMA approval. Our partner continues to work toward satisfying these conditions, but in December 2019, due to recent FDA communications, our partner informed us that these conditions will not be satisfied in 2020. As such we announced on December 13. 2019 that we expect a delay in the ISR launch until 2021.

RESEARCH AND DEVELOPMENT UPDATE

Updates on selected later-stage programs are below.

Tyvaso in pulmonary hypertension due to interstitial lung disease (PH-ILD) - *INCREASE*. On February 24, 2020, we reported that the *INCREASE* study of Tyvaso in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) met its primary endpoint of demonstrating improvement in six-minute walk distance (6MWD). Tyvaso also showed benefits across several key subgroups, including etiology of PH-ILD, disease severity, age, gender, baseline hemodynamics, and dose. Significant improvements were also observed in each of the study's secondary endpoints, including reduction in the cardiac biomarker NT-proBNP, time to first clinical worsening event, change in peak 6MWD at Week 12, and change in trough 6MWD at week 15. Treatment with Tyvaso of up to 12 breaths per session, four times daily, in the *INCREASE* study was well tolerated and the safety profile was consistent with previous Tyvaso studies and known prostacyclin-related adverse events.

We expect to submit the results to the FDA by mid-year in support of an efficacy supplement that is expected to result in revised labeling that reflects the outcome of the *INCREASE* study. Detailed study results will be provided through scientific disclosure at upcoming conferences and in peer-reviewed publications.

Treprostinil Technosphere® dry powder inhaler - *BREEZE*. Enrollment is ongoing for the *BREEZE* study comparing our new dry powder inhaler (DPI) form of treprostinil, which we in-licensed from MannKind, to Tyvaso.

The phase I *BREEZE* study (NCT03950739) seeks to evaluate 45 patients on a stable dose of Tyvaso after switching to our new DPI. The primary endpoint of the study is the number of subjects with treatment-emergent adverse events after three weeks of treatment with the DPI.

We expect to receive results of the *BREEZE* study by mid-year 2020. During the first half of 2020, we also plan to commence a second clinical study in healthy volunteers to compare the pharmacokinetics of Treprostinil Technosphere to Tyvaso. We expect these two studies, combined with long-term stability studies of the DPI product, will form the basis of a 505(b)(1) new drug application to the FDA for our treprostinil DPI delivery product.

Unituxin in relapsed/refractory neuroblastoma - ANBL1221. We are pursuing an indication expansion for Unituxin in relapsed/refractory neuroblastoma based on the results of the Children Oncology Group's ANBL1221 study (NCT01767194). We expect to meet with the FDA in the first half of this year to potentially support a subsequent supplemental biologics license application.

Tyvaso in pulmonary hypertension due to chronic obstructive pulmonary disease (PH-COPD) - *PERFECT*. Enrollment is ongoing for the phase III *PERFECT* study evaluating Tyvaso in patients with WHO Group 3 PH associated with chronic obstructive pulmonary disease (PH-COPD).

The phase III *PERFECT* study (NCT03496623) seeks to evaluate patients with PH-COPD. In a 30-week crossover study, 136 subjects will be randomized between inhaled treprostinil and placebo for a 26-week treatment period. The primary endpoint of the study is the change in 6MWD from baseline to week 12. A contingent design for the study allows for the evaluation of 314 patients in two parallel groups.

We expect to provide enrollment updates for the *PERFECT* study in the future.

Ralinepag phase III development programs - *ADVANCE CAPACITY* and *ADVANCE OUTCOMES*. We have two ongoing phase III clinical studies to support the potential registration of oral ralinepag for PAH.

ADAVANCE CAPACITY. The phase III *ADVANCE CAPACITY* study (NCT04084678) seeks to evaluate 193 subjects with PAH, randomized between oral ralinepag and placebo at a 2:1 ratio, along with PAH background therapy, for 28 weeks with an optional open label extension period.

The primary endpoint of the study is the change from baseline to week 28 in peak VO_2 assessed by cardiopulmonary exercise testing. We expect to begin enrolling this study in mid-year 2020.

ADVANCE OUTCOMES. The phase III *ADVANCE OUTCOMES* study (NCT03626688) seeks to evaluate 700 PAH patients, randomized 1:1 between oral ralinepag and placebo along with background therapy.

The primary endpoint is the time from randomization to the first adjudicated protocol-defined clinical worsening event. This study is currently enrolling patients. We plan to provide enrollment updates in the future.

Autologous cell therapy for PAH - *SAPPHIRE*. Conducted by our Canadian affiliate Northern Therapeutics, Inc., the phase II/III *SAPPHIRE* study seeks to evaluate the use of autologous endothelial progenitor cells (EPCs) transfected with human endothelial NO-synthase in patients with PAH taking conventional PAH treatments. The study seeks to enroll 45 PAH patients in one of three arms: (1) placebo for six months followed by autologous EPCs for six months; (2) autologous EPCs for six months followed by placebo for six months; and (3) autologous EPCs for twelve months.

The primary endpoint is the change in 6MWD from baseline to month six. This study is currently enrolling patients. We plan to provide enrollment updates in the future.

Unituxin in small cell lung cancer (SCLC) - *DISTINCT*. On February 3, 2020, we announced that the phase II/III *DISTINCT* study did not meet its primary endpoint. We continue to analyze data from the study and expect to disseminate data from the study either at an upcoming scientific conference or in a journal publication.

INDUCEMENT RESTRICTED STOCK UNITS

On February 21, 2020, we granted a total of 3,862 restricted stock units under our 2019 Inducement Stock Incentive Plan to three newly hired employees. These restricted stock units vest in three equal installments on February 28, 2021, February 28, 2022 and February 28, 2023, assuming continued employment on such dates, and are subject to the standard terms and conditions we filed with the SEC as Exhibit 10.2 to our Current Report on Form 8-K on March 1, 2019. We are providing this information in accordance with Nasdaq Listing Rule 5635(c)(4).

CONFERENCE CALL

We will host a teleconference on Wednesday, February 26, 2020, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing (866) 209-9943 in the United States, with international callers dialing +1 (825) 312-2282. A rebroadcast of the teleconference will be available for one week and can be accessed by dialing (800) 585-8367 in the United States, with international callers dialing +1 (416) 621-4642, and using access code: 1598163.

This teleconference will also be webcast and can be accessed via our website at http://ir.unither.com/events-presentations.

ABOUT UNITED THERAPEUTICS

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture and our bioinformatics leadership. We also believe that our determination to be responsible citizens — having a positive impact on patients, the environment and society — will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company.

NON-GAAP FINANCIAL INFORMATION

This press release contains a financial measure, non-GAAP earnings, which does not comply with United States generally accepted accounting principles (GAAP). This measure supplements our financial results prepared in accordance with GAAP as reported below.

We use non-GAAP earnings to assist us in: (1) planning, including the preparation of our annual operating budget; (2) allocating resources in an effort to enhance the financial performance of our business; (3) evaluating the effectiveness of our operational strategies; and (4) assessing our capacity to fund capital expenditures and expand our business. We believe this non-GAAP financial measure improves investors' understanding of our financial results by providing greater transparency with respect to the information our management uses to evaluate and compare the performance of our core operations and make operating decisions. This non-GAAP financial measure enables investors to see our business through the eyes of our management. However, there are limitations in the use of this non-GAAP financial measure in that it excludes certain operating expenses that are recurring in nature. In addition, our calculation of this non-GAAP financial measure may differ from the methodology used by other companies. The presentation of this non-GAAP financial measure should not be considered in isolation or as a substitute for our financial results prepared in accordance with GAAP. A reconciliation of net income, the most directly comparable GAAP financial measure, to non-GAAP earnings can be found in the table above under the heading, Non-GAAP Earnings.

FORWARD-LOOKING STATEMENTS

Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements related to our expectation of revenue growth in 2020, our expectations regarding distributor ordering patterns, our launch plans for Remunity, Trevyent and the ISR, our planned expansion of the Tyvaso label to include the results of the *INCREASE* study and to increase the addressable U.S. patient population for Tyvaso, our research and development plans and regulatory filings related to Treprostinil Technosphere, Unituxin, the *PERFECT* and *SAPPHIRE* studies, ralinepag, our organ transplantation programs, and our expectation that we will sustain our success in the long-term. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. Consequently, such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of February 26, 2020, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason.

UNITED THERAPEUTICS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In millions, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Net product sales	$ 311.1	$ 381.4	$ 1,448.8	$ 1,627.8
Total revenues	311.1	381.4	1,448.8	1,627.8
Operating expenses:				
Cost of product sales	28.8	31.9	117.6	198.7
Research and development	113.6	138.8	1,182.6	357.9
Selling, general and administrative	105.2	79.2	336.2	265.8
Total operating expenses	247.6	249.9	1,636.4	822.4
Operating income (loss)	63.5	131.5	(187.6)	805.4
Interest income	11.5	8.7	44.2	28.6
Interest expense	(10.0)	(4.3)	(44.2)	(13.9)
Other income (expense), net	3.3	(2.9)	22.6	(7.7)
Impairment of investment in privately-held company	—	(41.1)	—	(53.5)
Total other income (expense), net	4.8	(39.6)	22.6	(46.5)
Income (loss) before income taxes	68.3	91.9	(165.0)	758.9
Income tax (expense) benefit	(15.7)	(26.6)	60.5	(169.7)
Net income (loss)	$ 52.6	$ 65.3	$ (104.5)	$ 589.2
Net income (loss) per common share:				
Basic	$ 1.20	$ 1.50	$ (2.39)	$ 13.54
Diluted	$ 1.20	$ 1.48	$ (2.39)	$ 13.39
Weighted average number of common shares outstanding:				
Basic	43.9	43.6	43.8	43.5
Diluted	44.0	44.0	43.8	44.0

SELECTED CONSOLIDATED BALANCE SHEET DATA
(In millions)

	December 31,	
	2019	**2018**
Cash, cash equivalents and marketable securities	$ 2,253.4	$ 1,858.5
Total assets	3,913.4	3,401.0
Total liabilities and temporary equity	1,133.0	612.4
Total stockholders' equity	2,780.4	2,788.6

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