United Therapeutics Corporation Reports 2018 Fourth Quarter And Annual Financial Results

February 27, 2019

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Feb. 27, 2019 /PRNewswire/ -- United Therapeutics Corporation (Nasdaq: UTHR) today announced its financial results for the fourth quarter and year ended December 31, 2018.

"2018 was a truly transformative year for United Therapeutics. We signed four major agreements to acquire new product candidates, including an in-licensing agreement for ralinepag, representing our largest deal to date," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "At the same time, we continued to execute against our existing commercial and clinical goals, including the successful readout of our *FREEDOM-EV* clinical trial, significant progress toward near-term phase III readouts for our *BEAT* and *DISTINCT* studies, and an increase to a record number of patients being treated with our treprostinil therapies."

Recent Highlights

- Closed license agreement with MannKind for Treprostinil Technosphere®
- Appointed Nilda Mesa to the Board of Directors
- Health Canada approved Unituxin® (dinutuximab) for high-risk neuroblastoma
- Submitted efficacy supplement to FDA to include *FREEDOM-EV* data in the Orenitram® label
- In-licensed global rights to ralinepag, a phase III PAH drug candidate
- Presented survival data from *FREEDOM-EV* study of Orenitram® at the Pulmonary Vascular Research Institute Annual World Congress

Financial Results for the Quarter and Year Ended December 31, 2018 compared to the same periods in 2017

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenues	$ 381.4	$ 464.7	$ 1,627.8	$ 1,725.3
Net income	$ 65.3	$ 19.0	$ 589.2	$ 417.9
Non-GAAP earnings(1)	$ 147.1	$ 170.2	$ 676.0	$ 741.3
Net income, per basic share	$ 1.50	$ 0.44	$ 13.54	$ 9.50
Net income, per diluted share	$ 1.48	$ 0.43	$ 13.39	$ 9.31
Non-GAAP earnings, per diluted share(1)	$ 3.34	$ 3.89	$ 15.36	$ 16.51

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

Revenues

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

	Three Months Ended December 31,		Percentage	Year Ended December 31,		Percentage
	2018	2017	Change	2018	2017	Change
Net product sales:						
Remodulin®	$ 159.1	$ 180.1	(11.7)%	$ 599.0	$ 670.9	(10.7)%
Tyvaso®	106.9	92.4	15.7%	415.2	372.9	11.3%
Adcirca®	41.7	119.3	(65.0)%	323.7	419.7	(22.9)%
Orenitram®	49.6	48.0	3.3%	205.1	185.8	10.4%
Unituxin®	24.1	24.9	(3.2)%	84.8	76.0	11.6%
Total revenues	$ 381.4	$ 464.7	(17.9)%	$ 1,627.8	$ 1,725.3	(5.7)%

Revenues for the quarter and year ended December 31, 2018 decreased by $83.3 million and $97.5 million, respectively, as compared to the same periods in 2017.

Remodulin net product sales for the quarter and year ended December 31, 2018 decreased by $21.0 million and $71.9 million, respectively, as compared to the same periods in 2017. For the quarter and year ended December 31, 2018, international Remodulin net sales decreased by $30.7 million and $90.0 million, respectively, compared to the same periods in 2017, primarily due to the transfer of additional regulatory and commercial

responsibilities to an international distributor in the third quarter of 2017. As a result of this transfer, we recognized $23.7 million and $47.4 million of net product sales in the quarter and year ended December 31, 2017, respectively, related to the one-time purchase of Remodulin inventory by that distributor and we reduced the price at which we sell Remodulin to that distributor. The remaining decrease was primarily due to a reduction in quantities shipped to that distributor. For the quarter and year ended December 31, 2018, U.S. Remodulin net sales increased by $9.7 million and $18.1 million, respectively, compared to the same periods in 2017, primarily due to a price increase that was implemented in April 2018, which was the first price increase for Remodulin since 2010, and an increase in the number of patients being treated with Remodulin. For the year ended December 31, 2018, these increases were partially offset by the one-time $4.5 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Tyvaso net product sales for the quarter and year ended December 31, 2018 increased by $14.5 million and $42.3 million, respectively, as compared to the same periods in 2017. These increases were primarily due to price increases that were implemented in April 2017 and January 2018 and the reversal in the fourth quarter of 2018 of an estimated $15.4 million liability for Medicaid rebates, of which $13.6 million was initially recorded in 2017. In addition, Tyvaso net product sales increased due to an increase in the number of patients being treated with Tyvaso. These increases were offset by (1) the impact of replacing $6.2 million of commercial Tyvaso product that our specialty pharmaceutical distributor previously used in connection with a clinical trial; and (2) the one-time $3.5 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Adcirca net product sales for the quarter and year ended December 31, 2018 decreased by $77.6 million and $96.0 million, respectively, as compared to the same periods in 2017. These decreases were primarily due to the launch of a generic version of Adcirca in August 2018, partially offset by price increases that were implemented by Eli Lilly and Company in May 2017 and January 2018. In addition, we increased our allowance for product returns for Adcirca by $16.4 million in the third quarter of 2018 based on our estimates of inventory held by distributors and other downstream customers that would expire unsold as a result of the increased use of a generic version of Adcirca.

Orenitram net product sales for the quarter and year ended December 31, 2018 increased by $1.6 million and $19.3 million, respectively, as compared to the same periods in 2017. These increases were primarily due to an increase in the number of patients being treated with Orenitram, a price increase that was implemented in January 2018 and, for the year ended December 31, 2018, the one-time $3.7 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Unituxin net product sales decreased by $0.8 million for the quarter ended December 31, 2018 and increased by $8.8 million for the year ended December 31, 2018, as compared to the same periods in 2017. For the year ended December 31, 2018, Unituxin net product sales increased due to an increase in the number of vials sold and price increases that were implemented in April and December 2017.

During the fourth quarter of 2017, we amended our agreements with one of our U.S. specialty pharmacy distributors, in part to make the monthly minimum inventory requirement consistent across Remodulin, Tyvaso and Orenitram. This change resulted in a one-time decrease in total net product sales of $4.3 million as the distributor adjusted to the new contractual inventory requirement levels in the first quarter of 2018. On an individual product basis, net product sales of Remodulin decreased by $4.5 million, net product sales of Tyvaso decreased by $3.5 million, and net product sales of Orenitram increased by $3.7 million.

Expenses

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

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	Percentage Change	2018	2017	Percentage Change
Category:						
Cost of product sales	$ 32.2	$ 46.7	(31.0)%	$ 201.9	$ 103.1	95.8%
Share-based compensation (benefit) expense[1]	(0.3)	6.3	(104.8)%	(3.2)	2.6	(223.1)%
Total cost of product sales	$ 31.9	$ 53.0	(39.8)%	$ 198.7	$ 105.7	88.0%

(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 $14.5 million for the quarter ended December 31, 2018, as compared to the same period in 2017, was primarily attributable to a decrease in Adcirca sales.

The increase in cost of product sales of $98.8 million for the year ended December 31, 2018, as compared to the same period in 2017, was primarily attributable to a $96.9 million increase in royalty expense for Adcirca. As a result of an amendment to our license agreement with Lilly, effective December 1, 2017, our royalty rate on net product sales of Adcirca increased from five percent to an effective rate of approximately 42.5 percent.

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

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	Percentage Change	2018	2017	Percentage Change
Category:						
Research and development projects	$ 139.9	$ 91.5	52.9%	$ 370.0	$ 256.4	44.3%
Share-based compensation (benefit) expense[1]	(1.1)	22.1	(105.0)%	(12.1)	8.2	(247.6)%
Total research and development expense	$ 138.8	$ 113.6	22.2%	$ 357.9	$ 264.6	35.3%

(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 2018, which includes products in multiple phase III clinical trials in cardiopulmonary diseases and oncology as well as programs in regenerative medicine and organ manufacturing. The increase in research and development expense of $48.4 million for the quarter ended December 31, 2018, as compared to the same period in 2017, was primarily due to an up-front payment of $45.0 million under our license agreement with MannKind.

The increase in research and development expense of $113.6 million for the year ended December 31, 2018, as compared to the same period in 2017, was driven by an increase of $95.9 million in research and development expense for the treatment of cardiopulmonary diseases, primarily due to up-front payments of $55.0 million under our license and research agreements with MannKind and $10.0 million under our license agreement with Samumed, increased spending of $22.9 million on the development of drug delivery devices, including the Implantable System for Remodulin and RemUnity, and increased spending on several clinical and non-clinical studies. Research and development expense for cancer-related projects increased by $13.9 million due to an increase in spending on the *DISTINCT* study. Research and development expense for organ manufacturing projects increased by $3.9 million due to increased preclinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues.

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,			Year Ended December 31,		
	2018	2017	Percentage Change	2018	2017	Percentage Change
Category:						
General and administrative	$ 58.1	$ 51.4	13.0%	$ 217.8	$ 203.1	7.2%
Sales and marketing	16.9	17.6	(4.0)%	59.1	64.3	(8.1)%
Share-based compensation expense (benefit)[(1)]	4.2	90.1	(95.3)%	(11.1)	62.7	(117.7)%
Total selling, general and administrative expense	$ 79.2	$ 159.1	(50.2)%	$ 265.8	$ 330.1	(19.5)%

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

General and administrative, excluding share-based compensation. The increase in general and administrative expenses of $6.7 million for the quarter ended December 31, 2018, as compared to the same period in 2017, primarily resulted from a $5.0 million increase in consulting fees.

The increase in general and administrative expenses of $14.7 million for the year ended December 31, 2018, as compared to the same period in 2017, primarily resulted from: (1) a $10.3 million increase in consulting expenses; (2) a $4.7 million increase in compensation due to an increase in staffing; and (3) a $4.4 million increase in acquisition and integration costs related to the SteadyMed acquisition. The increase was partially offset by a $7.1 million decrease in legal fees incurred in connection with intellectual property litigation and a Department of Justice (DOJ) investigation.

Sales and marketing, excluding share-based compensation. Sales and marketing expenses for the quarter ended December 31, 2018, remained relatively consistent as compared to the same period in 2017.

The decrease in sales and marketing expenses of $5.2 million for the year ended December 31, 2018, as compared to the same period in 2017, primarily resulted from a decrease in marketing consulting fees.

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

	Three Months Ended December 31,			Year Ended December 31,		
	2018	2017	Percentage Change	2018	2017	Percentage Change
Category:						
Stock options	$ 13.7	$ 13.1	4.6%	$ 58.5	$ 43.0	36.0%
Restricted stock units	2.0	0.6	233.3%	7.3	2.2	231.8%
Share tracking awards plan (STAP)	(13.3)	104.6	(112.7)%	(93.4)	27.1	(444.6)%
Employee stock purchase plan	0.4	0.2	100.0%	1.2	1.2	— %
Total share-based compensation expense (benefit)	$ 2.8	$ 118.5	(97.6)%	$ (26.4)	$ 73.5	(135.9)%

Share-based compensation. The decreases in share-based compensation of $115.7 million and $99.9 million, respectively, for the quarter and year ended December 31, 2018, were primarily due to decreases in STAP expense of $117.9 million and $120.5 million, respectively, primarily driven by a decrease in our stock price for the quarter and year ended December 31, 2018, as compared to the same periods in 2017. The decrease in STAP expense for the year-ended December 31, 2018 was partially offset by an increase of $15.5 million in stock option expense due to additional awards granted and outstanding in 2018 and a $5.1 million increase in restricted stock unit expense due to additional awards granted and outstanding in 2018.

Settlement of Loss Contingency

In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation. During the second quarter of 2017, we recorded a $210.0 million accrual relating to this matter, and ultimately paid this amount, plus interest, to the U.S. Government upon settlement.

Impairments of Investments in Privately-Held Companies

During the years ended December 31, 2018 and 2017, we recorded impairment charges of $53.5 million and $49.6 million, respectively, related to our investments in privately-held companies.

Income Taxes

The provision for income taxes was $169.7 million for the year ended December 31, 2018, compared to $351.6 million for the same period in 2017. The change in the provision for income taxes was primarily due to the impacts of The Tax Cuts and Jobs Act (Tax Reform) and the nondeductible portion of an accrual in 2017 in connection with a civil settlement with the DOJ. For the years ended December 31, 2018 and 2017, the effective tax rates were approximately 22 percent and 46 percent, respectively.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, 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) loss contingency; (3) impairments of investments in privately-held companies; (4) license fees; (5) impact of Tax Reform; and (6) tax impact on non-GAAP earnings adjustments.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Net income, as reported	$ 65.3	$ 19.0	$ 589.2	$ 417.9
Adjust for the following charges:				
Share-based compensation expense (benefit)[1]	2.8	118.5	(26.4)	73.5
Settlement of loss contingency[2]	—	—	—	210.0
Impairments of investments in privately-held companies[3]	41.1	—	53.5	49.6
License fees[1]	51.0	—	71.0	—
Impact of Tax Reform[4]	(1.8)	71.0	(1.8)	71.0
Tax benefit[1][2]	(11.3)	(38.3)	(9.5)	(80.7)
Non-GAAP earnings	$ 147.1	$ 170.2	$ 676.0	$ 741.3
Non-GAAP earnings per share:				
Basic	$ 3.37	$ 3.94	$ 15.54	$ 16.85
Diluted	$ 3.34	$ 3.89	$ 15.36	$ 16.51
Weighted average number of common shares outstanding:				
Basic	43.6	43.2	43.5	44.0
Diluted	44.0	43.8	44.0	44.9

(1) We calculated the total tax impact of non-discrete quarterly non-GAAP earnings adjustments based on our annual effective tax rates, before considering discrete items, of approximately 21 percent and approximately 32 percent for each of the quarters and years ended December 31, 2018 and 2017, respectively.

(2) The tax benefit for the year ended December 31, 2017 includes $57.0 million of benefit for the estimated loss contingency recognized during the second quarter of 2017 relating to a DOJ investigation.

(3) This non-GAAP earnings adjustment is currently not considered tax deductible.

(4) The impact of Tax Reform is a significant and unusual component of tax expense, therefore in the calculation of non-GAAP earnings, it is presented separately from the tax benefit that is derived from the other non-GAAP adjustments.

Conference Call

We will host a one-hour teleconference on Wednesday, February 27, 2019, at 9:00 a.m. Eastern Time. The teleconference is accessible by dialing 1-877-351-5881, with international callers dialing 1-970-315-0533. A rebroadcast of the teleconference will be available for one week by dialing 1-855-859-2056, with international callers dialing 1-404-537-3406 and using access code 1595239.

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

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 excluding certain expenses that we do not consider when evaluating and comparing the performance of our core operations and making operating decisions. 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 relating to our research and development pipeline, including our *BEAT* and *DISTINCT* clinical studies. 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 27, 2019, 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. [uthr-g]

Orenitram, Remodulin, Tyvaso and Unituxin are registered trademarks of United Therapeutics Corporation.

Technosphere is a registered trademark of MannKind Corporation.

Adcirca is a registered trademark of Eli Lilly and Company.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Revenues:				
Net product sales	$ 381.4	$ 464.7	$ 1,627.8	$ 1,725.3
Total revenues	381.4	464.7	1,627.8	1,725.3
Operating expenses:				
Cost of product sales	31.9	53.0	198.7	105.7
Research and development	138.8	113.6	357.9	264.6
Selling, general and administrative	79.2	159.1	265.8	330.1
Settlement of loss contingency	—	—	—	210.0
Total operating expenses	249.9	325.7	822.4	910.4
Operating income	131.5	139.0	805.4	814.9
Other income (expense):				
Interest income	8.7	5.2	28.6	10.9
Interest expense	(4.3)	(3.5)	(13.9)	(9.0)
Other, net	(2.9)	0.3	(7.7)	2.3
Impairments of investments in privately-held companies	(41.1)	—	(53.5)	(49.6)
Total other (expense) income, net	(39.6)	2.0	(46.5)	(45.4)
Income before income taxes	91.9	141.0	758.9	769.5
Income tax expense	(26.6)	(122.0)	(169.7)	(351.6)
Net income	$ 65.3	$ 19.0	$ 589.2	$ 417.9
Net income per common share:				
Basic	$ 1.50	$ 0.44	$ 13.54	$ 9.50
Diluted	$ 1.48	$ 0.43	$ 13.39	$ 9.31
Weighted average number of common shares outstanding:				
Basic	43.6	43.2	43.5	44.0
Diluted	44.0	43.8	44.0	44.9

SELECTED CONSOLIDATED BALANCE SHEET DATA
(In millions)

	December 31,	
	2018	**2017**
Cash, cash equivalents and marketable securities	$ 1,858.5	$ 1,430.1
Total assets	3,401.0	2,879.4
Total liabilities and temporary equity	612.4	777.6
Total stockholders' equity	2,788.6	2,101.8

View original content:http://www.prnewswire.com/news-releases/united-therapeutics-corporation-reports-2018-fourth-quarter-and-annual-financial-results-300802817.html

SOURCE United Therapeutics Corporation

James Edgemond, (301) 608-9292, Jedgemond@unither.com