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United Therapeutics Corporation Reports 2016 Fourth Quarter And Annual Financial Results

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Feb. 22, 2017 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) today announced its financial results for the fourth quarter and year ended December 31, 2016.

"Our annual 2016 financial results reflect continued growth as net revenues reached \$1.6 billion and earnings exceeded \$700 million," said Martine Rothblatt, Ph.D., United Therapeutics' Chairman and Chief Executive Officer. "These financial results strengthen our ability to develop and advance our growing product pipeline, which includes seven phase III programs and multiple second generation Remodulin drug delivery systems."

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenues	\$ 409.0	\$ 404.9	\$ 1,598.8	\$ 1,465.8
Net income	\$ 110.3	\$ 104.6	\$ 713.7	\$ 651.6
Non-GAAP earnings(1)	\$ 187.2	\$ 189.1	\$ 748.6	\$ 631.7
Net income, per diluted share	\$ 2.43	\$ 2.10	\$ 15.25	\$ 12.72
Non-GAAP earnings, per diluted share(1)	\$ 4.12	\$ 3.80	\$ 16.00	\$ 12.33

(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 Change	Year Ended December 31,		Percentage Change
	2016	2015		2016	2015	
Net product sales:						
Remodulin®	\$ 151.2	\$ 140.5	7.6%	\$ 602.3	\$ 572.8	5.2%
Tyvaso®	93.6	119.2	(21.5)%	404.6	470.1	(13.9)%
Adcirca®	112.7	91.5	23.2%	372.2	278.8	33.5%
Orenitram®	38.3	37.2	3.0%	157.2	118.4	32.8%
Unituxin®	13.2	15.8	(16.5)%	62.5	20.5	204.9%
Other	—	0.7	(100.0)%	—	5.2	(100.0)%
Total revenues	\$ 409.0	\$ 404.9	1.0%	\$ 1,598.8	\$ 1,465.8	9.1%

Revenues for the quarter ended December 31, 2016 increased by \$4.1 million as compared to the same period in 2015. The growth in revenues primarily resulted from: (1) a \$21.2 million increase in Adcirca net product sales; (2) a \$10.7 million increase in Remodulin net product sales; and (3) a \$1.1 million increase in Orenitram net product sales, partially offset by: (1) a \$25.6 million decrease in Tyvaso net product sales; and (2) a \$2.6 million decrease in Unituxin net product sales.

Revenues for the year ended December 31, 2016 increased by \$133.0 million as compared to the same period in 2015. The growth in revenues primarily resulted from the following: (1) a \$93.4 million increase in Adcirca net product sales; (2) a \$42.0 million increase in Unituxin net product sales; (3) a \$38.8 million increase in Orenitram net product sales; and (4) a \$29.5 million increase in Remodulin net product sales, partially offset by a \$65.5 million decrease in Tyvaso net product sales.

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
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	2016	2015	Change	2016	2015	Change
Category:						
Cost of product sales	\$ 19.5	\$ 19.3	1.0%	\$ 72.1	\$ 60.2	19.8%
Share-based compensation expense(1)	8.9	6.0	48.3%	0.6	8.8	(93.2)%
Total cost of product sales	\$ 28.4	\$ 25.3	12.3%	\$ 72.7	\$ 69.0	5.4%

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

Cost of product sales. The increase in cost of product sales of \$11.9 million for the year ended December 31, 2016, as compared to the same period in 2015, was primarily attributable to increased sales.

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

	Three Months Ended December 31,		Percentage Change	Year Ended December 31,		Percentage Change
	2016	2015		2016	2015	
Project and non-project:						
Research and development expense	\$ 46.6	\$ 45.6	2.2%	\$ 157.6	\$ 157.4	0.1%
Share-based compensation expense (benefit)(1)	20.3	30.3	(33.0)%	(10.0)	87.7	(111.4)%
Total research and development expense	\$ 66.9	\$ 75.9	(11.9)%	\$ 147.6	\$ 245.1	(39.8)%

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

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
	2016	2015		2016	2015	
Category:						
General and administrative	\$ 45.9	\$ 42.9	7.0%	\$ 210.7	\$ 174.6	20.7%
Sales and marketing	17.5	24.7	(29.1)%	84.6	94.3	(10.3)%
Share-based compensation expense(1)	76.1	81.1	(6.2)%	21.5	183.8	(88.3)%
Total selling, general and administrative expense	\$ 139.5	\$ 148.7	(6.2)%	\$ 316.8	\$ 452.7	(30.0)%

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

General and administrative. The increase in general and administrative expenses of \$36.1 million for the year ended December 31, 2016, as compared to the same period in 2015, primarily resulted from: (1) a \$20.0 million increase in grants to a non-affiliated, non-profit organization that provides financial assistance to patients with PAH; and (2) \$9.3 million in expenses in connection with the disposition and write-down of various properties.

Share-based compensation expense. 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
	2016	2015		2016	2015	
Category:						
Share tracking awards plan	\$ 101.3	\$ 114.6	(11.6)%	\$ (15.2)	\$ 274.2	(105.5)%
Stock options	3.1	2.4	29.2%	24.8	4.9	406.1%
Other(1)	0.9	0.4	125.0%	2.5	1.2	108.3%
Total share-based compensation expense	\$ 105.3	\$ 117.4	(10.3)%	\$ 12.1	\$ 280.3	(95.7)%

(1) Includes expense related to restricted stock units for the year ended December 31, 2016 and employee stock purchase plan for the years ended December 31, 2016 and 2015.

Share-based compensation. The decrease of \$12.1 million and \$268.2 million, respectively, during the quarter and year ended December 31, 2016, as compared to the same periods in 2015, was primarily due to changes in our stock price and number of share tracking awards and stock options outstanding during the periods.

Gain on Sale of Intangible Asset

In September 2015, we sold for \$350.0 million in cash the Rare Pediatric Priority Review Voucher (PPRV) that we received from the U.S. Food and Drug Administration in connection with the approval of Unituxin. The proceeds from the sale of the PPRV were recognized as a gain on the sale of an intangible asset, as the PPRV did not have a carrying value on our consolidated balance sheet at the time of sale.

Income Taxes

The provision for income taxes was \$346.5 million for the year ended December 31, 2016 compared to \$392.8 million for the same period in 2015. The decrease in the provision for income taxes corresponded primarily to a decrease in non-deductible compensation related to our share tracking awards plan, which in turn resulted from the decrease in our stock price. For the years ended December 31, 2016 and 2015, the effective tax rates were approximately 33 percent and 38 percent, respectively.

Non-GAAP Earnings

Non-GAAP earnings is defined as net income, adjusted for: (1) interest expense; (2) license fees; (3) depreciation and amortization; (4) impairment charges; (5) share-based compensation expense (benefit), net (including expenses relating to stock options, share tracking awards, restricted stock units and our employee stock purchase plan); and (6) tax impact on non-GAAP earnings adjustments. For 2015, we also adjusted non-GAAP earnings to eliminate the gain resulting from the sale of the PPRV in September 2015.

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,	
	2016	2015	2016	2015
Net income, as reported	\$ 110.3	\$ 104.6	\$ 713.7	\$ 651.6
Adjust for the following charges:				
Interest expense	2.2	0.5	3.9	4.7
Depreciation and amortization	7.8	8.0	31.6	32.9
Impairment charges	4.3	—	4.3	—
Share-based compensation expense	105.3	117.4	12.1	280.3
Gain on sale of intangible asset	—	—	—	(350.0)
Tax (benefit) expense(1)	(42.7)	(41.4)	(17.0)	12.2
Non-GAAP earnings	<u>\$ 187.2</u>	<u>\$ 189.1</u>	<u>\$ 748.6</u>	<u>\$ 631.7</u>
Non-GAAP earnings per share:				
Basic	<u>\$ 4.44</u>	<u>\$ 4.14</u>	<u>\$ 17.09</u>	<u>\$ 13.73</u>
Diluted	<u>\$ 4.12</u>	<u>\$ 3.80</u>	<u>\$ 16.00</u>	<u>\$ 12.33</u>
Weighted average number of common shares outstanding:				
Basic	<u>42.2</u>	<u>45.7</u>	<u>43.8</u>	<u>46.0</u>
Diluted	<u>45.4</u>	<u>49.7</u>	<u>46.8</u>	<u>51.2</u>

(1) Non-GAAP earnings adjustments are presented net of the impact of our actual effective income tax rates of approximately 36 percent and 33 percent for the quarters ended December 31, 2016 and 2015, respectively and 33 percent and 38 percent for the years ended December 31, 2016 and 2015, respectively. We changed the presentation of our non-GAAP earnings in the first quarter of 2015 for all periods presented to reflect the impact of our estimated effective income tax rates on each component. The sum of non-GAAP earnings in each of the quarters in 2016 and 2015, respectively, will not equal non-GAAP earnings for the full year if there are differences between the estimated effective income tax rate applied to each quarter and the actual effective tax rate for the full year.

Conference Call

We will host a half-hour teleconference on Wednesday, February 22, 2017, 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 59599305.

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

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions.

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 ability to develop and advance products within our pipeline. 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 22, 2017, 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.

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,	
	2016	2015	2016	2015
Revenues:				
Net product sales	\$ 409.0	\$ 404.2	\$ 1,598.8	\$ 1,460.6
Other	—	0.7	—	5.2
Total revenues	409.0	404.9	1,598.8	1,465.8
Operating expenses:				
Cost of product sales	28.4	25.3	72.7	69.0
Research and development	66.9	75.9	147.6	245.1
Selling, general and administrative	139.5	148.7	316.8	452.7
Total operating expenses	234.8	249.9	537.1	766.8
Operating income	174.2	155.0	1,061.7	699.0
Other (expense) income:				
Interest expense	(2.2)	(0.5)	(3.9)	(4.7)
Gain on sale of intangible asset	—	—	—	350.0
Other, net	(0.5)	1.5	2.4	0.1
Total other (expense) income, net	(2.7)	1.0	(1.5)	345.4
Income before income taxes	171.5	156.0	1,060.2	1,044.4
Income tax expense	(61.2)	(51.4)	(346.5)	(392.8)
Net income	\$ 110.3	\$ 104.6	\$ 713.7	\$ 651.6
Net income per common share:				
Basic	\$ 2.61	\$ 2.29	\$ 16.29	\$ 14.17
Diluted	\$ 2.43	\$ 2.10	\$ 15.25	\$ 12.72
Weighted average number of common shares outstanding:				
Basic	42.2	45.7	43.8	46.0
Diluted	45.4	49.7	46.8	51.2

(In millions)

	December 31,	
	2016	2015
Cash, cash equivalents and marketable securities	\$ 1,053.1	\$ 991.8
Total assets	2,325.6	2,184.4
Total liabilities and temporary equity	474.3	595.8
Total stockholders' equity	1,851.3	1,588.6

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/united-therapeutics-corporation-reports-2016-fourth-quarter-and-annual-financial-results-300411068.html>

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