United Therapeutics Corporation Reports Third Quarter 2018 Financial Results

October 31, 2018

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., Oct. 31, 2018 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: UTHR) today announced its financial results for the quarter ended September 30, 2018.

"We are pleased to see continued growth in the number of U.S. patients treated with our prostacyclin product franchise during the quarter," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "We've been busy bringing in exceptional new pipeline opportunities and advancing our six Phase III clinical trials."

Third Quarter Highlights

- Announced that our *FREEDOM-EV* study of Orenitram® met its primary endpoint.
- Settled patent litigation with Watson Laboratories, Inc. (Watson), relating to Tyvaso®. Under the terms of the settlement, Watson is permitted to launch a generic version of Tyvaso in the U.S. beginning on January 1, 2026 (or earlier under certain circumstances).
- Completed the acquisition of SteadyMed Ltd. and its drug product candidate Trevyent®, which is a development-stage drug-device combination product that combines SteadyMed's PatchPump® technology with treprostinil to treat pulmonary arterial hypertension (PAH). We anticipate resubmitting the Trevyent NDA to the FDA during the first half of 2019.
- In-licensed MannKind Corp.'s Treprostinil Technosphere®, a phase III-ready development-stage drug-device combination product that combines MannKind's dry inhalation technology with treprostinil for the treatment of PAH.
- In-licensed the U.S. and Canadian rights to Samumed LLC's SM04646, a phase I development-stage oral Wnt pathway inhibitor, to treat idiopathic pulmonary fibrosis.
- Completed enrollment of the *DISTINCT* study of dinutuximab in patients with small cell lung cancer (n=472).

Financial Results for the Three Months Ended September 30, 2018 compared to the Three Months Ended September 30, 2017

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

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Revenues	$ 412.7	$ 445.5	$ (32.8)	(7)%
Net income	$ 106.5	$ 276.3	$ (169.8)	(61)%
Non-GAAP earnings(1)	$ 174.9	$ 206.9	$ (32.0)	(15)%
Net income, per basic share	$ 2.44	$ 6.37	$ (3.93)	(62)%
Net income, per diluted share	$ 2.42	$ 6.27	$ (3.85)	(61)%
Non-GAAP earnings, per diluted share(1)	$ 3.98	$ 4.69	$ (0.71)	(15)%

(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 following table presents the components of total revenues (dollars in millions):

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Net product sales:				
Remodulin®	$ 153.6	$ 187.3	$ (33.7)	(18)%
Tyvaso®	107.8	88.9	18.9	21%
Adcirca®	74.6	99.8	(25.2)	(25)%
Orenitram®	53.8	52.5	1.3	2%
Unituxin®	22.9	17.0	5.9	35%
Total revenues	$ 412.7	$ 445.5	$ (32.8)	(7)%

Revenues for the three months ended September 30, 2018 decreased by $32.8 million as compared to the same period in 2017. Remodulin net product sales decreased by $33.7 million due to a $36.5 million decrease in international net product sales, partially offset by a $2.8 million increase in U.S. net product sales. International Remodulin net product sales are lower relative to 2017 due to $23.7 million of net product sales recognized in the third quarter of 2017 related to a one-time purchase of Remodulin by an international distributor, in connection with the transfer of additional regulatory and commercial responsibilities to that distributor. In addition, our international net product sales decreased due to lower quantities shipped to the

aforementioned distributor, after taking the one-time purchase into account. Tyvaso net product sales increased by $18.9 million due to the comparative impact of an additional one-time $12.2 million liability for estimated Medicaid rebates recorded in the third quarter of 2017 and a price increase implemented in January 2018. Adcirca net product sales decreased by $25.2 million due to a decrease in bottles sold, due in large part to the launch of a generic version of Adcirca in August 2018, and an approximate $16.4 million increase in our estimated allowance for product returns, partially offset by a price increase implemented by Lilly. Unituxin net product sales increased by $5.9 million due to an increase in the number of vials sold and a price increase implemented in December 2017.

Expenses

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

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Category:				
Cost of product sales	$ 49.5	$ 21.3	$ 28.2	132 %
Share-based compensation expense (benefit)(1)	2.4	(1.8)	4.2	233 %
Total cost of product sales	$ 51.9	$ 19.5	$ 32.4	166 %

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

Cost of product sales, excluding share-based compensation. The increase in cost of product sales of $28.2 million for the three months ended September 30, 2018, as compared to the same period in 2017, was primarily due to a $26.8 million increase in the 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 following table summarizes research and development expense by major category (dollars in millions):

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Category:				
Research and development projects	$ 92.8	$ 62.0	$ 30.8	50 %
Share-based compensation expense (benefit)(1)	8.3	(7.0)	15.3	219 %
Total research and development expense	$ 101.1	$ 55.0	$ 46.1	84 %

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

Research and development expense, excluding share-based compensation. The increase in research and development expense of $30.8 million for the three months ended September 30, 2018, as compared to the same period in 2017, was driven by the continued investment in our product pipeline to treat cardiopulmonary diseases and cancer as well as our programs in regenerative medicine and organ manufacturing.

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

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Category:				
General and administrative	$ 56.1	$ 46.6	$ 9.5	20 %
Sales and marketing	13.3	15.8	(2.5)	(16) %
Share-based compensation expense (benefit)(1)	40.7	(15.2)	55.9	368 %
Total selling, general and administrative expense	$ 110.1	$ 47.2	$ 62.9	133 %

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

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

	Three Months Ended September 30,		Dollar Change	Percentage Change
	2018	2017		
Category:				
Stock options	$ 16.6	$ 13.1	$ 3.5	27 %
Restricted stock units	2.4	0.6	1.8	300 %
Share tracking awards plan (STAP)	32.2	(38.0)	70.2	185 %
Employee stock purchase plan	0.2	0.3	(0.1)	(33) %
Total share-based compensation expense (benefit)	$ 51.4	$ (24.0)	$ 75.4	314 %

The increase in share-based compensation expense of $75.4 million for the three months ended September 30, 2018, as compared to the same period in 2017, was primarily due to: (1) a $70.2 million increase in STAP expense related to an increase in our stock price during the three months ended September 30, 2018, as compared to a decrease in our stock price during the same period in 2017; and (2) a $3.5 million increase in stock

option expense due to additional awards granted and outstanding in 2018.

Impairment of Investment in a Privately-Held Company

During the quarter ended September 30, 2018, one of the privately-held companies in which we have invested experienced an event triggering an impairment analysis to evaluate the recoverability of our investment. We determined that the current fair value of our investment was lower than its carrying value, resulting in an impairment charge of $12.4 million. As of September 30, 2018, the adjusted carrying value of our investment in this company is $41.1 million. During the three-and nine-month periods ended September 30, 2018, we recorded $12.4 million of impairment charges related to our investments in privately-held companies. During the three-and nine-month periods ended September 30, 2017, we recorded $3.1 million and $49.6 million, respectively, of impairment charges related to our investments in privately-held companies.

Income Tax Expense

The provision for income taxes was $33.6 million for the three months ended September 30, 2018, as compared to $44.4 million for the same period in 2017. The provision for income taxes is based on an estimated annual effective tax rate (ETR) for the entire year. The estimated annual ETR is subject to adjustment in subsequent quarterly periods if components used to calculate the estimated annual ETR are updated or revised. Our actual ETR as of September 30, 2018 and September 30, 2017 was approximately 21 percent and approximately 37 percent, respectively. Our actual ETR for the nine months ended September 30, 2018 decreased as compared to the same period in 2017 due to the impacts of The Tax Cuts and Jobs Act (Tax Reform), the nondeductible portion of an accrual in the second quarter of 2017 in connection with a civil settlement with the Department of Justice, and a decrease in impairment charges not currently meeting the criteria for tax deductibility.

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) impairment of investment in privately-held company; (4) license fees; and (5) tax impact on non-GAAP earnings adjustments.

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

	Three Months Ended September 30,	
	2018	**2017**
Net income, as reported	$ 106.5	$ 276.3
Adjusted for the following charges:		
Share-based compensation expense (benefit)(1)	51.4	(24.0)
Loss contingency(2)	—	0.9
Impairment of investment in privately-held company(2)	12.4	3.1
License fees(1)	20.0	—
Tax benefit(1)(3)	(15.4)	(49.4)
Non-GAAP earnings	$ 174.9	$ 206.9
Non-GAAP earnings per share:		
Basic	$ 4.01	$ 4.77
Diluted	$ 3.98	$ 4.69
Weighted average number of common shares outstanding:		
Basic	43.6	43.4
Diluted	44.0	44.1

(1) We calculated the total tax impact of non-discrete quarterly non-GAAP earnings adjustments based on our estimated annual effective tax rates, before considering discrete items, of approximately 22 percent and approximately 33 percent for the quarters ended September 30, 2018 and September 30, 2017, respectively.

(2) As of September 30, 2018, these non-GAAP earnings adjustments did not meet the criteria for tax deductibility.

(3) The tax benefit for the three months ended September 30, 2017 includes $57.0 million of benefit for the estimated loss contingency recognized during the second quarter of 2017 relating to the DOJ investigation of our support of 501(c)(3) organizations that provide financial assistance to patients.

Conference Call

We will host a half-hour teleconference on Wednesday, October 31, 2018, 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: 4179147.

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 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 the development of our research and development pipeline, including our planned resubmission of the Trevyent NDA. 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 October 31, 2018, 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]

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

	Three Months Ended September 30,	
	2018	2017
	(Unaudited)	
Revenues:		
Net product sales	$ 412.7	$ 445.5
Total revenues	412.7	445.5
Operating expenses:		
Cost of product sales	51.9	19.5
Research and development	101.1	55.0
Selling, general and administrative	110.1	47.2
Total operating expenses	263.1	121.7
Operating income	149.6	323.8
Other income (expense):		
Interest income	7.9	2.2
Interest expense	(4.1)	(3.3)
Other, net	(0.9)	1.1
Impairment of investment in privately-held company	(12.4)	(3.1)
Total other expense, net	(9.5)	(3.1)
Income before income taxes	140.1	320.7
Income tax expense	(33.6)	(44.4)
Net income	$ 106.5	$ 276.3
Net income per common share:		
Basic	$ 2.44	$ 6.37
Diluted	$ 2.42	$ 6.27
Weighted average number of common shares outstanding:		
Basic	43.6	43.4
Diluted	44.0	44.1

SELECTED CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in millions)

	September 30, 2018
Cash, cash equivalents and marketable investments	$ 1,833.5
Total assets	3,412.1
Total liabilities and temporary equity	719.3
Total stockholders' equity	2,692.8

View original content:http://www.prnewswire.com/news-releases/united-therapeutics-corporation-reports-third-quarter-2018-financial-results-300740919.html

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