

# United Therapeutics Announces FDA Acceptance of Second Resubmission of Oral Treprostinil NDA

Written by Australian Business

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SILVER SPRING, Md., Sept. 11, 2013 /PRNewswire/ -- United Therapeutics Corporation (NASDAQ: [UTHR](#)) announced today that the U.S. Food and Drug Administration (FDA) has acknowledged the resubmission of the new drug application (NDA) for treprostinil diolamine extended release tablets (oral treprostinil) for the treatment of pulmonary arterial hypertension. The FDA classified the resubmission as a complete, class 2 response to its

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arch 22, 2013  
complete response letter, and set a user fee goal date of February 16, 2014.

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

**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 regarding the FDA's user fee goal date of February 16, 2014. 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 September 11, 2013, 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]

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