



Liquidia Provides Update on Hatch-Waxman Litigation and to Host Call on September 1, 2022, at 8:00am E.T.

August 31, 2022

- District Court ruling was favorable on '066 patent and unfavorable on '793 patent
- All patent claims asserted have been found to be either invalid or not infringed by District Court or U.S. Patent Trial and Appeal Board (PTAB)
- PTAB decision to invalidate all claims of '793 patent is not affected
- Ability to seek final FDA approval of YUTREPIA™ (treprostinil) inhalation powder is contingent on affirmation of the PTAB decision or reversal of District Court decision regarding the '793 patent

MORRISVILLE, N.C., Aug. 31, 2022 (GLOBE NEWSWIRE) -- Liquidia Corporation (NASDAQ: LQDA) announced today that a ruling was issued by Judge Andrews, who is presiding over the litigation filed by United Therapeutics Corporation (UTC) in the United States District Court for the District of Delaware under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) that alleges Liquidia infringes U.S. Patent No. 9,593,066 ('066 Patent), U.S. Patent No. 10,716,793 ('793 Patent) and U.S. Patent No. 9,604,901 ('901 patent).

The company will host a conference call and webcast on Thursday, September 1 at 8:00 a.m. Eastern Time. The call can be accessed by dialing 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and entering the conference code: 4265646. A webcast of the call will be available on Liquidia's website at <https://liquidia.com/index.php/investors/events-and-presentations>.

Taking today's ruling together with prior PTAB decisions, Liquidia has now demonstrated in at least one forum that all claims asserted against it are invalid or not infringed. Based on the arguments presented at trial, the Court ruled that 5 of 6 asserted claims of the '066 patent are invalid and that the only valid claim is not infringed by Liquidia. Judge Andrews also found Liquidia would induce infringement of the 5 asserted claims in the '793 patent. The Court's decision does not affect the PTAB's prior decision that all claims in the '793 patent are unpatentable. The '901 patent was not addressed in the ruling because UTC previously stipulated that Liquidia does not infringe any of the asserted claims based on the Court's construction of certain terms in the patent.

Roger Jeffs, Chief Executive Officer of Liquidia, said: "We are pleased that all three patents asserted against us have been found to be either invalid or not infringed among the different legal proceedings. While we are disappointed with the Court's decision on the '793 patent, we are optimistic that the PTAB's favorable decision will be affirmed on appeal, thereby unlocking the path to potential approval of YUTREPIA by mid-2024, if not earlier. We will aggressively pursue the appeals process, including an appeal of Judge Andrews' decision, in hope of bringing the final resolution sooner. While this is not the perfect outcome we had hoped for, it is incrementally positive as it does provide us with a definitive path to resolving the patent dispute and making YUTREPIA available as a treatment option for patients, which is our singular focus."

UTC has stated in district court filings that it will appeal the PTAB's decision regarding the '793 patent to the Court of Appeals for the Federal Circuit if the PTAB denies UTC's request for rehearing the IPR. Accordingly, Liquidia's ability to seek final approval for YUTREPIA (treprostinil) inhalation powder will be contingent upon either the affirmation of the PTAB's earlier decision in the *inter partes* review (IPR) regarding the '793 patent or the reversal of Judge Andrews' decision regarding the '793 patent.

About YUTREPIA™ (treprostinil) inhalation powder

YUTREPIA is an investigational, inhaled dry powder formulation of treprostinil delivered through a proven, convenient, palm-sized device. On November 5, 2021, the FDA issued a tentative approval for YUTREPIA, which is indicated for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms. YUTREPIA was designed using Liquidia's PRINT® technology, which enables the development of drug particles that are precise and uniform in size, shape, and composition, and that are engineered for optimal deposition in the lung following oral inhalation. Liquidia has completed INSPIRE, or Investigation of the Safety and Pharmacology of Dry Powder Inhalation of Treprostinil, an open-label, multi-center phase 3 clinical study of YUTREPIA in patients diagnosed with PAH who are naïve to inhaled treprostinil or who are transitioning from Tyvaso® (nebulized treprostinil). YUTREPIA was previously referred to as LIQ861 in investigational studies.

Tyvaso® is a registered trademark of United Therapeutics Corporation.

About Liquidia Corporation

Liquidia Corporation is a biopharmaceutical company focused on the development and commercialization of products in pulmonary hypertension and other applications of its PRINT® Technology. The company operates through its two wholly owned subsidiaries, Liquidia Technologies, Inc. and Liquidia PAH, LLC. Liquidia Technologies has developed YUTREPIA™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH). Liquidia PAH provides the commercialization for

pharmaceutical products to treat pulmonary disease, such as generic Treprostinil Injection. For more information, please visit www.liquidia.com.

Cautionary Statements Regarding Forward-Looking Statements

This press release may include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical facts, including statements regarding our future results of operations and financial position, our strategic and financial initiatives, our business strategy and plans and our objectives for future operations, are forward-looking statements. Such forward-looking statements, including statements regarding clinical trials, clinical studies and other clinical work (including the funding therefor, anticipated patient enrollment, safety data, study data, trial outcomes, timing or associated costs), regulatory applications and related submission contents and timelines, including the potential for final FDA approval of the NDA for YUTREPIA, the timeline or outcome related to appeals or rehearing requests arising from our patent litigation in the U.S. District Court for the District of Delaware or *inter partes* review proceedings conducted at the PTAB, the issuance of patents by the USPTO and our ability to execute on our strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable decisions of the PTAB in the IPRs for the '793 and '901 patents and of the Court in the Hatch-Waxman litigation are not determinative of the outcome of any appeal of those decisions. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the SEC, including the impact of the coronavirus (COVID-19) outbreak on our Company and our financial condition and results of operations, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

Contact Information

Media & Investors:

Jason Adair
Senior Vice President, Corporate Development and Strategy
919.328.4400
jason.adair@liquidia.com

 [Primary Logo](#)

Source: Liquidia Corporation