



Aquestive Therapeutics Reaches Agreement to Extend Principal Payments Due Under Credit Facility to March 30, 2023 and Receives Bridge Waiver of Principal Debt Payment in Advance of Concluding Formal Agreement

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WARREN, N.J., October 6, 2021 -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, announced today that it has reached an agreement with its lenders providing for a bridge waiver of the first principal payment due under its 12.5% Senior Secured Notes (the "Notes") in order to provide sufficient time for the parties to execute a definitive agreement to extend the time when the first principal payment is due under the Notes to March 30, 2023.

Pursuant to the proposed amendment of the Notes, the amortization schedule under the Notes would be amended to provide for the date of the first principal payment to be made on March 30, 2023, while maintaining the current maturity date and interest payment obligations under the Notes (the "Definitive Agreement"). In consideration of this extension, upon the execution of the intended Definitive Agreement, Aquestive will agree to pay to the holders of the Notes an aggregate payment of \$2.7 million payable in four equal quarterly installments beginning on March 30, 2022. The bridge waiver provided by the lenders resulted in the deferral of the first principal payment due under the Notes and expires upon the occurrence of the earlier to occur of the execution of the intended Definitive Agreement and December 31, 2021 or such later date consented to by the holders of the Notes.

Keith Kendall, Chief Executive Officer of Aquestive, stated, "We appreciate and value the continued constructive support received from our lenders, as further evidenced by their prior agreement to extend until June 30, 2022 at the Company's option to access additional debt of \$30 million under the Credit Facility upon FDA approval of our product candidate Libervant™ (diazepam) Buccal Film for U.S. market access. We believe the bridge waiver and proposed amendment terms agreed to by our lenders demonstrate the confidence of our stakeholders in our investment strategy and performance to date. We expect that the Definitive Agreement will be executed in the next few days. This amendment of our Credit Facility, our access to the additional \$30 million of debt under the Credit Facility, strong operating results and appropriate ATM access will continue to provide the capital to meet our immediate needs including the potential launch of Libervant, if approved by the FDA for U.S. market access. We continue to believe that Libervant, our non-invasive and innovative PharmFilm® product candidate for refractory epilepsy, is well positioned to improve the quality of life for patients suffering from this disease with this first of its kind treatment option."

About Libervant

Libervant™ is a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a benzodiazepine intended for rapid treatment of acute uncontrolled seizures in selected, refractory patients with epilepsy on stable regimens of AEDs who require intermittent use of diazepam to control bouts of increased seizure activity. Aquestive is developing Libervant as an alternative to Diastat (diazepam rectal gel), the current standard of care rescue therapy for patients with refractory epilepsy which, as a rectal gel, is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive adequate treatment or foregoes treatment altogether. The Company believes that Libervant will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. The U.S. Food and Drug Administration (FDA) has accepted for filing the resubmission of the New Drug Application (NDA) for Libervant and assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021. Based upon the Agency's guidance, the submission included additional statistical modeling and supporting analyses of the existing clinical data. The Company continues to believe that no additional clinical studies will be required for FDA approval of Libervant for U.S. market access.

About Aquestive Therapeutics

Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan® (clobazam) oral film, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Forward-Looking Statement

This press release includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the impact and importance of the Credit Facility amendment, the potential approval of Libervant™, the impact of and prospects for Libervant and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers’ ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the risk that the Definitive Agreement may not be agreed to, risks associated with the Company’s development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in establishing a PDUFA date for and FDA approval of Libervant or failure to receive approval; ability to address the concerns identified in the FDA’s Complete Response Letter (CRL) for Libervant received by the Company in September 2020; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of our sales and marketing capabilities; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company’s products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company’s products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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