Aquestive Therapeutics Provides End of Year Business Update, Including Progress of its Proprietary CNS Assets, Financial and Legal Matters

December 20, 2018

- Projects full year 2018 revenues over $67 million, exceeding expectations, and projects end-of-year cash and cash equivalents in the range of $58 million to $60 million

- Delivers positive developments across Aquestive's proprietary CNS portfolio, led by the commercial launch of Sympazan™ (clobazam) Oral Film; expected NDA filing for Exservan™ (riluzole) Oral Film in January 2019; plan for rolling submission for Libervant™ (diazepam) Buccal Film to be submitted in January 2019

- Anticipates branded Suboxone® (buprenorphine / naloxone) Film in the U.S. and international, as well as any authorized generic in the U.S., to be a significant revenue contributor to Aquestive through at least 2023

- Hosts investment community conference call at 8:00 a.m. ET on December 20

WARREN, N.J., Dec. 20, 2018 /PRNewswire/ -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company pharmaceutical company focused on identifying, developing, and commercializing differentiated products to solve therapeutic problems, is reporting positive developments across its business.

Sympazan ™ Launch Propels Aquestive's First Proprietary Franchise

In November 2018, the company received approval from the U.S. Food and Drug Administration (FDA) for its first proprietary commercial product, Sympazan ™, for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older. Key pharmacokinetic (PK) data has been published in *Epilepsia* and presented at the American Epilepsy Society 2018 Annual Meeting in early December.

With the product now in channel, sales and marketing plans are being executed to activate customer demand and new prescriptions. Aquestive's commercial team of 50+ experienced professionals have already completed thousands of interactions with local healthcare providers, payers that cover approximately 280 million lives, and pharmacists in markets nationwide. The company has also scheduled more than 40 speaker programs through February 2019. Important information for physicians is available at https://sympazanhcp.com, where healthcare professionals can access educational resources, request PharmFilm® samples, and download copay cards that can assist LGS families.

"The first scripts have been written and filled. We are very encouraged by the reception of Sympazan in the market and feel that our engagements with customers are positioning us well for the future launch of Libervant ™, when approved," said Ken Marshall, Chief Commercial Officer of Aquestive Therapeutics. "We look forward to building on our momentum in 2019."

Regulatory Filings Are Advancing for Libervant ™ and Exservan ™ in 2019

Aquestive is developing diazepam buccal film (DBF or Libervant ™) for the treatment of seizure clusters in patients with refractory epilepsy. The company recently held a pre-NDA (New Drug Application) meeting with the FDA to review data and pharmacokinetic models generated thus far from multiple clinical studies. Based on the FDA's feedback, the company is planning to complete a single-dose, crossover study in a small number of epilepsy patients comparing DBF and Diastat dosing and, in parallel, advance plans for filing an NDA in 2019.

"We are pleased with the feedback given by the FDA. We'll develop the additional data as quickly as possible, and we have a clear path to submission and approval," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "Patients suffering from seizure clusters have been waiting a long time for an alternative to the current treatments available, and we are excited to bring these patients a medication that is fast-acting and easy to administer. Based on our data, we believe Libervant has the potential to significantly improve patient outcomes."

Libervant is a novel formulation of diazepam as a small, thin film strip for placement inside the cheek. Libervant leverages Aquestive's proprietary PharmFilm® technology and is in development for the management of select patients with refractory epilepsy who require intermittent use of diazepam to control episodes of increased seizure activity or seizure clusters. Currently, the only product with FDA-approval for treatment is Diastat, a rectally-applied gel.

Aquestive is also planning to submit an NDA in January 2019 for riluzole oral film (ROF or Exservan ™). The company recently completed a swallowing safety study after receiving the FDA's permission to shorten the study. The primary objective of the study was to evaluate the effect, if any, of

investigational ROF on swallowing safety in subjects with amyotrophic lateral sclerosis (ALS). The study successfully met its primary endpoint and showed that Exservan has no adverse effect on swallowing safety in subjects with ALS.

Legal Proceedings and New Drivers of Suboxone® Film Business

Aquestive and Indivior PLC (LON: INDV) are filing a petition with the U.S. Court of Appeals for the Federal Circuit (CAFC) for a rehearing by the original panel of judges, as well as a rehearing *en banc*, on the CAFC's ruling to vacate the preliminary injunction (PI) granted by the U.S. District Court of New Jersey to enjoin Dr. Reddy's Laboratories ("DRL") from launching its generic buprenorphine/naloxone sublingual film product, which utilizes Aquestive's PharmFilm® technology. The PI will remain in place to enjoin DRL's "at-risk" entry into the U.S. market, until the CAFC rules on the joint petition. This decision will have no impact on the core Aquestive patent portfolio.

"We will continue to work with Indivior to assert and protect our intellectual property embedded in SUBOXONE® Sublingual Film against at-risk generic entrants," said Mr. Kendall. "This will continue to be a significant source of revenue for Aquestive for the foreseeable future."

Aquestive's Suboxone revenues are driven by order volume from both branded and authorized generic products. Aquestive has a sole and exclusive worldwide manufacturing agreement with Indivior for both branded and authorized generic Suboxone and will continue to fulfill non-U.S. orders, which also continue to grow as a percent of total Suboxone business.

Early Asset Pipeline Progressing

Several proprietary assets in early stages of development show promise for clinical advancement in 2019. Aquestive is continuing to optimize the formulations and advance proof-of-concept studies for AQST-108 (epinephrine) and AQST-305 (octreotide). Interactions with U.S. and ex-U.S. regulatory authorities and potential study investigators have provided valuable input into plans for clinical development. Additional clinical trials for both products will take place in 2019.

Solid Cash Position and Access to Non-Dilutive Capital Sources

Aquestive expects full-year 2018 revenues to be more than $67 million and expects to end 2018 with cash and cash equivalents in the range of $58 million to $60 million. The company plans to provide full year 2019 guidance in conjunction with the year-end conference call in March 2019.

"With the cash we have on-hand, along with cash generated by our ongoing business, and additional options to monetize non-strategic, partnered product royalty streams, we have the resources we need to fulfill our business plans," said Mr. Kendall.

Investment Community Conference Call

The company will host an investment community conference call at 8:00 a.m. ET on Thursday, December 20, 2018. Investors and analysts may participate in the conference call by dialing (866) 417-5886 from the U.S. and (409) 217-8235 internationally, followed by the conference ID: 3376049. There will also be a simultaneous, live webcast available on the Investors section of the company's website at https://investors.aquestive.com/events-and-presentations. The webcast will be archived for 30 days.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company committed to identifying, developing and commercializing differentiated products to address unmet medical needs. Aquestive Therapeutics has a late-stage proprietary product pipeline focused on the treatment of CNS diseases, and is working to advance orally-administered complex molecules that it believes can be alternatives to invasively-administered standard of care therapies. As the leader in developing and delivering drugs via its PharmFilm® technology, Aquestive Therapeutics also collaborates with pharmaceutical partners to bring new molecules to market in differentiated and highly-marketable dosage forms.

SYMPAZAN IMPORTANT SAFETY INFORMATION
BOXED WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS
SYMPAZAN is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.

WARNINGS AND PRECAUTIONS
Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants SYMPAZAN has a CNS depressant effect. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol as the effects of other CNS depressants or alcohol may be potentiated.

Somnolence or Sedation
SYMPAZAN causes dose-related somnolence and sedation, which generally begins within the first month of treatment and may diminish with continued treatment. Monitor patients for somnolence and sedation, particularly with concomitant use of other CNS depressants. Caution patients against engaging in hazardous activities requiring mental alertness, i.e., operating dangerous machinery or motor vehicles, until the effect of SYMPAZAN is known.

Withdrawal Symptoms
Abrupt discontinuation of SYMPAZAN should be avoided. The risk of withdrawal symptoms is greater with higher doses. Withdraw SYMPAZAN gradually to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus.

Serious Dermatological Reactions

Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam in both children and adults. Discontinue SYMPAZAN at the first sign of rash, unless the rash is clearly not drug-related.

Physical and Psychological Dependence
Patients with a history of substance abuse should be under careful surveillance when receiving SYMPAZAN.

Suicidal Behavior and Ideation
AEDs, including SYMPAZAN, increase the risk of suicidal thoughts or behavior in patients. Patients treated with SYMPAZAN should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Inform patients, their caregivers, and families of the increased risk of suicidal thoughts and behaviors. Advise them to be alert for and report immediately to healthcare providers any emergence or worsening signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm.

ADVERSE REACTIONS
Adverse reactions (≥10% and more frequently than placebo) included constipation, somnolence or sedation, pyrexia, lethargy, and drooling.

DRUG INTERACTIONS
The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. Limit dosage and duration of concomitant use of benzodiazepines and opioids and follow patients closely for respiratory depression and sedation. Concomitant use of SYMPAZAN with other CNS depressants, including alcohol, may increase the risk of sedation and somnolence. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol, as effects of other CNS depressants or alcohol may be potentiated.

Hormonal contraceptives that are metabolized by CYP3A4; effectiveness may be diminished when given with SYMPAZAN. Additional non-hormonal forms of contraception are recommended when using SYMPAZAN. Dose adjustment may be necessary of drugs metabolized by CYP2D6 and of SYMPAZAN when co-administered with strong CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, ticlopidine).

USE IN SPECIFIC POPULATIONS
Pregnancy and Lactation: SYMPAZAN may cause fetal harm and should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have taken benzodiazepines during the later stages of pregnancy can develop dependence, withdrawal syndrome and symptoms suggestive of floppy infant syndrome. SYMPAZAN is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from SYMPAZAN, discontinue nursing or discontinue the drug. Encourage patients to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit http://www.aedpregnancyregistry.org/.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click here to see full Prescribing Information, including Boxed Warning.

Forward-Looking Statement
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "project," "will," "would," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. Such statements include, but are not limited to, statements about regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, and other statements that are not historical facts.

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, 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; the risks of delays in FDA approval of our drug candidates or failure to receive approval; the risks inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); development of our sales and marketing capabilities; the rate and degree of market acceptance of our product candidates; the success of any competing products; the size and growth of our product markets; the effectiveness and safety of our product candidates; risks associated with intellectual property rights and infringement; unexpected patent developments; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Registration Statement on Form S-1 declared effective by the SEC on July 24, 2018. As with any pharmaceutical product candidate under development, there are significant risks with respect to the development, regulatory approval and commercialization of new products. Given these 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. We assume no obligation to update our forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required under applicable law.

Media inquiries:
Christopher Hippolyte
christopher.hippolyte@syneoshealth.com
212-364-0458

Investor inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282

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