Aquestive Therapeutics Exceeds Top End of Guidance Range for Preliminary Unaudited Full Year 2019 Total Revenues and Provides Initial Full Year 2020 Guidance

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- Anticipates full year 2019 preliminary unaudited total revenues to be approximately $52 million, exceeding previously provided full year revenue guidance
- Anticipates fourth quarter 2019 preliminary unaudited total revenues to be approximately $16 million
- Expects preliminary unaudited cash and cash equivalents as of December 31, 2019 of approximately $49 million
- Provides initial full year 2020 anticipated financial guidance

WARREN, N.J., Jan. 10, 2020 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on developing and commercializing differentiated products that meet patients' unmet needs and solve therapeutic problems, today reported anticipated preliminary unaudited total revenues for the fourth quarter and full year ended December 31, 2019 and provided initial full year 2020 guidance.

"In addition to exceeding the top end of our revenue guidance, we achieved significant milestones, as promised, in 2019. First, we completed our rolling submission of the New Drug Application (NDA) for our therapeutic candidate Libervant™ (diazepam) Buccal Film for the management of seizure clusters to the U.S. Food and Drug Administration (FDA) in November 2019. Next, we successfully completed a number of early stage clinical trials regarding AQST-108 (epinephrine), advancing toward our February 2020 Pre-IND meeting with the FDA to clarify the clinical and regulatory path forward. These milestones establish a path forward in 2020 to advance our pipeline and commercial opportunities," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Sympazan® continued to extend its reach in the prescribing community that will ultimately be vital to the successful launch of Libervant, subject to approval by the FDA. We entered 2020 with a strong cash position of approximately $49 million and, with the announcement by Sunovion of a May 2020 PDUFA date for APL-130277, we believe that we have a clear timetable to work toward securing substantial additional non-dilutive capital in mid-2020. We anticipate current capital and revenues from monetization of our rights in APL-130277, subject to approval by the FDA, to fully support our commercial activities, the expected launch of Libervant, the continued development of AQST-108 and the identification, investigation and development of additional product candidates."

Preliminary Unaudited 2019 Total Revenues and Cash Position

Preliminary unaudited total revenues are anticipated to be approximately $16 million for the fourth quarter 2019 and approximately $52 million for the full year ended December 31, 2019. 2019 total revenue performance was driven by the continued strength throughout the year, prior to Indivior's announcement of the discontinuance of its authorized generic product, of Suboxone® and Indivior's authorized generic product. Additionally, our first proprietary epilepsy product, Sympazan, grew steadily from launch, and we recognized co-development and license fees and royalty revenues in the period on license activity.

Preliminary unaudited cash and cash equivalents as of December 31, 2019 were approximately $49 million. In December 2019, the Company completed a public offering of 8,050,000 shares of common stock for gross proceeds of $40.3 million and net proceeds of $37.5 million.

Initial Full Year 2020 Financial Guidance

Aquestive is providing initial full year 2020 financial guidance as follows based upon the assumptions outlined below:

- Total revenues of approximately $35 million to $45 million
  - Supply of branded Suboxone at similar volumes to fourth quarter 2019, representing a market share of approximately 48%, and implemented product price adjustments, but no further meaningful volumes from the discontinued Sandoz authorized generic product
  - Expected revenues from Sympazan net sales, co-development programs, and license fees and royalties from licensed products
  - Excludes any net revenues from Libervant as there can be no guaranty of approval or commercialization
- Non-GAAP adjusted gross margins of approximately 70% to 75% on total revenues
  - Reflective of the anticipated higher profitability of Suboxone manufacturing revenues and expected greater mix of higher margin proprietary revenue
- Non-GAAP adjusted EBITDA loss of approximately $65 million to $70 million
  - Reflective of anticipated more profitable revenue and significant cost rationalization in the company's plant and other legacy aspects of the business, offset by expected substantially higher investments in R&D driven by AQST-108 and preparation for the anticipated launch of Libervant
- Cash burn of approximately $65 million to $70 million after considering interest, capital spending and working capital effects, but prior to any additional capital transactions.

Aquestive expects to report fourth quarter and full year 2019 audited results on Thursday, March 12, 2020.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. Aquestive is advancing a late-stage proprietary product pipeline to treat CNS conditions and 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.

Non-GAAP Outlook
In providing outlook for non-GAAP adjusted gross margins and non-GAAP adjusted EBITDA, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. We are providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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 may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of Libervant and our other product candidates; ability to obtain FDA approval and advance Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, 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, business strategies, market opportunities, 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 and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as the orphan drug product for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks our product in the U.S. for seven years for the same indication, including the possible earlier approval of the product candidate, Valtoco® (diazepam intranasal solution) with respect to our product candidate Libervant (diazepam buccal film); 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 legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; 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; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks associated with Indivior's announcement of its intention to cease production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk 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 action 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 governmental 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 risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. 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. 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.

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 the Boxed Warning.

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