



Aquestive Therapeutics Reports First Quarter 2019 Financial Results and Recent Business Highlights

05.08.19 at 7:00 AM EDT

- U.S. launch of Sympazan® (clobazam) Oral Film progressing to plan
- Rolling NDA submission for Libervant™ (diazepam) Buccal Film expected to start in second quarter 2019
- Phase 1 Proof of Concept study initiated for an optimized formulation of epinephrine sublingual film (AQST-108)
- Reported first quarter 2019 revenues of \$12.6 million driven mostly by licensed products, as well as co-development fees, and first full quarter of Sympazan net sales
- Hosts investment community conference call at 8:00 a.m. ET on May 8, 2019

WARREN, N.J., May 8, 2019 /PRNewswire/ -- 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 financial results for the first quarter ended March 31, 2019 and provided an update on recent developments in its business.



"We started the year focused on the commercial, regulatory and development milestones that we believe will catalyze our growth and bring value to shareholders. We are progressing as planned across our key initiatives, including the launch of Sympazan®, the initiation and execution of a crossover study for Libervant™, agreeing with the FDA to move forward with the NDA filing process for that asset, as well as the initiation of the Phase 1 Proof of Concept study for AQST-108," said Keith J. Kendall, Chief Executive Officer of Aquestive.

Proprietary Pipeline Overview and Business Update

Aquestive is working to build a portfolio of differentiated medicines that can offer physicians and patients, who have difficulty using currently available treatment options, improved clinical and usability features based on the Company's PharmFilm® technology. The Company's late stage proprietary products are initially focused on CNS conditions, and other patient populations with high unmet need.

- **The launch of Sympazan® (clobazam) Oral Film for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years and older is progressing to plan.** The Company has seen steady increases in the number of new prescriptions and number of physicians writing Sympazan prescriptions for patients in their practice, month to month. The Company recently reached an agreement with a national Pharmacy Benefits Manager (PBM) on coverage of Sympazan across its commercial book of business, and has several more agreements in the final stages of legal review. The Company is on target to secure access for 70% of commercial lives by year end 2019. The Company has also made substantial progress toward securing coverage within Medicaid – a significant payer in the LGS category - with the top 5 Medicaid States currently providing reimbursement for Sympazan.
- **Aquestive expects to commence a rolling NDA submission for Libervant™ (diazepam) Buccal Film in the second quarter 2019.** Enrollment in the single dose crossover study has progressed and is on pace to be completed in the third quarter 2019. The Company continues to target filing the Adult New Drug Application (NDA) for Libervant in the second half of this year. Libervant has the potential to be the first oral therapy approved by the U.S. Food and Drug Administration (FDA) for the management of seizure clusters in refractory epilepsy patients.
- **Aquestive announced that the FDA has accepted its NDA for Exservan™ (riluzole) Oral Film.** Exservan is intended to be used for the treatment of amyotrophic lateral sclerosis (ALS). The PDUFA (Prescription Drug User Fee Act) goal date is November 30, 2019. The Company is also exploring regulatory and commercial opportunities for Exservan outside the U.S.
- **The Company is developing AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis and severe allergic reactions.** A Phase I Proof of Concept study to evaluate an optimized product formulation is underway, with data expected in the third quarter 2019.
- **Suboxone and the authorized generic buprenorphine-naloxone film continue to retain significant market share, despite the at risk launches of several generic products in the first quarter 2019.** Aquestive has a strong order book through the first 7 months of 2019, based on the slow erosion of brand market share, strong uptake of the authorized generic, trusted product quality, and the continued double-digit, year-over-year growth in the U.S. addiction recovery

market.

Leadership Team Updates

Aquestive is also announcing some recent changes among its leadership team, which are designed to support the organization through its next period of growth and pipeline advances. Daniel Barber has been appointed to the new role of Senior Vice President, Chief Operating Officer (COO) of the Company. Mr. Barber's expanded responsibilities will include end-to-end product operations, inclusive of corporate strategy, product development, manufacturing, quality and supply. Peter Boyd has assumed the new role of Senior Vice President, Business Process and Information Technology. In this role, Mr. Boyd will focus on optimizing key processes and strengthening the Company's data analytics and information technology capabilities. Finally, Cassie Jung has been promoted to the role of Vice President, Operations. Ms. Jung will oversee the Company's manufacturing operations and teams in Portage, Indiana.

First Quarter 2019 Financial Results

Total revenues were \$12.6 million in the first quarter 2019, compared to \$23.4 million reported for the first quarter 2018. This year-over-year decrease reflected a decline in license fees and manufacturing revenue in the quarter, mostly due to the suspension of license fees related to Suboxone that are pending the outcome of patent litigation against the generics which launched in the market at risk and to shifts in the timing of production of Suboxone brand and Sandoz authorized generic products. The Company expects to fill orders for the balance of the year that will bring future results in line with our guidance.

Aquestive's net loss for the first quarter 2019 was \$14.7 million, or \$0.59 loss per share. The net income for the first quarter 2018 was \$4.1 million. The year-over-year increase in net loss in the first quarter 2019 was driven primarily by lower revenue in the first quarter 2019, as well as higher investments in commercialization expenses from the launch of Sympazan commencing in December 2018, continued investments in clinical studies for Libervant and AQST-108, and higher costs associated with becoming a public company.

2019 Outlook

Aquestive is reaffirming its full year guidance and financial outlook for 2019. The Company expects:

- Total revenues of \$33 million to \$45 million, including Suboxone and Sandoz authorized generic manufacturing revenue of \$23 million to \$30 million;
- Non-GAAP gross margins of 70% to 72% on total revenues;
- Non-GAAP Adjusted EBITDA loss of \$40 million to \$45 million; and
- Cash burn of approximately \$45 million to \$50 million after considering interest, capital spending and working capital effects, but prior to any non-dilutive capital transactions.

Today's Conference Call and Webcast Reminder

The management team will host an investment community conference call today, May 8, 2019, at 8:00 a.m. ET. 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: 2041119.

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 recorded webcast will be available on that same link approximately two hours after the completion of the call and will be archived for 30 days.

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 Financial Information

This press release and our webcast earnings call regarding our first quarter 2019 financial results contains financial measures that do not comply with U.S. generally accepted accounting principles (GAAP), such as Adjusted EBITDA, non-GAAP gross margins, non-GAAP costs and expenses, and non-GAAP net income (loss), because such measures exclude, as applicable, share-based compensation, interest expense, interest income, depreciation, amortization, and income taxes.

Specifically, the Company adjusts net income (loss) for one-time IPO related expenditures; change in fair value of warrants; for recurring non-cash expenditures, including share compensation expenses – post-IPO; depreciation and amortization; and for interest expense, interest income and income taxes, with a result of Adjusted EBITDA. Similarly, manufacturing and supply expense, research and development expense, and selling, general and administrative expense were adjusted for the recurring non-cash expenditures of share compensation expenses – post-IPO and depreciation and amortization. Adjusted EBITDA and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight

regarding the Company's ongoing operating performance.

These measures supplement the Company's financial results prepared in accordance with GAAP. Aquestive management uses these measures to analyze its financial results, its future manufacturing and supply expenses, gross margins, research and development expense and selling, general and administrative expense and to help make managerial decisions. In management's opinion, these non-GAAP measures provide added transparency into the operating performance of Aquestive and added insight into the effectiveness of our operating strategies and actions. We may provide one or more revenue measures adjusted for certain discrete items, such as fees collected on certain licensed products, in order to provide investors added insight into our revenue stream and breakdown, along with providing our GAAP revenue. Such measures are intended to supplement, not act as substitutes for, comparable GAAP measures and should not be read as a measure of liquidity for Aquestive. Adjusted EBITDA and the other non-GAAP measures are also likely calculated in a way that is not comparable to similarly titled measures reported by other companies.

Non-GAAP Outlook

In providing outlook for non-GAAP adjusted EBITDA and non-GAAP gross margin, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. A description of the adjustments which have been applicable in determining Adjusted EBITDA are reflected in the table below. In providing outlook for non-GAAP gross margin, we adjust for non-cash share-based compensation and depreciation and amortization. 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 contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "believe," "could," "estimate," "expect," "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, product orders and fulfillment, 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; issues related to the outsourcing of certain operational and staff functions to third parties; the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; the size and growth of our product markets; the effectiveness and safety of our products and product candidates; risks associated with intellectual property rights and infringement, including the outcome of any patent infringement litigation relating to the Company's products; 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 concerns that may arise regarding the safety or efficacy of the Company's products and product candidates; risks related to legal proceedings, including ongoing patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; the impact 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 included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019, as updated in our subsequent quarterly report 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 guidance in SEC filings 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.

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

Potiation 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 ($\geq 10\%$ 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.

Media inquiries:

Christopher Hippolyte

christopher.hippolyte@syneoshealth.com

212-364-0458

Investor inquiries:

Stephanie Carrington

stephanie.carrington@icrinc.com

646-277-1282

AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive (Loss)/Income
(In thousands, except share and per share data amounts)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---------------------------------|------------|
| | 2019 | 2018 |
| Revenues | \$ 12,643 | \$ 23,411 |
| Costs and Expenses: | | |
| Manufacture and supply | 3,506 | 5,636 |
| Research and development | 4,303 | 4,901 |
| Selling, general and administrative | 17,908 | 7,569 |
| Total costs and expenses | 25,717 | 18,106 |
| (Loss)/income from operations | (13,074) | 5,305 |
| Other income/(expenses): | | |
| Interest expense | (1,926) | (1,927) |
| Interest income | 274 | 24 |
| Change in fair value of warrant | - | 697 |
| Net (loss)/income before income taxes | (14,726) | 4,099 |
| Income taxes | - | - |
| Net (loss)/income | (14,726) | 4,099 |
| Comprehensive (loss)/income | \$ (14,726) | \$ 4,099 |
| Net (loss)/income per share - basic and diluted | \$ (0.59) | 0.27 |
| Weighted-average number of common shares outstanding - basic and diluted | 24,963,603 | 15,077,647 |

AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except for share and per share amounts)
(Unaudited)

| | March 31, 2019 | December 31, 2018 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 39,934 | \$ 60,599 |
| Accounts receivable, net | 7,489 | 6,481 |
| Inventories, net | 5,137 | 5,441 |
| Prepaid expenses and other current assets | 3,398 | 1,680 |
| Total current assets | 55,958 | 74,201 |
| Property and equipment, net | 11,594 | 12,207 |
| Intangible assets, net | 191 | 204 |
| Other assets | 236 | 239 |
| Total assets | \$ 67,979 | \$ 86,851 |
| Liabilities and shareholders' (deficit)/equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 22,088 | \$ 27,631 |
| Deferred revenue, current | 700 | 721 |
| Loans payable, current | 6,850 | 4,600 |
| Total current liabilities | 29,638 | 32,952 |
| Loans payable, net | 40,742 | 42,603 |
| Deferred revenue, net of current portion | 2,405 | - |
| Asset retirement obligations | 1,250 | 1,216 |
| Total liabilities | 74,035 | 76,771 |
| Commitments and contingencies | | |
| Shareholders' (deficit)/equity: | | |
| Common stock, \$.001 par value. Authorized 250,000,000 shares; 24,975,139 and 24,957,309 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively | 25 | 25 |
| Additional paid-in capital | 72,873 | 71,431 |

| | | |
|--|------------------|------------------|
| Accumulated deficit | (78,954) | (61,376) |
| Total shareholders' (deficit)/equity | (6,056) | 10,080 |
| Total liabilities and shareholders' (deficit)/equity | <u>\$ 67,979</u> | <u>\$ 86,851</u> |

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - Net (Loss)/Income to Adjusted EBITDA
(In Thousands)
(Unaudited)

| | Three Months Ended | |
|----------------------------------|--------------------|-----------------|
| | March 31, | |
| | 2019 | 2018 |
| GAAP net (loss)/income | \$ (14,726) | \$ 4,099 |
| Non-GAAP adjustments: | | |
| Share-based Compensation Expense | 1,520 | - |
| Depreciation and Amortization | 749 | 953 |
| Interest Expense, net | 1,926 | 1,927 |
| Interest income | (274) | (24) |
| Change in fair value of warrant | - | (697) |
| Income Taxes | - | - |
| Total non-GAAP adjustments | <u>3,921</u> | <u>2,159</u> |
| Adjusted EBITDA | <u>\$ (10,805)</u> | <u>\$ 6,258</u> |

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Expenses to Adjusted Expenses
(In Thousands)
(Unaudited)

| | Three Months Ended | |
|----------------------------------|--------------------|------------------|
| | March 31, | |
| | 2019 | 2018 |
| Total costs and expenses | \$ 25,717 | \$ 18,106 |
| Non-GAAP adjustments: | | |
| Share-based compensation expense | (1,520) | - |
| Depreciation and amortization | (749) | (953) |
| Adjusted costs and expenses | <u>\$ 23,448</u> | <u>\$ 17,153</u> |

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Manufacture & Supply Expense to Adjusted Manufacture and Supply Expense
(In Thousands, except percentages)
(Unaudited)

| | Three Months Ended | |
|---|--------------------|-----------------|
| | March 31, | |
| | 2019 | 2018 |
| Manufacture and Supply Expense | \$ 3,506 | \$ 5,636 |
| <i>Gross Margin on total revenue</i> | 72% | 76% |
| Non-GAAP adjustments: | | |
| Share-based compensation expense | (44) | - |
| Depreciation and amortization | (606) | (772) |
| Adjusted manufacture and supply expense | <u>\$ 2,856</u> | <u>\$ 4,864</u> |
| <i>Non-GAAP Gross Margin on total revenue</i> | <u>77%</u> | <u>79%</u> |

AQUESTIVE THERAPEUTICS, INC.

Reconciliation of Non-GAAP Adjustments - GAAP Research and Development Expense to Adjusted Research and Development Expense
(In Thousands)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---------------------------------|-----------------|
| | 2019 | 2018 |
| Research and Development Expense | \$ 4,303 | \$ 4,901 |
| Non-GAAP adjustments: | | |
| Share-based compensation expense | (208) | - |
| Depreciation and amortization | (62) | (78) |
| Adjusted research and development expense | <u>\$ 4,033</u> | <u>\$ 4,823</u> |

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - GAAP Selling, General and Administrative Expenses to Adjusted Selling, General and Administrative Expenses
(In Thousands)
(Unaudited)

| | Three Months Ended March 31, | |
|---|---------------------------------|-----------------|
| | 2019 | 2018 |
| Selling, General and Administrative Expenses | \$ 17,908 | \$ 7,569 |
| Non-GAAP adjustments: | | |
| Share-based compensation expense | (1,268) | - |
| Depreciation and amortization | (81) | (103) |
| Adjusted selling, general and administrative expenses | <u>\$ 16,559</u> | <u>\$ 7,466</u> |

View original content to download multimedia: <http://www.prnewswire.com/news-releases/aquestive-therapeutics-reports-first-quarter-2019-financial-results-and-recent-business-highlights-300845889.html>

SOURCE Aquestive Therapeutics, Inc.