

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 5, 2025

**Aquestive Therapeutics, Inc.**  
(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation)

001-38599  
(Commission File Number)

82-3827296  
(I.R.S. Employer Identification No.)

30 Technology Drive  
Warren, NJ 07059  
(908) 941-1900  
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AQST	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On November 5, 2025, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the third quarter ended September 30, 2025 and provided an update on recent developments in its business. A copy of the Company's press release and the attached financial schedules are attached as Exhibit 99.1 to this Current Report On Form 8-K and incorporated in this Item 2.02 by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 7.01 Regulation FD Disclosure.**

The Company is furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of an investor presentation, to be given at meetings with institutional investors, analysts and others. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later Company filing or other means. A copy of the Company's investor presentation is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Events and Presentations page in the Investors section of the Company's website located at [www.aquestive.com](http://www.aquestive.com), although the Company reserves the right to discontinue that availability at any time.

The information in this Item 7.01 (including Exhibit 99.2) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit Number	Description
<a href="#">99.1</a>	Press Release, dated November 5, 2025, announcing the Company's reported financial results for the third quarter ended September 30, 2025 and providing an update on recent developments in its business.
<a href="#">99.2</a>	Aquestive Therapeutics, Inc. Q3 Earnings Supplemental Materials dated November 5, 2025.

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: **November 5, 2025**

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr  
Name: A. Ernest Toth, Jr.  
Title: Chief Financial Officer



**Aquestive Therapeutics Reports Third Quarter 2025 Financial Results  
and Provides Business Update**

- *Planned U.S. launch of Anaphylm™ in the first quarter of 2026, if approved by the FDA*
- *Advanced Anaphylm regulatory activities in Canada and the EU*
- *Added clinical leadership to drive long-term success*
- *Strengthened balance sheet to support planned commercial launch execution of Anaphylm*
- *Company to host investor call on November 6, 2025, at 8:00am ET*

Warren, N.J., November 5, 2025 – Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today announced financial results for the third quarter ended September 30, 2025 and provided a strategic business update.

"The third quarter was another period of strong execution for Aquestive as we move closer to the launch of Anaphylm, if approved by the FDA," said Daniel Barber, Chief Executive Officer of Aquestive. "The FDA's decision not to convene an Advisory Committee further advances our regulatory path, and our NDA remains on track for the scheduled January 31, 2026 PDUFA goal date. We are fully engaged in U.S. launch preparations, continuing to build commercial readiness across distribution, medical affairs, and marketing channels, while also advancing regulatory discussions in Canada and the EU. Following our recently completed equity financing and strategic funding commitments, we believe we are well positioned to deliver on our mission to make epinephrine emergency treatment more accessible, portable, and patient-friendly. Finally, we remain committed to developing additional products from our AdrenaVerse™ epinephrine prodrug platform."

**Anaphylm™ (dibutepinephrine) Sublingual Film**

If approved by the United States Food and Drug Administration (FDA), Anaphylm would be the first and only oral medication for the rescue treatment of severe allergic reactions, including anaphylaxis. Aquestive believes that Anaphylm's needle-free, portable, and easy-to-administer formulation can help overcome barriers to epinephrine use and improve patient compliance in emergency situations.

During the third quarter 2025, the FDA confirmed that it will not require an Advisory Committee meeting to review the Company's New Drug Application (NDA) for Anaphylm. The NDA continues to progress toward its scheduled January 31, 2026 PDUFA goal date. Aquestive has responded to all information requests received to date and remains in active communication with the FDA. Following the mid-cycle review, the FDA inspected clinical sites in the adult pivotal studies and no major findings resulted from these inspections. It is possible that further inspections could be necessary for the FDA approval of Anaphylm.

Preparations continue for a potential U.S. launch of Anaphylm in the first quarter of 2026, if approved by the FDA. The Company continues to expand its commercial and medical infrastructure, meet key manufacturing readiness milestones, and advance strategic distribution and market access initiatives to enable a timely and effective launch. Concurrent with the Company's U.S. pre-launch activities, Aquestive continues to advance its global expansion strategy, initiating regulatory engagement in Canada and preparatory efforts in the EU. These markets represent important opportunities to expand access to the Company's non-invasive epinephrine therapy globally.

In October 2025, Aquestive broadened its patent estate for Anaphylm with the issuance of two new patents extending protection into 2037. The Company's expanding portfolio underscores the innovation behind its proprietary PharmFilm® technology and reinforces Anaphylm's long-term commercial potential.

### **AQST-108 (epinephrine) Topical Gel**

Aquestive continues to advance its product candidate AQST-108, a topical epinephrine gel in development for the treatment of alopecia areata (AA). The Company remains on track to submit an Investigational New Drug (IND) application to the FDA in the fourth quarter of 2025, with a clinical study expected to begin in the first half of 2026. AQST-108 is designed to provide a targeted, non-systemic therapeutic option for AA, which affects approximately 6.7 million people in the U.S. Existing therapies such as Janus kinase (JAK) inhibitors are systemic, costly, and carry black box warnings. By contrast, a topical, locally acting epinephrine gel could address a significant unmet need and capture meaningful market share in this growing segment.

Aquestive recently announced the addition of new leadership over its AdrenaVerse™ clinical pipeline activities and reiterated its commitment to developing additional products from this technology platform.

### **Commercial Collaborations and Other Programs**

Aquestive continues to manufacture Indivior's Suboxone® Sublingual Film product and the Company's other global collaborations, including Sympazan® (clobazam) Oral Film product for Asserpio Holdings, Inc. in the U.S., and Ondif® (Ondansetron) Oral Film product for Hypera Pharma in Brazil. Aquestive's manufacturing business remains steady, with the gradual decline of Suboxone being offset by growth across newer collaborations. The Company, being a U.S. based manufacturer with intellectual property domiciled in the U.S., confirms that its supply chain currently remains largely unaffected by both implemented and proposed government tariffs, providing continued reliability and stability in production and global distribution for the near term.

Sales of royalty-based products, inclusive of Sympazan® (clobazam) Oral Film for the treatment of seizures associated with Lennox-Gastaut Syndrome in patients two years of age and older, and Azstarys® (serdexmethylphenidate and dexmethylphenidate) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age and older, continued to contribute to the Company's revenue in the third quarter of 2025.

Libervant® (diazepam) Buccal Film remains tentatively approved until January 11, 2027, the scheduled date of expiration of U.S. market orphan drug exclusivity of an FDA approved product of another company. Aquestive continues to believe that expanding patient access to non-invasive seizure rescue therapies is vital and remains committed to putting Libervant in the hands of patients when granted full approval for U.S. market access by the FDA.

### **Third Quarter 2025 Financials**

Excluding the impact of one-time recognition of deferred revenue in the third quarter of 2024, total revenues increased by \$0.5 million, or 4% year over year to \$12.8 million in the third quarter 2025. As a reminder, the one-time recognition of deferred revenue in the prior year was due to the termination of a licensing and supply agreement. Including the deferred revenue recognized in the prior year, total revenues decreased to \$12.8 million in the third quarter 2025 from \$13.5 million in the third quarter 2024.

Manufacture and supply revenue increased to \$11.5 million in the third quarter 2025 from \$10.7 million in the third quarter 2024, primarily due to increases in Sympazan and Suboxone revenues.

Research and development expenses decreased to \$4.5 million in the third quarter 2025 from \$5.3 million in the third quarter 2024. The decrease in research and development expenses was primarily due to lower clinical trial costs associated with the continued advancement of the Anaphylm development program, partially offset by increases in share-based compensation.

Selling, general and administrative expenses increased to \$15.3 million in the third quarter 2025 from \$12.1 million in the third quarter 2024. The increase primarily represents higher commercial spending of approximately \$1.8 million, higher legal fees of approximately \$1.0 million, higher regulatory expenses related to Anaphylm of approximately \$0.6 million, higher personnel costs of approximately \$0.2 million, and higher share-based compensation expenses of approximately \$0.2 million, partially offset by lower regulatory and licensing fees of \$0.5 million, and lower consulting fees of approximately \$0.2 million.

Aquestive's net loss for the third quarter 2025 was \$15.4 million, or \$0.14 for both basic and diluted loss per share, compared to the net loss in the third quarter 2024 of \$11.5 million, or \$0.13 for both basic and diluted loss per share. Excluding the impact of one-time recognition of deferred revenue, the net loss in the third quarter 2024 was \$12.7 million. The increase in net loss was primarily driven by decreases in revenues and interest income and other income, net and increases in selling, general and administrative expenses, partially offset by decreases in research and development expenses.

Non-GAAP adjusted EBITDA loss was \$8.6 million in the third quarter 2025, compared to non-GAAP adjusted EBITDA loss of \$6.6 million in the third quarter 2024. Excluding the impact of one-time recognition of deferred revenue, non-GAAP adjusted EBITDA in the third quarter 2024 was a loss of \$7.8 million.

Cash and cash equivalents were \$129.1 million as of September 30, 2025.

#### 2025 Outlook

Aquestive's full-year 2025 financial guidance is below.

The Company expects:

	<b>Guidance</b>
Total revenue (in millions)	\$44 to \$50
Non-GAAP adjusted EBITDA loss (in millions)	\$47 to \$51

#### Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Thursday, November 6, 2025.

In order to participate, please register in advance [here](#) to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Aquestive's website at: [Third Quarter 2025 Earnings Call](#).

#### About Anaphylm™

Anaphylm™ (dibutepinephrine) Sublingual Film is a polymer matrix-based epinephrine prodrug product candidate. Anaphylm is similar in size to a postage stamp, weighs less than an ounce, and begins to dissolve on contact. No water or swallowing is required for administration. The primary packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket, and is designed to withstand weather excursions such as exposure to rain and/or sunlight. The Anaphylm trade name for AQST-109 has been conditionally approved by the FDA. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of the product candidate.

#### About Libervant®

Libervant® (diazepam) Buccal Film is a buccally, or inside of the cheek, administered film formulation of diazepam, a benzodiazepine intended for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy. Aquestive developed Libervant as an alternative to the device-based products currently available for patients with refractory epilepsy, including a rectal gel and nasal spray products. The FDA approval for U.S. market access received in April 2024 for Libervant was for these epilepsy patients between two and five years of age. However, the FDA converted this approval to a "tentative approval" due to a recent court ruling finding that the FDA did not have authority to approve Libervant for U.S. market access for patients aged between two and five years due to the existing orphan drug market exclusivity granted by the FDA to an intranasal spray of another company. The FDA granted tentative approval in August 2022 for Libervant for treatment of these epilepsy patients twelve years of age and older. U.S. market access for Libervant patients is currently subject to the expiration of the existing orphan drug market exclusivity of the previously FDA approved drug scheduled to occur in January 2027.

### About AQST-108

AQST-108 (epinephrine) Topical Gel is a topically delivered adrenergic agonist prodrug gel product candidate. Aquestive completed a first in human study for AQST-108 that measured the amount of epinephrine that remained on the skin or was found in circulation over time after the application of the gel. AQST-108 is based on Aquestive's AdrenaVerse™ platform that contains a library of over twenty epinephrine prodrug product candidates intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

### Important Safety Information

Do not give Libervant to your child between the ages of two and five if your child is allergic to diazepam or any of the ingredients in Libervant or has an eye problem called acute narrow angle glaucoma.

### What is the most important information I should know about Libervant?

- **Libervant is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
  - shallow or slowed breathing,
  - breathing stops (which may lead to the heart stopping),
  - excessive sleepiness (sedation).

**Do not allow your child to drive a motor vehicle, operate heavy machinery, or ride a bicycle until you know how taking Libervant with opioids affects your child.**

- **Risk of abuse, misuse, and addiction.** Libervant is used in children 2 to 5 years of age. The unapproved use of Libervant has a risk for abuse, misuse, and addiction, which can lead to overdose and serious side effects including coma and death.
- **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including diazepam (the active ingredient in Libervant).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your child's healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
  - **Your child can develop an addiction even if your child takes Libervant as prescribed by your child's healthcare provider.**
  - **Give Libervant exactly as your child's healthcare provider prescribed.**
  - Do not share Libervant with other people.
  - Keep Libervant in a safe place and away from children.
- **Physical dependence and withdrawal reactions. Libervant is intended for use if needed in order to treat higher than usual seizure activity. Benzodiazepines, including Libervant, can cause physical dependence and withdrawal reactions, especially if used daily. Libervant is not intended for daily use.**
  - **Do not suddenly stop giving Libervant to your child without talking to your child's healthcare provider.** Stopping Libervant suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures that will not stop (status epilepticus), sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, homicidal thoughts, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child gets any of these symptoms.
  - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning, or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.

- Physical dependence is not the same as drug addiction. Your child's healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- Do not give your child more Libervant than prescribed or give Libervant more often than prescribed.

**Libervant can make your child sleepy or dizzy and can slow your child's thinking and motor skills.**

- Do not allow your child to drive a motor vehicle, operate machinery, or ride a bicycle until you know how Libervant affects your child.
- Do not give other drugs that may make your child sleepy or dizzy while taking Libervant without first talking to your child's healthcare provider. When taken with drugs that cause sleepiness or dizziness, Libervant may make your child's sleepiness or dizziness much worse.

**Like other antiepileptic medicines, Libervant may cause suicidal thoughts or actions in a small number of people, about 1 in 500.**

- **Call a healthcare provider right away if your child has any of these symptoms, especially if they are new, worse, or worry you:**
  - thoughts about suicide or dying
  - new or worse depression
  - feeling agitated or restless
  - trouble sleeping (insomnia)
  - acting aggressive, being angry or violent
  - other unusual changes in behavior or mood
  - attempts to commit suicide
  - new or worse anxiety or irritability
  - an extreme increase in activity and talking (mania)
  - new or worse panic attacks
  - acting on dangerous impulses
- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your child's healthcare provider as scheduled.
- **Call your child's healthcare provider between visits as needed, especially if you are worried about symptoms.** Suicidal thoughts or actions can be caused by things other than medicines. If your child has suicidal thoughts or actions, your child's healthcare provider may check for other causes.

**What are the possible side effects of Libervant?**

- The most common side effects of Libervant are sleepiness and headache.
- These are not all the possible side effects of Libervant.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800 FDA-1088.

For more information about Libervant, talk to your doctor, and see Product Information: Medication Guide and Instructions For Use.

**About Aquestive Therapeutics, Inc.**

Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has four licensed commercialized products marketed by its licensees in the U.S. and around the world and is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. Aquestive is advancing a late-stage proprietary product candidate for the treatment of severe allergic reactions, including anaphylaxis, and an early-stage

epinephrine prodrug topical gel product candidate for various possible dermatological conditions, including alopecia areata. For more information, visit [Aquestive.com](http://Aquestive.com) and follow us on LinkedIn.

**Non-GAAP Financial Information**

This press release and our webcast earnings call regarding our quarterly financial results contains financial measures that do not comply with U.S. generally accepted accounting principles (GAAP), such as non-GAAP adjusted EBITDA loss, non-GAAP adjusted gross margins, non-GAAP adjusted costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation expense, interest expense, interest expense related to the sale of future revenue, interest income, depreciation, amortization, and income taxes.

Specifically, the Company adjusts net loss for certain non-cash expenses, including share-based compensation expenses; depreciation and amortization; and interest expense related to the sale of future revenue, interest income and other income, net and income taxes, with a result of non-GAAP adjusted EBITDA loss. Similarly, manufacture and supply expense, research and development expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Non-GAAP adjusted EBITDA loss 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, and its future manufacture 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. The Company 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. Non-GAAP adjusted EBITDA loss 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 the 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. In order to inform our outlook measures of non-GAAP adjusted EBITDA and non-GAAP gross margin, a description of the 2025 and 2024 adjustments which have been applicable in determining non-GAAP Adjusted EBITDA and non-GAAP gross margin for these periods are reflected in the tables below. In providing outlook for non-GAAP gross margin, the Company adjusts for non-cash share-based compensation expense and depreciation and amortization. The Company is 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

Certain statements in this press release include “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 include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (dibutepinephrine) Sublingual Film through clinical development and approval by the FDA, including whether the clinical data submitted to the FDA will be adequate enough for the FDA to approve Anaphylm, and the following commercial launch of Anaphylm, if approved by the FDA; the advancement and related timing of potential international regulatory filings and market approvals of Anaphylm outside of the U.S.; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care, if Anaphylm is approved by the FDA; the potential for additional FDA inspections of clinical study and other sites and the results of those inspections; launch preparedness activities being sufficient to build commercial readiness for Anaphylm and approved patents providing long-term commercial success for Anaphylm, if approved by the FDA; the advancement, growth and related timing of our AdrenaVerse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel for the treatment of alopecia areata, through clinical development and FDA regulatory approval; the advancement and related timing of approval for U.S. market access by the FDA of Libervant® (diazepam) Buccal Film; the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones for our product candidates; the potential growth of markets for our product candidates; our future financial and operating results and financial position, including with respect to our 2025 financial outlook, estimated cash runway and sufficiency to support the launch of Anaphylm, if approved by the FDA; our production and distribution channels being unaffected by implemented and proposed government tariffs in the near term; and 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm, AQST-108, and our other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including for Anaphylm, Libervant and AQST-108, or failure to receive FDA approval at all of any of these product candidates; risk of FDA inspections of manufacturing and clinical study sites for any of our product candidates, including Anaphylm; risk of government shutdown on the ability of the FDA to act on the approval of our product candidates, including Anaphylm and AQST-108; risk of the Company’s ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic (PK/PD) comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA’s comments on our NDA, including the risk that the FDA may require additional clinical studies, for approval of Anaphylm; risks associated with the success of any competing products, including generics; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm, Libervant and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, Libervant and AQST-108, should these product candidates be approved by the FDA; risk of the impact of our obligations under the Company’s Purchase Agreement and the Royalty Rights Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Senior Secured Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, if such product candidates should be approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunset product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; 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 in the U.S. and abroad of Libervant, Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our 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 our products; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office or, if issued, will be sufficient to provide long-term commercial success of these product candidates; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of government tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. 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 the Company or any person acting on its 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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Libervant®, PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

**Investor inquiries:**

Astr Partners

Brian Korb

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

	September 30, 2025	December 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 129,063	\$ 71,546
Trade and other receivables, net	11,801	7,344
Inventories	7,884	6,044
Prepaid expenses and other current assets	2,925	3,286
Total current assets	151,673	88,220
Property and equipment, net	3,918	3,799
Right-of-use assets, net	4,769	5,182
Other non-current assets	3,199	4,223
Total assets	<u>\$ 163,559</u>	<u>\$ 101,424</u>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 10,865	\$ 10,287
Accrued expenses	5,128	5,907
Lease liabilities, current	601	510
Deferred revenue, current	1,092	1,048
Liability related to the sale of future revenue, current	1,000	1,000
Royalty obligations, current	561	87
Loans payable, current	6,327	26
Total current liabilities	25,574	18,865
Notes payable, net	29,940	32,500
Royalty obligations, net	23,948	20,129
Liability related to the sale of future revenue, net	61,977	62,718
Lease liabilities	4,508	4,968
Deferred revenue, net of current portion	19,663	20,005
Other non-current liabilities	2,058	2,395
Total liabilities	167,668	161,580
<b>Contingencies</b>		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 121,658,113 and 91,413,742 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	121	91
Additional paid-in capital	410,908	302,967
Accumulated deficit	(415,138)	(363,214)
Total stockholders' deficit	(4,109)	(60,156)
Total liabilities and stockholders' deficit	<u>\$ 163,559</u>	<u>\$ 101,424</u>

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

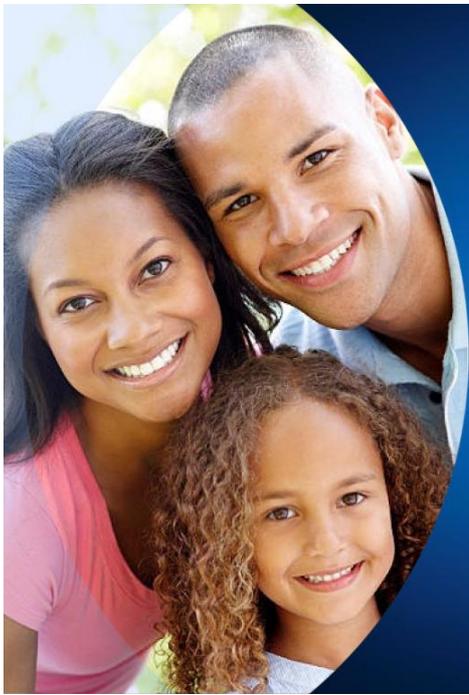
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues	\$ 12,807	\$ 13,542	\$ 31,530	\$ 45,694
Costs and expenses:				
Manufacture and supply	4,506	4,437	12,719	13,352
Research and development	4,530	5,269	13,996	15,363
Selling, general and administrative	15,250	12,126	47,027	34,171
Total costs and expenses	24,286	21,832	73,742	62,886
Loss from operations	(11,479)	(8,290)	(42,212)	(17,192)
Other income/(expenses):				
Interest expense	(2,779)	(2,780)	(8,342)	(8,343)
Interest expense related to royalty obligations	(1,433)	(1,359)	(4,304)	(4,075)
Interest expense related to the sale of future revenue	(61)	(59)	(181)	(175)
Interest income and other income, net	306	979	3,115	2,703
Net loss before income taxes	(15,446)	(11,509)	(51,924)	(27,082)
Net loss	\$ (15,446)	\$ (11,509)	\$ (51,924)	\$ (27,082)
Comprehensive loss	\$ (15,446)	\$ (11,509)	\$ (51,924)	\$ (27,082)
<b>Loss per share attributable to common stockholders:</b>				
Basic and diluted (in dollars per share)	\$ (0.14)	\$ (0.13)	\$ (0.51)	\$ (0.32)
<b>Weighted average common shares outstanding:</b>				
Basic and diluted (in shares)	110,584,371	91,082,081	101,857,974	85,224,263

**AQUESTIVE THERAPEUTICS, INC.**  
**Reconciliation of Non-GAAP Adjustments - Net Loss to Non-GAAP Adjusted EBITDA**  
**(In Thousands)**  
**(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
GAAP net loss	\$ (15,446)	\$ (11,509)	\$ (51,924)	\$ (27,082)
Share-based compensation expense	2,777	1,577	6,248	4,696
Interest expense	2,779	2,780	8,342	8,343
Interest expense related to royalty obligations	1,433	1,359	4,304	4,075
Interest expense related to the sale of future revenue	61	59	181	175
Interest income and other income, net	(306)	(979)	(3,115)	(2,703)
Depreciation and Amortization	139	159	418	571
Total non-GAAP adjustments	\$ 6,883	\$ 4,955	\$ 16,378	\$ 15,157
Non-GAAP adjusted EBITDA	\$ (8,563)	\$ (6,554)	\$ (35,546)	\$ (11,925)
Excluding Non-GAAP adjusted R&D expenses	(3,204)	(4,943)	(11,901)	(14,521)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	\$ (5,359)	\$ (1,611)	\$ (23,645)	\$ 2,596

AQUESTIVE THERAPEUTICS, INC.  
Reconciliation of Non-GAAP Adjustments - GAAP Expenses to Non-GAAP Adjusted Expenses  
(In Thousands, except percentages)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
<b>Total costs and expenses</b>	\$ 24,286	\$ 21,832	\$ 73,742	\$ 62,886
Non-GAAP adjustments:				
Share-based compensation expense	(2,777)	(1,577)	(6,248)	(4,696)
Depreciation and amortization	(139)	(159)	(418)	(571)
<b>Non-GAAP adjusted costs and expenses</b>	<u>\$ 21,370</u>	<u>\$ 20,096</u>	<u>\$ 67,076</u>	<u>\$ 57,619</u>
<b>Manufacture and Supply Expense</b>	\$ 4,506	\$ 4,437	\$ 12,719	\$ 13,352
<i>Gross Margin on total revenue</i>	65 %	67 %	60 %	71 %
Non-GAAP adjustments:				
Share-based compensation expense	(130)	(102)	(358)	(271)
Depreciation and amortization	(111)	(130)	(338)	(482)
<b>Non-GAAP adjusted manufacture and supply expense</b>	<u>\$ 4,265</u>	<u>\$ 4,205</u>	<u>\$ 12,023</u>	<u>\$ 12,599</u>
<i>Non-GAAP Gross Margin on total revenue</i>	67 %	69 %	62 %	72 %
<b>Research and Development Expense</b>	\$ 4,530	\$ 5,269	\$ 13,996	\$ 15,363
Non-GAAP adjustments:				
Share-based compensation expense	(1,310)	(310)	(2,048)	(788)
Depreciation and amortization	(16)	(16)	(47)	(54)
<b>Non-GAAP adjusted research and development expense</b>	<u>\$ 3,204</u>	<u>\$ 4,943</u>	<u>\$ 11,901</u>	<u>\$ 14,521</u>
<b>Selling, General and Administrative Expenses</b>	\$ 15,250	\$ 12,126	\$ 47,027	\$ 34,171
Non-GAAP adjustments:				
Share-based compensation expense	(1,337)	(1,165)	(3,842)	(3,637)
Depreciation and amortization	(12)	(13)	(33)	(35)
<b>Non-GAAP adjusted selling, general and administrative expenses</b>	<u>\$ 13,901</u>	<u>\$ 10,948</u>	<u>\$ 43,152</u>	<u>\$ 30,499</u>



## Third Quarter 2025 Earnings Supplemental Materials

November 5, 2025

Advancing medicines.  
Solving problems.  
Improving lives.

# Disclaimer

Certain statements in this press release include "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 include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (dibutepinephrine) Sublingual Film through clinical development and approval by the FDA, including whether the clinical data submitted to the FDA will be adequate enough for the FDA to approve Anaphylm, and the following commercial launch of Anaphylm, if approved by the FDA; the advancement and related timing of potential international regulatory filings and market approvals of Anaphylm outside of the U.S.; that Anaphylm will be the first and only oral administration of epinephrine and accepted as an alternative to existing standards of care, if Anaphylm is approved by the FDA; launch preparedness activities being sufficient to build commercial readiness for Anaphylm and approved patients providing long-term commercial success for Anaphylm, if approved by the FDA; the advancement, growth and related timing of our AdrenaVerse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel for the treatment of alopecia areata, through clinical development and FDA regulatory approval; the timing of international filings for approval of Libervant® (diazepam) Buccal Film; the potential benefits our products and product candidates could bring to patients; that patients will prefer film over available alternative epinephrine delivery products; the potential growth of markets for our product candidates; our future financial and operating results and financial position, including with respect to our 2025 financial outlook, estimated cash runway and sufficiency to support the launch of Anaphylm, if approved by the FDA and achieve other business initiatives; and 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm, AQST-108, and our other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including for Anaphylm, Libervant and AQST-108, or failure to receive FDA approval at all of any of these product candidates; risk of government shutdown on the ability of the FDA to act on the approval of our product candidates, including Anaphylm; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our pharmacokinetic and pharmacodynamic (PK/PD) comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA's comments on our NDA, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risks associated with the success of any competing products, including generics; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product candidates, including Anaphylm, Libervant and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outsourcing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to commence principal payments on our 13.5% Senior Secured Notes in 2026, and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, Libervant and AQST-108, should these product candidates be approved by the FDA; risk of the impact of our obligations under the Company's Purchase Agreement and the Royalty Rights Agreement with third parties, each of which agreements requires the Company to make payments to each counterparty thereof, respectively, of a portion of our revenues, on our ability to contribute to the funding of our operations and the payment of principal and interest on our debt; the risk of our obligations under such Purchase Agreement and Royalty Rights Agreement impacting our ability to refinance our 13.5% Senior Secured Notes; risk that our manufacturing capabilities will be sufficient to support demand of our product candidates in the U.S. and abroad, if such product candidates should be approved by the FDA and other regulatory authorities, and our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunsetting product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; 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 in the U.S. and abroad of Libervant, Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA and other regulatory authorities, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our 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 our products; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office or, if issued, will be sufficient to provide long-term commercial success of these product candidates; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access thereof; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business, including imposition of government tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. 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 the Company or any person acting on its 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company's securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

PharmFilm®, Libervant® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. The trade name "Anaphylm" for AQST-109 has been conditionally approved by the FDA. Final approval of the Anaphylm™ proprietary name is conditioned on FDA approval of the product candidate, AQST-109. All other registered trademarks referenced herein are the property of their respective owners.

## Q3 2025 earnings key messages

### **Anaphylm™ (dibutepinephrine) Sublingual Film for severe allergic reactions, including anaphylaxis**

- U.S. Food and Drug Administration (FDA) confirms that it will not require an Advisory Committee to review the Company's New Drug Application for Anaphylm
- Preparing for a U.S. launch in Q1 2026, if approved by FDA
  - Continued expansion of commercial and medical infrastructure
  - Expanding awareness of Anaphylm through engagement with Health Care Professionals and advocacy groups
  - Continuing critical work with payers to raise awareness and prepare for launch
- Continue to focus on global expansion
  - Successful meeting with Health Canada occurred in September 2025; progressing towards a New Drug Submission in Canada
  - Initial meeting held with the European Union (EU); preparations underway for an EU submission
- Broadened the patent estate for Anaphylm with the issuance of two new patents
  - Extend patent protection into 2037

## Q3 2025 earnings key messages - continued

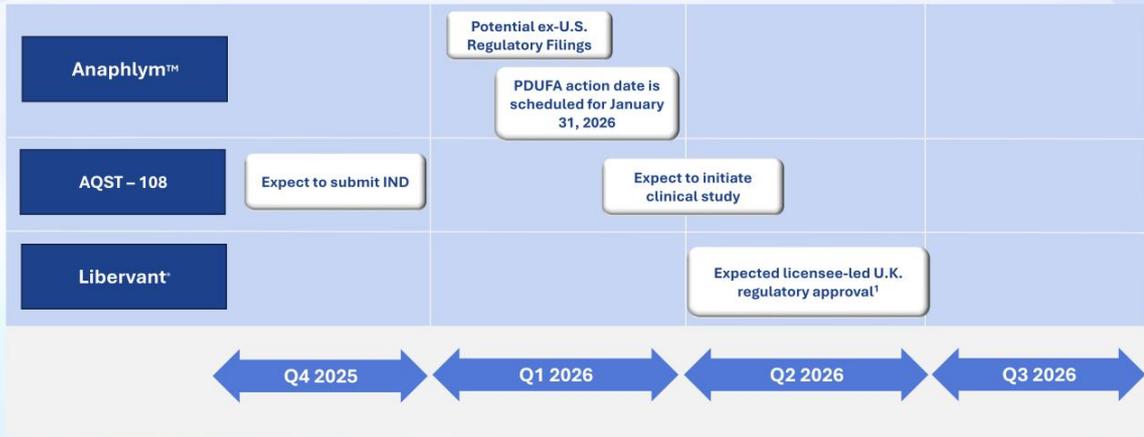
### **AQST-108 and the expansion of AdrenaVerse™ platform**

- Plan to open Investigational New Drug application for AQST-108 with FDA in Q4 2025
- Expect to initiate a clinical study for AQST-108 for Alopecia Areata in 1H 2026
- Strengthened clinical leadership to reiterate commitment to developing new product candidates from this platform

### **Strengthened balance sheet to support commercial launch execution**

- In August 2025, the Company successfully completed an equity raise of \$85MM including participation by several large institutional healthcare investors
- The Company also completed a strategic financing for \$75MM with RTW Investments, LP subject to FDA approval of Anaphylm and refinancing of the Company's existing debt

## Upcoming expected key milestones



1. Licensee filed for Libervant approval in the EU with the EMA in August 2025.

# Third Quarter Results

## Expected to meet near-term milestones with projected cash runway into 2027



## Manufacturing operations continue to generate cash



## 2025 guidance as of November 5, 2025

### 2025 Outlook

- Total revenues of approximately \$44-\$50 million
- Non-GAAP adjusted EBITDA loss of approximately \$47-\$51 million

**Thank You**

