

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ____ to ____

Commission File Number: 001-38599

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of Incorporation
or organization)

30 Technology Drive, Warren, NJ 07059
(908) 941-1900

82-3827296
(I.R.S. Employer Identification Number)

(Address, Zip Code and Telephone Number of Registrant's Principal Executive Offices)

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

The number of outstanding shares of the registrant's common stock, par value of \$0.001 per share (the "Common Stock"), as of the close of business on August 7, 2025 was 99,723,635.

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 the current U.S. federal administration initiatives and their impact on our business, including imposition of tariffs and other trade restrictions; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in this Quarterly Report on Form 10-Q. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in the risk factors of the Company's 2024 Annual Report on Form 10-K and our other Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K and our other filings with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of this Quarterly Report on Form 10-Q, whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-looking statements included in this Quarterly Report on Form 10-Q as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Aquestive," the "Company," "we," "us," and "our" refer to Aquestive Therapeutics, Inc.

Overview

Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing pharmaceutical products to deliver complex molecules through administrations that are alternatives to invasive and inconvenient standard of care therapies. We are advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis, under the "Anaphylm™" trade name, and our Adrenaverse™ epinephrine prodrug pipeline platform. We have four licensed commercialized products which are marketed by our licensees in the U.S. and around the world. We are the exclusive manufacturer of these licensed products. Aquestive 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. Our production facilities are located in Portage, Indiana, and our corporate headquarters and primary research laboratory facilities are based in Warren, New Jersey.

We manufacture licensed products at our facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our licensed products, proprietary product and product candidates currently in development. Our facilities have been inspected by the FDA, TGA, and DEA, and are subject to inspection by all applicable health agencies, including ANVISA and EMA. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by us.

Complex Molecule Portfolio

We have developed a proprietary pipeline of complex molecule-based product candidates as alternatives to invasively administered standard of care therapeutics addressing large market opportunities. The active programs in our complex molecule pipeline portfolio are:

- **Anaphylm™** (epinephrine) Sublingual Film – the first and only non-device based, orally delivered epinephrine product candidate in development that has shown clinical results comparable to auto-injectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis. Epinephrine is the standard of care in the treatment of anaphylaxis and is typically administered via intramuscular injection (IM), including manual auto-injectors such as EpiPen and Auvi-Q, which require patients or their caregivers to inject epinephrine into the patient's thigh during an emergency allergic reaction. As a result of this route of administration, many patients and their caregivers are reluctant to use injectable products. In August 2024, a nasal spray device was approved by the FDA for the treatment of severe allergic reactions, including anaphylaxis. However, Anaphylm would, if approved by the FDA, allow a patient to simply place a dissolvable strip, approximately the size and weight of a postage stamp, under the tongue, providing an appropriate medication where it is needed and when it is needed.

The FDA conditionally accepted the proprietary name Anaphylm™ (pronounced "ana-film") as the proposed brand name for Anaphylm. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of Anaphylm, if any.

On February 24, 2022, following a Phase 1 clinical study conducted by the Company outside of the U.S., the FDA cleared our IND for Anaphylm, allowing for clinical investigation of Anaphylm in the U.S. The FDA confirmed that

the 505(b)(2) regulatory approval pathway is acceptable for the development of Anaphylm. The FDA granted Fast Track designation of Anaphylm in March 2022.

Throughout 2022 and 2023, we reported positive topline data from several clinical studies evaluating multiple oral film formulations and dosage strengths of Anaphylm in healthy adult subjects, including cross over studies comparing the PK and PD of epinephrine delivered via Anaphylm compared to current standards of care, EpiPen and IM injectors. These studies demonstrated that treatment with Anaphylm was well tolerated, with no serious adverse events, significant medical events, or treatment-related severe adverse events reported. The data from these clinical studies formed the basis for the EOP2 meeting with the FDA in December of 2022, which provided clarity as to the FDA's expectations regarding key clinical program areas for design of revised dosing instructions expected for use in our pivotal clinical trial.

In the fourth quarter of 2023, we received comments from the FDA on the protocol for our pivotal clinical study for Anaphylm, which comments indicated that our proposed endpoints, sample size, and statistical analysis for the proposed pivotal clinical study were reasonable and provided clarity on PK sustainability with repeat-dose requirements. We incorporated the FDA's feedback into the pivotal clinical study design, which study commenced in the fourth quarter of 2023.

In January 2024, we completed a Type C meeting with the FDA in which the FDA found that we had adequately addressed the FDA's previous concerns noted in the EOP2 meeting, including addressing (1) the impact of any product hold time, (2) the potential for emesis (vomiting), and (3) the impact of potential mouth conditions such as angioedema (swelling), by removing product hold time from the administration instructions and providing additional information on how to characterize emesis in our NDA submission with the FDA. Regarding mouth conditions, the FDA recommended administering Anaphylm after oral exposure to a known allergen and assessing PK performance thereunder. This study replaced our previously planned angioedema study. In those comments, the FDA did not outline any new clinical development requirements for the Anaphylm program. The FDA reserved judgement on the sufficiency of the Anaphylm clinical development program until completion of ongoing and planned studies, the results of which were presented at a pre-NDA interaction with the FDA on November 22, 2024.

In March 2024, we released topline data from our pivotal clinical study for Anaphylm. The two-part, Phase 3, single-center, open-label, randomized study was designed to compare the PK and PD of single and repeat doses of Anaphylm versus single and repeat doses of the IM injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The results of this study demonstrated that the primary endpoint, epinephrine PK biocomparability of the single administration of Anaphylm to the single administration of Adrenalin (epinephrine IM injection) and epinephrine autoinjectors in healthy adult subjects was met. The study also met its secondary endpoints, which included evaluating the PK sustainability of Anaphylm following repeat administration, as well as its safety and tolerability of Anaphylm following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors.

In June 2024, we reported positive topline PK data from the Company's temperature / pH study of Anaphylm. The single-dose, five-period, randomized crossover study was designed to compare the PK and PD of Anaphylm just after consuming normal water at different temperatures (hot, cold, and room temperature) as well as water of different pHs (acidic- lemon water, and basic- baking soda water). The most consumed beverages, such as soda, milk, coffee, and juice, have acidity between lemon water and normal water. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at predefined time points after dosing, in 30 healthy adult subjects. Topline PK and PD data from the study showed no statistically significant difference in PK and PD results between the different groups based on temperature and pH variability in the mouth.

In July 2024, we reported positive topline data from the self-administration PK study of Anaphylm. The single-dose, three-period, randomized crossover study was designed to compare the PK and PD of Anaphylm self-administered, Anaphylm healthcare provider (HCP)-administered, and Adrenalin IM injection HCP- administered. The primary PK parameters were the Cmax and the AUC exposures, at predefined time points after dosing in 36 healthy adult subjects. The median time to maximum concentration (Tmax) was 15 minutes for both the Anaphylm self-administered and HCP-administered arms, while the median Tmax for the Adrenalin IM injection HCP-administered arm was 50 minutes post-administration. Also, there was no statistical difference between the Anaphylm self-administered and HCP- administered arms of the study based on a comparison of epinephrine exposures across the first 60 minutes post-administration. Topline PD data from the study showed no difference in the median increase in systolic blood pressure, diastolic blood pressure, and heart rate whether Anaphylm was self-administered or HCP-administered.

In October 2024, we reported positive topline data from an oral allergy syndrome challenge study (now referred to as the "OASIS" study), meeting both primary and secondary endpoints. The two-part study demonstrated that

Anaphylm's PK and PD profile during allergen-induced oral physiological changes was consistent with its profile without an allergen challenge. In addition, following allergen exposure where 94% of subjects exhibited moderate to severe symptoms per the predefined oral severity score, rapid symptom resolution was observed beginning as early as 2 minutes post-administration. The median time to complete symptom resolution was 12 minutes compared to 74 minutes at screening baseline, with 50% of all symptoms across all subjects resolving by 5 minutes. The mean time of symptom resolution for edema, which affected approximately 25% of subjects, was 5 minutes after Anaphylm administration. The PK profile remained consistent, with median Tmax maintained at 12 minutes and comparable Cmax values between allergen-exposed and non-exposed cohorts. The safety profile was favorable, with all adverse events classified as mild to moderate and resolving without medical intervention.

Also in October 2024, at the ACAAI 2024 Annual Meeting in Boston, we presented results from a subsequent analysis of our pivotal study data demonstrating Anaphylm's consistent PK and PD profile regardless of variable placement or intraoral movement. The analysis showed that 87.5% of subjects maintained consistent film placement during disintegration. In the 12.5% of subjects where movement was noted, there were no significant differences in Cmax and Tmax. These findings further demonstrate that initial placement or subsequent movement of the sublingual film had no impact on epinephrine PK or PD comparability to epinephrine autoinjectors.

On November 22, 2024, we received positive pre-NDA written response feedback from the FDA prior to our planned NDA submission in the first quarter of 2025. The FDA did not indicate in those responses that any additional adult clinical trials would be necessary for submitting the NDA for Anaphylm. In addition, the FDA agreed with our planned NDA content and format for the submission, planned safety evaluation, and planned pediatric trial. The FDA also provided further guidance on additional data views to be included in the planned NDA submission and continued to emphasize its focus on PK sustainability for a single dose. In addition, the FDA requested minor modifications to the pediatric trial protocol which requested modifications were incorporated in the final pediatric trial protocol. Finally, the FDA noted that due to the new route of administration and the data supporting this route of administration, an advisory committee meeting may be necessary prior to FDA approval and we are preparing for this potential request from the FDA.

We completed the NDA submission to the FDA in the first quarter of 2025. The pediatric study in subjects from the ages of 7 to 17 (weight greater than or equal to 30 kgs) was completed with positive topline data reported on April 1, 2025. A total of thirty-two patients completed the study. The PK results were consistent with previous adult studies. Anaphylm was shown to be safe and well-tolerated with no serious adverse events reported.

On June 16, 2025, the NDA submission was accepted by the FDA and a PDUFA target action date of January 31, 2026 was assigned. We are planning on initiating a product launch of Anaphylm, if approved by the FDA, in the first quarter of 2026. The Company is concurrently pursuing regulatory strategies outside the United States. It recently announced that it plans to hold an in-person meeting with Health Canada to discuss its planned New Drug Submission for Anaphylm. The Company submitted the initial briefing book to EMA and plans to submit a Marketing Authorization Application as soon as possible.

- **AQST-108 (epinephrine) Topical Gel** – Our product candidate, AQST-108 is composed of the prodrug dipivefrin which is enzymatically cleaved into epinephrine after administration. AQST-108, is a topically delivered adrenergic agonist prodrug, which we believe has the potential to support the re-establishment of immune privilege in the hair follicle and we are pursuing its development for the treatment of alopecia areata, which is an autoimmune disease leading to hair loss on the scalp, face and, in more severe cases, other body areas. We completed the first human clinical trial for AQST-108. The two-part trial was designed to assess the safety and local tolerability of AQST-108. Part 1 was designed as a single ascending dose escalation study to assess the safety and PK of five different dose levels. The 1.0% dose of AQST-108 was chosen based on the down selection from the highest dose to move into the Part 2 study of the development program. In Part 2, three formulations based on excipient variations were evaluated in twelve healthy subjects. In Parts 1 and 2, no serious adverse events or topical adverse events were observed. In Part 2, the calculated percentage of AQST-108 observed in the skin remained consistent across all studied formulations and zero post-dose AQST-108 concentrations in plasma were observed. We received pre-IND FDA feedback in the fourth quarter of 2024 to align on the Phase 2a clinical trial design. We are continuing pre-clinical development studies in advance of plans to open an IND in the fourth quarter of 2025 and initiate the Phase 2a clinical trial in the first half of 2026.