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 16, 2026

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

184 Liberty Corner Road, Suite 305,
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 7.01 Regulation FD Disclosure.

Aquestive Therapeutics, Inc. (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 given to investors, analysts and others at the Jefferies Global Healthcare Conference on November 16, 2026 is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the Company's website located at 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 99.1) 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, 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
99.1	Aquestive Therapeutics, Inc. Jefferies Global Healthcare Conference Presentation, dated November 16, 2026
104	Cover Page Interaction Data File (embedded within the Inline XBRL document)

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 16, 2026

Aquestive Therapeutics, Inc.

By: /s/ A. Ernest Toth, Jr

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

Aquestive

Jefferies Global Healthcare Conference

November 16, 2026



Disclaimer

This presentation and the accompanying oral commentary have been prepared by Aquestive Therapeutics, Inc. ("Aquestive," the "Company," "we," "our" or "us") and contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements made by management during the presentation, any question-and-answer session and any related webcast or replay. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "target," "potential," "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 Anaphylm™ (dibutepinephrine) sublingual film through the FDA regulatory review and approval process; our ability to address the matters identified by the FDA in the Complete Response Letter ("CRL") dated January 30, 2026; the FDA's review of the Class 2 resubmission of the Anaphylm NDA and potential approval by the March 16, 2027 PDUFA goal date; whether the FDA will complete its review and take action by the PDUFA goal date; the Company's commercial launch strategy, launch readiness and potential launch of Anaphylm, if approved, including the anticipated size and deployment of our sales force, the number and types of prescribers we intend to target, anticipated prescriber and market coverage, our patient support and product-fulfillment programs, and our payer engagement and market-access strategy; the significance, interpretation and sufficiency of the human factors and pharmacokinetic study results and the pharmacokinetic and pharmacodynamic data supporting the NDA resubmission; whether the NDA resubmission adequately addresses the deficiencies identified by the FDA in the CRL; the potential approval of Anaphylm by the FDA; potential international regulatory submissions and marketing authorizations for Anaphylm, including the anticipated timing of submissions in Canada and the European Union, and our ability to identify and enter into ex-U.S. licensing or partnering arrangements on acceptable terms, or at all; Anaphylm's potential to be the first and only non-invasive, orally delivered epinephrine product and to be accepted by patients, prescribers and payors as an alternative to existing standards of care, if approved by the FDA; the pharmacokinetic and pharmacodynamic profile of Anaphylm relative to other epinephrine products based on cross-study comparisons; the advancement, growth and related timing of our AdrenaVerse™ pipeline epinephrine prodrug product candidates, including AQST-108 (epinephrine) topical gel, including design and timing of clinical studies; anticipated timelines, milestones, and guidance relating to regulatory submissions, clinical studies, regulatory interactions, and potential approvals, which are subject to change based on regulatory feedback, protocol alignment, data sufficiency, and other factors outside the Company's control; the timing and outcome of FDA review of Libervant, including potential final approval, label expansion and commercial availability; Eton Pharmaceuticals, Inc.'s ("Eton") U.S. commercialization of Libervant; the potential receipt by the Company of contingent milestone and royalty payments; the Company's manufacture and supply of Libervant; the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones, product orders and fulfillment; our cash requirements, cash funding and cash burn; our cash position and the availability, timing, amount and conditions of funding under our strategic funding agreement with RTW Investments and our debt facility with Oaktree Capital Management, including funding contingent upon FDA approval of Anaphylm; short-term and longer-term liquidity and the ability to fund our business operations; our growth and future financial and operating results and financial position, including with respect to our 2026 financial outlook; projected peak annual net sales and other commercial estimates; the size, growth and projected value of the epinephrine market; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on the Company's current expectations and beliefs and are subject to 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, the possibility that the FDA may disagree with the Company's interpretation of study results, findings or conclusions, determine that the Anaphylm NDA resubmission does not adequately address the deficiencies identified in the January 30, 2026 Complete Response Letter, request additional information, analyses, human factors studies, clinical studies or inspections, consider issues raised in citizen petitions or similar submissions, or otherwise delay or decline approval; the risk that the FDA may not complete its review or take action by the March 16, 2027 PDUFA goal date, including if the FDA extends the goal date; risks that topline or summary human factors, pharmacokinetic or pharmacodynamic results may differ from final analyses or may be interpreted differently by regulatory authorities; risks relating to FDA inspections of manufacturing and clinical-study sites; risks related to government shutdowns, reductions in government workforce or other governmental resource constraints that may adversely affect the FDA's ability to review or act upon regulatory submissions in a timely manner or at all; risks associated with launch readiness and the potential commercial launch, reimbursement, market acceptance, manufacturing and supply of Anaphylm, if approved; the risk that our planned sales-force size and deployment, prescriber targeting, patient-support programs, payer engagement and market-access strategy may not achieve the coverage, access, adoption or financial returns we anticipate; risks associated with obtaining regulatory approvals outside the United States, including that foreign authorities may require different, additional or more extensive clinical, nonclinical, human factors, pharmacokinetic or manufacturing data than anticipated or may not accept data generated for U.S. regulatory purposes; the risk that we may be unable to identify or enter into ex-U.S. licensing or partnering arrangements on acceptable terms, or at all; risks of delays or changes to the timing, design, cost, conduct, data or success of clinical studies for AQST-108 and uncertainty regarding its potential indications; delays in or failure to obtain final FDA approval or label expansion for Libervant; changes in regulatory requirements or the effect of competing products' exclusivity; Eton's commercialization costs and execution; whether and when contingent milestone events are achieved, which depend on FDA actions and Eton's commercialization efforts; the amount of any royalties, which depends on net sales; Eton's right to terminate the license agreement; Aquestive's ability to meet its manufacture and supply obligations; competition, including from generic products, pricing, reimbursement and market acceptance; risks associated with the Company's cash requirements, funding, cash burn, projected cash runway, liquidity and access to debt and equity financing; the possibility that funding expected to become available upon FDA approval of Anaphylm or other milestones, including under our strategic funding agreement and debt facility, may not become available when anticipated or at all; risks that the Company's manufacturing capabilities may be insufficient to support demand for its product candidates and licensed products; the risk that projected peak annual net sales, market size, market growth and other commercial estimates may prove materially inaccurate because they are based on assumptions regarding regulatory approval, product labeling, pricing, reimbursement, competition, prescribing behavior and market adoption, as well as internal estimates and third-party data that we have not independently verified; the risk that survey results, market research findings and stated preferences may not predict actual prescribing, utilization, adherence, clinical outcomes or market adoption; the risk that cross-study comparisons are not predictive of comparative clinical performance; eroding market share for Suboxone®; the Company's obligations under its Purchase Agreement and Royalty Rights Agreement; regulatory, legal, intellectual property, cybersecurity, economic, political and market risks; and the other uncertainties described in the "Risk Factors" section and elsewhere 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 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 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 any forward-looking statement, outlook or guidance after the date of this presentation, whether as a result of new information, future events or otherwise, except as required by applicable law.

The industry, market and competitive-position data used in this presentation, including epidemiologic data, market projections, survey results and data regarding other products used in cross-study comparisons, are derived from the Company's internal estimates, research and industry experience and from third-party industry publications, surveys, studies and product labeling, none of which the Company has independently verified. Such data reflect assumptions and limitations, involve risks and uncertainties, are subject to change and should not be given undue weight. No head-to-head studies have been conducted comparing Anaphylm with any other epinephrine product.

This presentation and the accompanying oral commentary are for informational purposes only and do 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. This presentation is intended for investors and is not intended for, and should not be used as, promotional material for any product or product candidate. Anaphylm and AQST-108 are investigational product candidates that have not been approved by the FDA or any other regulatory authority; their safety and efficacy have not been established.

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

© 2026 Aquestive Therapeutics, Inc.

Advancing Medicines to Bring Meaningful Improvement to Patients' Lives

6 FDA approvals
with products available on six continents

2.5+ billion
PharmFilm® doses shipped worldwide

100+ patent applications
filed in the U.S. and worldwide

20+ years
Since the company was founded

2 core technologies:
PharmFilm and AdrenaVerse™

$1.5+ billion[1]
in potential peak annual net sales from pipeline assets

1. Company estimate of potential peak annual net sales in a given year, assuming regulatory approval and successful commercialization; not a revenue forecast. Includes potential Libervant net sales to be recorded by our licensee; Aquestive would receive milestones, royalties, and supply revenue rather than product sales.

Dedicated and Experienced Leadership Team



Daniel Barber
President, CEO & Director



Peter Boyd
Chief People Officer



Melina Cioffi
SVP, Regulatory Affairs



Matthew Davis
Chief Development Officer



Matthew Greenhawt
Chief Medical Officer



Cassie Jung
Chief Operating Officer



Sherry Korczynski
Chief Commercial Officer



Ernie Toth
Chief Financial Officer



Thomas A. Zalewski
Chief Legal Officer,
Chief Compliance Officer

Aquestive

Our Technologies

PharmFilm®





PharmFilm® is a unique and versatile technology for high-performance drug delivery. Aquestive scientists combine the customizable features of PharmFilm® with patented formulation and engineering processes to optimize the delivery of active pharmaceutical ingredients (APIs).

AdrenaVerse™



The AdrenaVerse™ platform contains a library of over 20 epinephrine prodrugs that demonstrate control of absorption and conversion rates across a variety of dosage forms including lotions, creams, and ointments (LCOs) and delivery sites. The AdrenaVerse platform enables us to pursue a variety of allergy and dermatology indications.

Our Products

Aquestive is the go-to formulation development and commercial manufacturing partner for oral thin film products worldwide

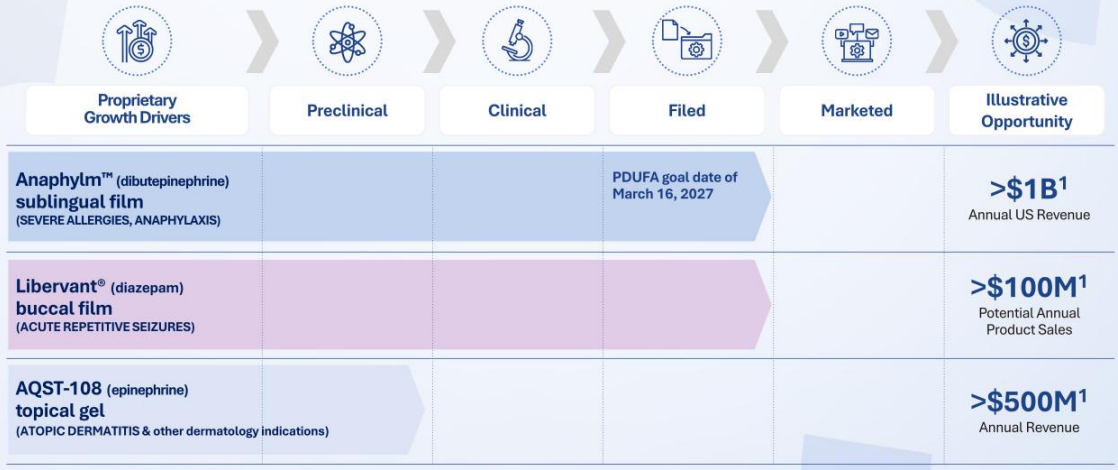
Validation from

4 licensed commercial products [1-4]



1. Ondif collaboration with Hypera-Pharma (Brazil). 2. Sympazan collaboration with Cosette Pharmaceuticals, Inc. (worldwide). 3. Emylif collaboration with Zambon (EU).
4. Suboxone collaboration with Indivior (worldwide).

Diversified Pipeline Fuels Our Growth Plan

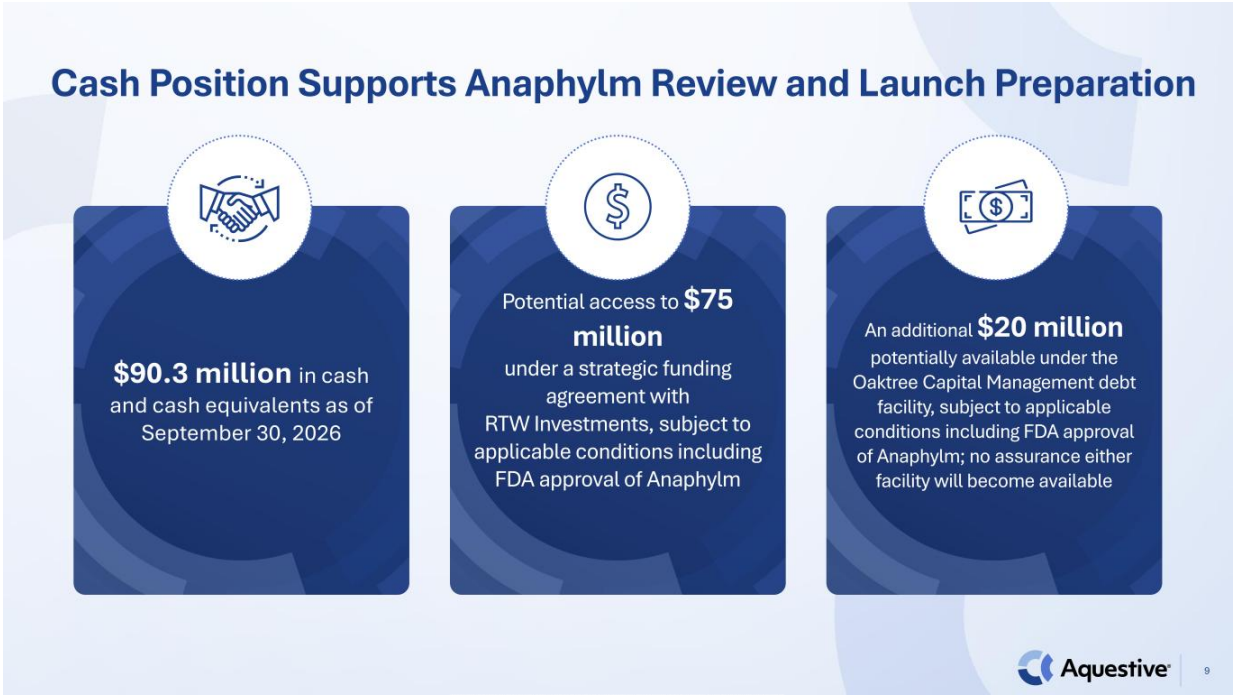


1. Company estimates of potential peak annual net sales and annual U.S. product sales, as applicable, in a given year, assuming regulatory approval and successful commercialization; not forecasts of revenue for any period. Actual results may differ materially. 2. Libervant is licensed to Eton Pharmaceuticals, Inc., which is responsible for U.S. commercialization. Aquestive's economics consist of contingent milestone payments, royalties on Eton's net sales, and supply revenue from manufacturing Libervant for Eton.

Anaphylm Regulatory Milestones



- Anaphylm advances toward a March 16, 2027, PDUFA goal date following FDA acceptance of the NDA resubmission.
- Ex-U.S. filings are targeted for Canada by year-end 2026 and the E.U. in Q1 2027; timing remains subject to regulatory requirements and change


Cash Position Supports Anaphylm Review and Launch Preparation
$90.3 million in cash and cash equivalents as of September 30, 2026
Potential access to $75 million under a strategic funding agreement with RTW Investments, subject to applicable conditions including FDA approval of Anaphylm
An additional $20 million potentially available under the Oaktree Capital Management debt facility, subject to applicable conditions including FDA approval of Anaphylm; no assurance either facility will become available
Aquestive
9

Lead Asset

ANAPHYLM™ (dibutepinephrine) sublingual film

ANAPHYLM™ (dibutepinephrine) sublingual film is an investigational product candidate that has not been approved by the U.S. Food and Drug Administration. Safety and efficacy have not been established. Statements regarding potential benefits, clinical performance, market opportunity, commercialization plans and regulatory timing are subject to FDA review and approval.

Challenges with Current Epinephrine Auto-Injectors (EAIs)

EAI device-related issues deter device carriage, increase the chances of leaving them at home, make them less accessible when needed and reduce the likelihood of carrying two devices.[1-6]



Inconvenient size and shape of EAI device and/or carrying case



Complicated administration leading to improper use, EAI device malfunctions, and hesitancy to use an EAI device



Social stigma and/or forgetfulness



Needle phobia and anxiety

1. Golden DBK, et al. (2024). *Ann Allergy Asthma Immunol*, *132*(2), 124–176.
2. Pouessel G, et al. (2025). *Clin Exp Allergy*, *55*(1), 36–51.
3. Lieberman JA, et al. (2023). *Ann Allergy Asthma Immunol*, *131*(2), 185–193.e10.
4. Wang J. (2024). *J Food Allergy*, *6*(1), 32–36.
5. Portnoy J, et al. (2019). *J Allergy Clin Immunol Pract*, *7*(7), 2252–2261.
6. Curtis C, et al. (2014). *Ann Allergy Asthma Immunol*, *112*(6), 560–562.

A Novel Approach to Epinephrine Delivery



Anaphylm™ (dibutepinephrine) sublingual film

First and only non-device, orally delivered epinephrine product candidate



Device-Free
Easy to Carry



Needle-Free
Easy to Use



Designed to
Work Quickly[1]

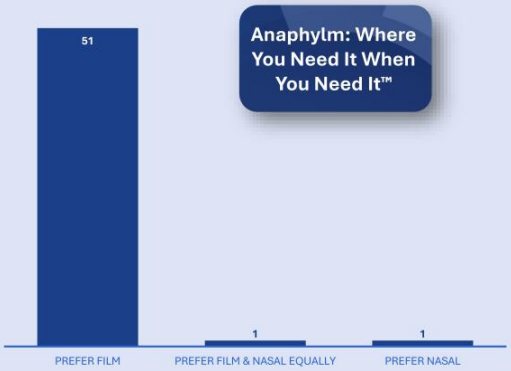
1. Aquestive Therapeutics data on file.

ANAPHYLM™ (dibutepinephrine) sublingual film is an investigational product candidate that has not been approved by the U.S. Food and Drug Administration. Safety and efficacy have not been established. Statements regarding potential benefits, clinical performance, market opportunity, commercialization plans and regulatory timing are subject to FDA review and approval.

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96% of Survey Respondents Preferred Film in a Hands-On Preference Survey[1,2]

Survey Results



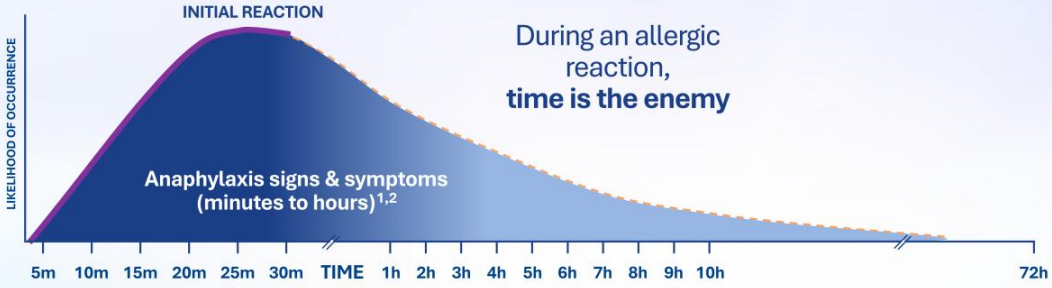
Survey Methodology:

- Double-blinded survey with 27 adult patients and 26 caregivers of pediatric patients at risk for anaphylaxis
- Respondents were mailed an envelope containing one empty, non-labeled nasal spray device and one non-labeled placebo film strip
- Respondents kept envelopes sealed until an on-camera interview video call was conducted during which they opened the envelope[2]
- Respondents were asked to assume that, if these products were made available for prescribing by their health care provider (HCP), both products would be:
  - Equal in general efficacy and safety to each other and to their current epinephrine auto-injector (EAI)
  - Endorsed by their HCP
  - Equal in out-of-pocket cost to each other

1. Aquestive Therapeutics data on file. 2. Survey results reflect stated respondent preferences under controlled survey conditions and should not be interpreted as evidence of actual prescribing, utilization, adherence, clinical outcomes or market adoption.

Anaphylaxis:

A rapid-onset, life-threatening allergic reaction requiring immediate intervention



During an allergic reaction,
time is the enemy

30+ minute delay = **Triple risk**[1]

Benefits of epinephrine
far outweigh the risks[2]

1. Xiaowei Liu , Sangil Lee , Christine M Lohse , Cassandra T Hardy , Ronna L Campbell Biphasic Reactions in Emergency Department Anaphylaxis Patients: A Prospective Cohort Study, DOI: 10.1016/j.jaip.2019.10.027 2. Shaw, Maggie L, Gaps in Anaphylaxis Care, Epinephrine Use Highlight Resource Need, Nov. 6, 2021.

Rapid Relief Needed When It Matters Most[1]

Anaphylm reaches peak absorption in just **12 minutes**



12 MIN | 20 MIN | 30 MIN | 30 MIN | 50 MIN

5 MINUTES — Therapeutic blood concentrations **in as little as 5 minutes** (over 100 pg/ml)

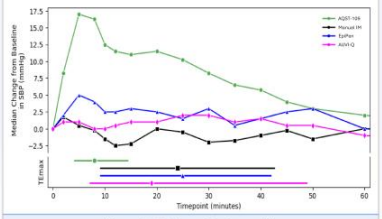
12 MINUTES — **Median T-max of 12 minutes**

1. Aquestive data on file; neffy® T-max data are from its approved labeling. Cross-study comparisons are not head-to-head, and no conclusions regarding comparative efficacy, equivalence or superiority should be drawn. Therapeutic blood concentrations do not establish clinical onset or treatment effect. Anaphylm is investigational; safety and efficacy have not been established.

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Pivotal study | PD changes[1]

Systolic Blood Pressure (SBP)

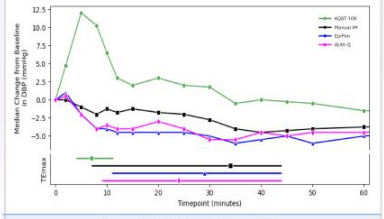


Mean SBP E_{max} 23.9 mmHg

Median SBP TE_{max} 8 min

AQST-109 SBP sustains elevation over comparators for 47-55 minutes

Diastolic Blood Pressure (DBP)

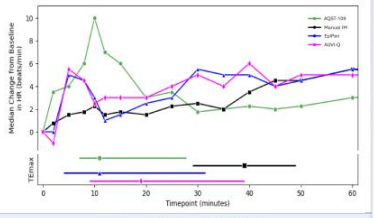


Mean DBP E_{max} 13.2 mmHg

Median DBP TE_{max} 7 min

AQST-109 DBP sustains elevation over comparators for 50-54 minutes

Heart Rate (HR)



Mean HR E_{max} 15.3 BPM

Median HR TE_{max} 11 min

AQST-109 HR sustains elevation over comparators for 25-27 minutes

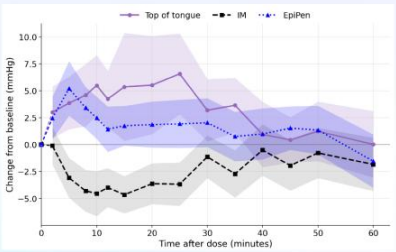
The graphs show the observed magnitude, time to peak change and duration of elevation in BP and HR versus randomized reference treatments.*

Error bars represent TE_{max} IQR. Data are from study AQ109301.
*The effect of these PD differences on symptoms, ED use, hospitalization or other clinical outcomes has not been established. Comparisons are descriptive only; no superiority or comparative clinical performance has been established. The effect of these PD differences on symptoms, ED use, hospitalization, or other clinical outcomes has not been established.
BP, blood pressure; **DBP**, diastolic blood pressure; **HR**, heart rate; **IM**, intramuscular; **min**, minute; **mmHg**, millimeters of mercury; **SBP**, systolic blood pressure.

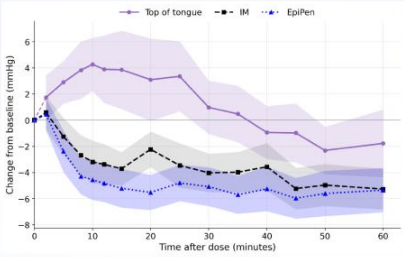
1. Golden D, Greenhawt M, Confer N, Kraus CN. Pharmacokinetics and pharmacodynamics of AQST-109: phase 3 results comparing epinephrine sublingual film with intramuscular injection. Ann Allergy Asthma Immunol. 2026;136(4):400-408.e2. doi:10.1016/j.anai.2025.11.023.

109 study | Additional treatment arm evaluated a misplacement scenario

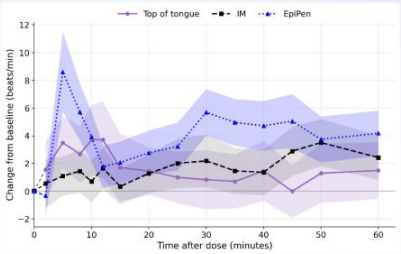
Systolic Blood Pressure*



Diastolic Blood Pressure*



Heart Rate*



- Top-of-tongue administration produced a measurable pharmacodynamic response despite lower PK exposure after a single dose[1].
- In a cross-study comparison, the observed PD change was generally similar to EAI comparator data. Cross-study comparisons do not predict comparative clinical performance; no head-to-head comparison was conducted[2]

1. Aquestive Therapeutics data on file (Study 109109 CSR). 2. Golden D, et al. Ann Allergy Asthma Immunol. 2026;136(4):400-408.e2. Cross-study comparison; not a head-to-head comparison.
*Mean changes with 95% confidence intervals. Top-of-tongue is not the proposed method of administration. FDA has not evaluated the clinical significance of these data.

It's not just "the carry"....

Pharmacologic Performance[1]

- Higher C_{max} and faster T_{max}
- Pharmacodynamic response observed within the first minute after administration
- High E_{max*} and fast $TE_{max†}$, peaking between 5-11 minutes
- Robust pharmacodynamic activity observed within minutes following administration and before the TE_{max*}
- Prodrug avoids vasoconstriction

*The maximum PD effect a drug can produce, regardless of how much the dose is increased beyond that point
†Time to maximal effect

1. Based on pharmacokinetic and pharmacodynamic study results. Clinical outcomes may not correlate directly with PK/PD measures. ANAPHYLM is an investigational product candidate that has not been approved by the FDA, and product labeling remains subject to FDA review and approval.

US Launch Preparations for

ANAPHYLM™ (dibutepinephrine) sublingual film

Anaphylaxis: A Large, Growing Market with Significant Unmet Need



32-40 million people at chronic risk for severe systemic Type 1 reaction in the US[1]

1 in 10 adults; 1 in 13 children



Direct cost of anaphylaxis is **$1.2 billion**[2]



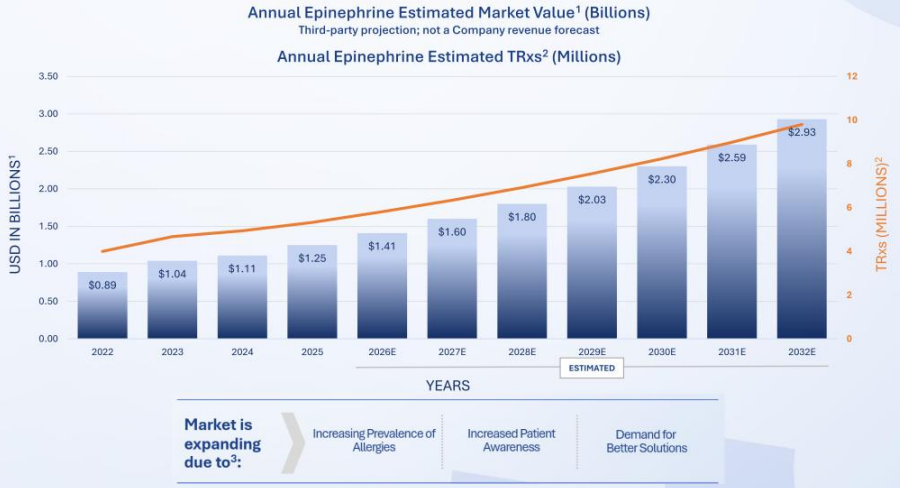
52% of surveyed patients with prior anaphylaxis never received an epinephrine autoinjector Rx[2]



60% of patients prescribed an autoinjector did not have it available[2]

1. Wood et al. J Allergy Clin Immunol. 2014;133:461-467. 2. Fromer, L., The American Journal of Medicine (2016); 129, 1244-1250

The epinephrine market continues to grow; could reach ~7.5M TRxs and ~$2.03B by 2029



Market is expanding due to[3]:

- Increasing Prevalence of Allergies
- Increased Patient Awareness
- Demand for Better Solutions

1. U.S. Epinephrine for Anaphylaxis Treatment Market Size, Share & Industry Analysis; Fortune Business Insights, Mar 23, 2026; https://www.fortunebusinessinsights.com/u-s-epinephrine-for-anaphylaxis-treatment-market-110494 2. Symphony Health Data through 12/31/2025, Metys National Projected Data, All Market Data is limited to US & Surrounding Territories. 3. Aquestive Therapeutics data on file; Precedence Research, "Epinephrine Market Size, Share and Trends 2025–2034"

Broad Scientific and Prescriber Engagement Builds Anaphylm Awareness[1]

50
Conferences Attended & Planned

876+
Booth Engagements

1090+
Prescriber interactions

14
Manuscripts drafted

10
Conference abstracts submitted

1. Year-to-date information.

Sales Force Designed to Target Priority Epi Prescribers

Sales footprint expected to capture the majority of prescribing opportunity while maximizing commercial efficiency

Focused Deployment Plans

~75

SALES REPRESENTATIVES AT LAUNCH

Engagement with priority allergists and pediatricians

Designed to maximize reach and return with a disciplined commercial footprint

Concentrated reach to Target HCPs

~8K

Target HCPs

Priority 1–5 archetypes

~30%

MARKET COVERED

Focused launch universe

Priority Specialty Coverage



Coverage metrics shown are based on the 75 representative planning scenario; final launch deployment is expected to range from 65–80 representatives. Planned deployment and subject to Anaphylm FDA approval.

Proactive Payer Engagement Supports Post-Approval Access Readiness

Market access capabilities are in place, with payer insights informing the next phase of engagement



Anaphylm: Significant Licensing Opportunity Potential Ex-US



- Worldwide need for a convenient, needle-free approach to epinephrine delivery
- Targeting regulatory submissions in Canada by year-end 2026 and the European Union in Q1 2027
- U.S. NDA resubmission accepted, with a PDUFA goal date of March 16, 2027
- Potential to leverage the clinical, regulatory and manufacturing foundation developed for the U.S. program
- Seeking experienced regional partners to support regulatory approval and commercialization outside the U.S.
- Ex-U.S. licensing rights available

ANAPHYLM™ (dibutepinephrine) sublingual film is an investigational product candidate that has not been approved by the U.S. Food and Drug Administration. Safety and efficacy have not been established. Statements regarding potential benefits, clinical performance, market opportunity, commercialization plans and regulatory timing are subject to FDA review and approval.

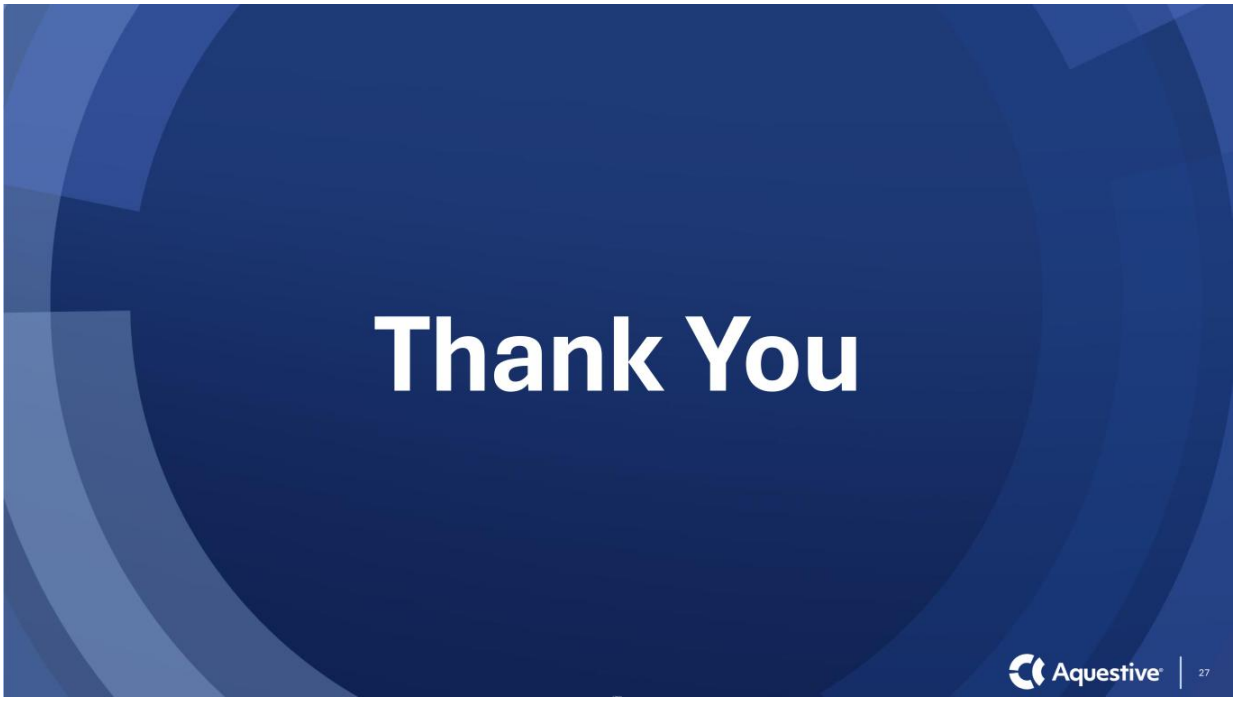
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Positioned for the Next Phase of Growth

- **Potentially Differentiated clinical profile** based on pharmacodynamic activity and absorption
- **Near-term regulatory catalyst** with March 16, 2027, PDUFA goal date
- **Large and growing market** with significant unmet need
- **Focused commercial model** designed for efficient U.S. launch, if approved
- **Global opportunity** through ex-U.S. regulatory filings and partnering
- **Multiple growth drivers** beyond Anaphylm through our AdrenaVerse™ platform

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