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): September 27, 2024

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(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 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 and accompanying oral commentary, to be given at a virtual investor day event (the "Investor Day Event") and other 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 or a later Company filing or by other means. A copy of the Company's investor presentation at the Investor Day Event 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 and accompanying webcast are available on the Events & Presentations page in the Investors section of the Company's website located at www.aquestive.com, although the Company reserves the right to discontinue that availability at any time.

A copy of the Company's current corporate presentation given to investors, analysts and others 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 Company's corporate presentation is available on the Events & Presentations page in the Investors section of 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 and Exhibit 99.2) 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 8.01 Other Events.

On September 27, 2024, the Company issued a press release providing an update of its Adrenaverse™ epinephrine prodrug platform, including the development of its product candidates Anaphylm™ (epineprhine) Sublingual Film and AQST-108 (epinephrine) Topical Gel, to be provided at the Investor Day Event being hosted by the Company. A copy of the Company's press release is attached hereto as Exhibit 99.3 and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Aquestive Therapeutics, Inc. Investor Presentation dated September 27, 2024
99.2	Aquestive Therapeutics, Inc. Corporate Presentation dated September 27, 2024
99.3	Press Release of Investor Day, dated September 27, 2024

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: **September 27, 2024**

Aquestive Therapeutics, Inc.

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


Aquestive
Adrenaverse™ Prodrug Platform
Investor Day
September 27, 2024

Disclaimer

This presentation and the accompanying oral commentary have been prepared by Aquestive Therapeutics, Inc. ("Aquestive", the "Company", "our" or "us") and contains 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™ (epinephrine) Sublingual Film through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the timing of submission of supporting and pediatric clinical studies, holding a pre-New Drug Application (NDA) meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; 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 advancement and related timing of our product candidate Libervant™ (diazepam) Buccal Film for the indicated epilepsy patient population aged between six and eleven years through clinical development and FDA regulatory approval and the following launch of Libervant for this patient population if approved by the FDA; the approval for U.S. market access of Libervant for the labeled patient population aged six years and older and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for these epilepsy patients six years of age and older; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel (and potential alternative indications), through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of Alopecia areata for AQST-108, and holding a pre-investigational new drug application meeting (IND) with the FDA, and the following launch of AQST-108, if approved by the FDA; the commercial opportunity of Libervant, Anaphylm, AQST-108 and our other product candidates, including potential revenues (including projected peak annual sales) generated from commercialization of these products and product candidates should these product candidates be approved by the FDA; our ability to price AQST-108 competitively and to leverage our commercial, distribution and manufacturing capabilities and infrastructure for AQST-108 and other product candidates, if approved by the FDA; the potential growth of our patent portfolio including the extension of patent protection for AQST-108 should the pending patents be approved by the U.S. Patent and Trademark Office (PTO); the potential benefits our products and product candidates could bring to patients; 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 (including for pediatric patients), AQST-108, and the Company's other product candidates; risks associated with the Company's distribution work for Libervant, including any delays or changes to the timing, cost and success of Company's distribution activities and expansion of market access to patients aged two to five for Libervant; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm, AQST-108, Libervant for patients aged between six and eleven and other product candidates, or failure to receive FDA approval at all of any of these product candidates; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's future clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risk that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients aged six years and older until the expiration of the orphan drug market exclusivity period of the nasal spray product due to expire in January 2027, or for other reasons; risk of loss of U.S. market approval of Libervant for patients aged between two and five resulting from a legal challenge relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA's approval for U.S. market access of Libervant for this pediatric patient population, or for other reasons; 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 Libervant and other product candidates, including Anaphylm and AQST-108; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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 fund commercialization activities relating to Libervant for patients between two and five years of age and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, AQST-108 and Libervant for patients aged between six and eleven, should these product candidates be approved by the FDA, and for Libervant patients of six years and older upon expiration of the orphan drug marketing exclusivity period of the nasal spray product; risk that our manufacturing capabilities will be sufficient to support demand for Libervant for patients between two and five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the 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 for epilepsy patients between two and five years of age, and for older epilepsy patients if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant and Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to 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 PTO; 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 2023 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 presentation 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® 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.

Aquestive®

Today's agenda

Topic	Presenters
Introductions and company overview	**Dan Barber** *Chief Executive Officer* Aquestive Therapeutics
Scientific overview of adrenergic receptors	**J. David Farrar, PhD** *Associate Professor* Immunology/Molecular Biology UT Southwestern Medical Center
Adrenaverse™ prodrug platform capabilities	**Steve Wargacki, PhD** *Chief Science Officer* Aquestive Therapeutics
AQST 108 (epinephrine) Topical Gel indication and clinical program overview	**Carl Kraus, MD** *Chief Medical Officer* Aquestive Therapeutics
Market opportunity	**Dan Barber** *Chief Executive Officer* Aquestive Therapeutics
Q&A and Closing Remarks	

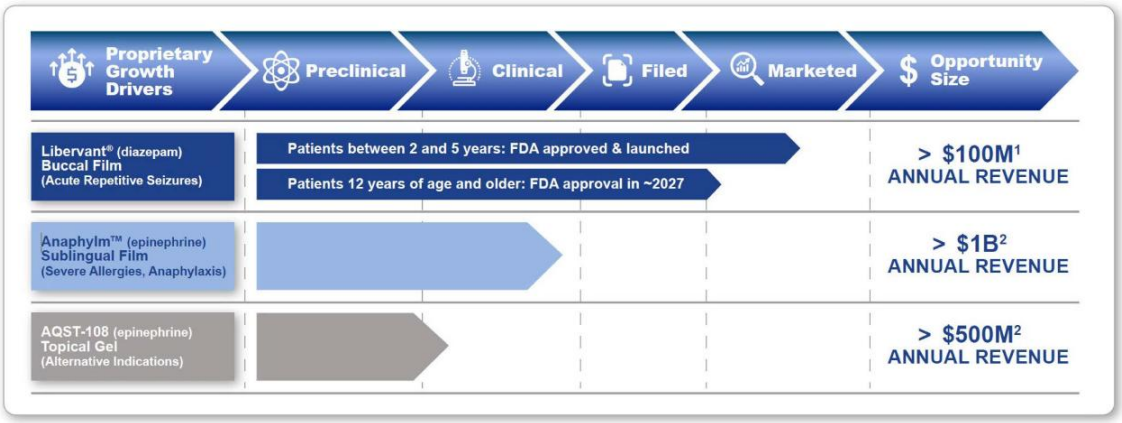
Drug delivery technologies

PharmFilm®

Adrenaverse™ Prodrug Platform

Adrenaverse platform contains a library of over 20 epinephrine prodrugs *that demonstrate control of absorption and conversion rates across a variety of dosage forms and delivery sites, including allergy, topical (dermatological), and more.*

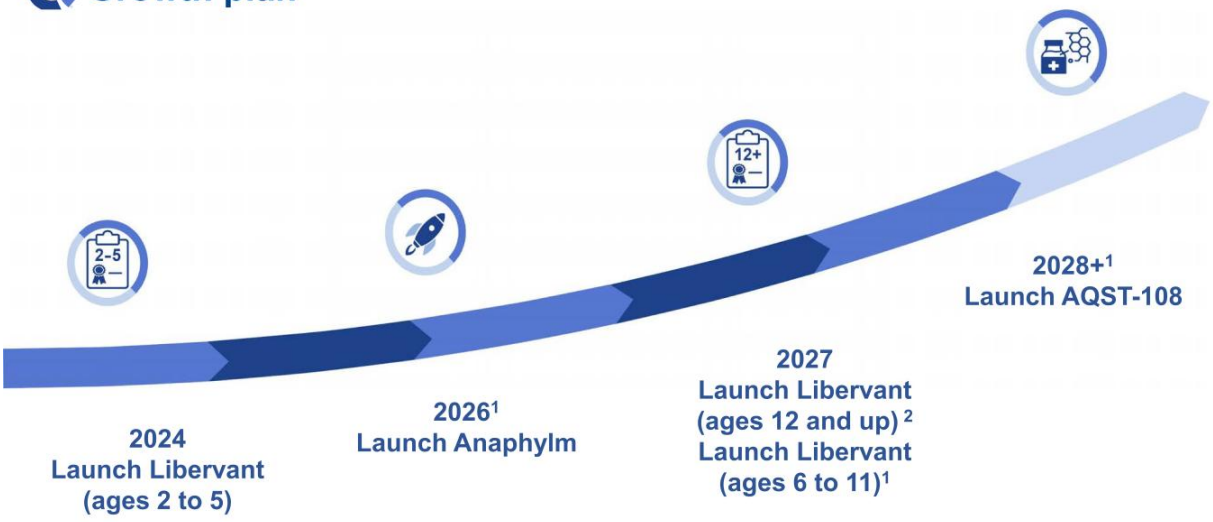
Diversified pipeline



1. Annual revenue includes revenue for patients 12 and up after launch in 2027. 2. Aquestive Therapeutics data on file.

Aquestive

Growth plan

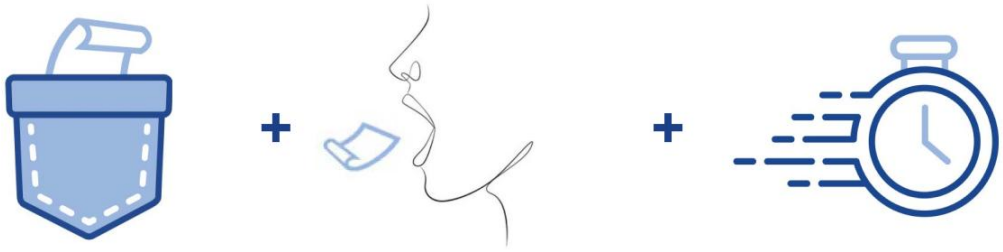


1. Assumes satisfaction of all predetermined clinical endpoints and approved by U.S. Food and Drug Administration (FDA). 2. Estimate is based on an orphan drug market exclusivity block until January of 2027 by an FDA approved nasal spray product.

Aquestive

Anaphylm™ (epinephrine) Sublingual Film

Anaphylm is the first and only non-device based, orally delivered epinephrine product candidate



Easy To Carry	Easy To Administer	Works Quickly[1]

1. Aquestive Therapeutics data on file.

Anaphylm is fast-acting and well-tolerated, with a safety profile comparable to standard of care (SOC)[1]

1 Rapid absorption as demonstrated by:

- Consistent time to peak drug concentration (Tmax) of 12-15 minutes
- Onset of pharmacodynamics (PD) effects within 2-5 minutes

2 Consistent pharmacokinetics (PK) demonstrated across 5 administration procedures:

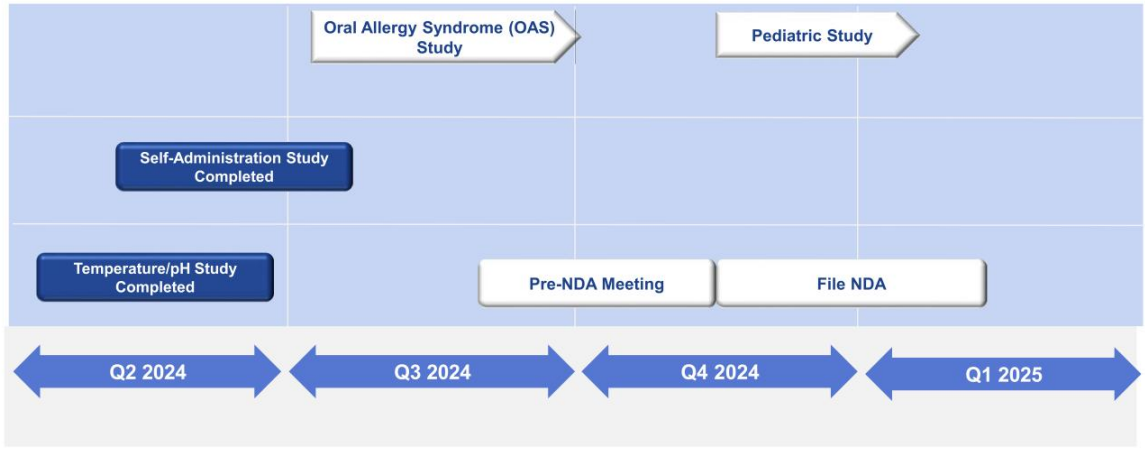
- Performed consistently in the presence of food (clinically), drink, temperature, and local swelling (non-clinically)
- Same peak concentration levels as autoinjectors of epinephrine

3 Safety and tolerability:

- Adverse events (AE's) were generally mild, all were transient and resolved without intervention

1. Aquestive Therapeutics data on file.

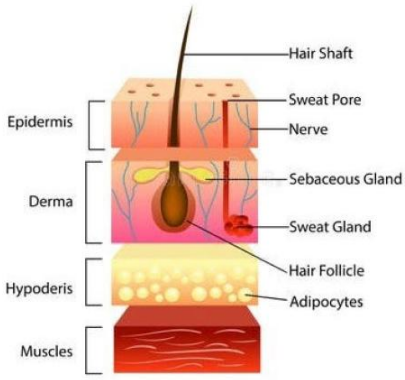
Expected clinical timeline for Anaphlym™



Aquestive

Our thesis (the big idea)

Human Skin Structure

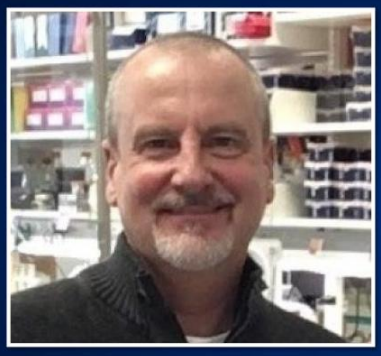


- **The utility of exogeneous epinephrine for the treatment of medical conditions has been limited due to the molecule's five-minute half-life as well as poor absorption capabilities[1]**
- **Aquestive's Adrenaverse technology unlocks the potential of epinephrine by addressing both problems[2]**

1. Jeong, W.Y., Kwon, M., Choi, H.E. *et al.* Recent advances in transdermal drug delivery systems: a review. *Biomater Res* **25**, 24 (2021). 2. Aquestive Therapeutics data on file.

Aquestive

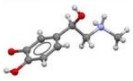

Scientific Overview of
Adrenergic Receptors
Dr. J. David Farrar



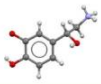
J. David Farrar, PhD

- Associate Professor
- UT Southwestern Medical Center, Dallas, TX
- PhD in Immunology
- 53 Publications with >4000 citations
- Specializes in neural regulation of immune function

Epinephrine and Norepinephrine regulate key biological functions

Adrenaline (Epinephrine) 

Secreted predominantly by the adrenal gland

Noradrenaline (Norepinephrine) 

Secreted by sympathetic nerve fibers that innervate peripheral tissues

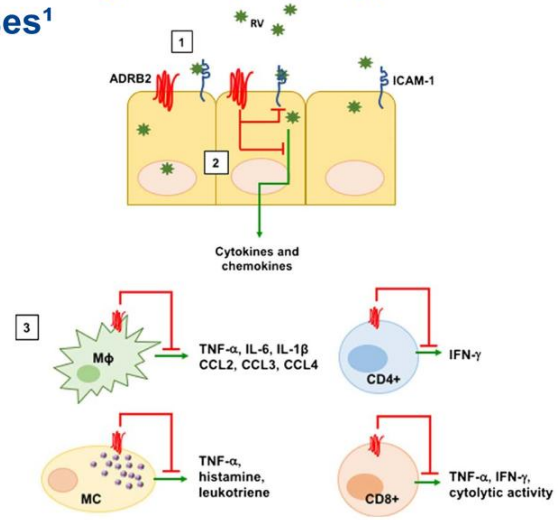
Physiological Regulation
- Digestion
- Body temperature
- Blood pressure
- Heart rate
- Breathing
- "Fight or Flight" response

Effects on Immune Cells
- Pathogen recognition
- Antibody production
- Immune cell trafficking
- General immune suppression

Signaling through the adrenergic receptor suppresses a variety of inflammatory processes[1]

Innate immune cells
- Macrophages
- Neutrophils
- Mast cells
- Dendritic cells
- Natural Killer (NK) cells

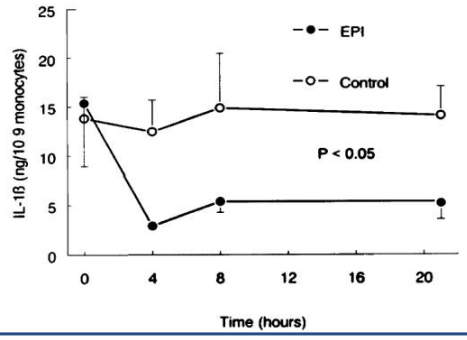
Adaptive immune cells
- T cells
- NK T cells
- B cells



1. Didem Ağaç, Michelle A. Gill and J. David Farrar, "Adrenergic Signaling at that Interface of Allergic Asthma and Viral Infections", Frontiers in Immunology, April 11, 2018; 9:736. doi: 10.3389/fimmu.2018.00736. PMID: 29696025; PMCID: PMC5904268.,

Epinephrine is a potent inhibitor of inflammatory cytokines in humans

Epinephrine inhibits endotoxin-induced IL-1beta production; roles of tumor necrosis factor – alpha and IL-10[1]

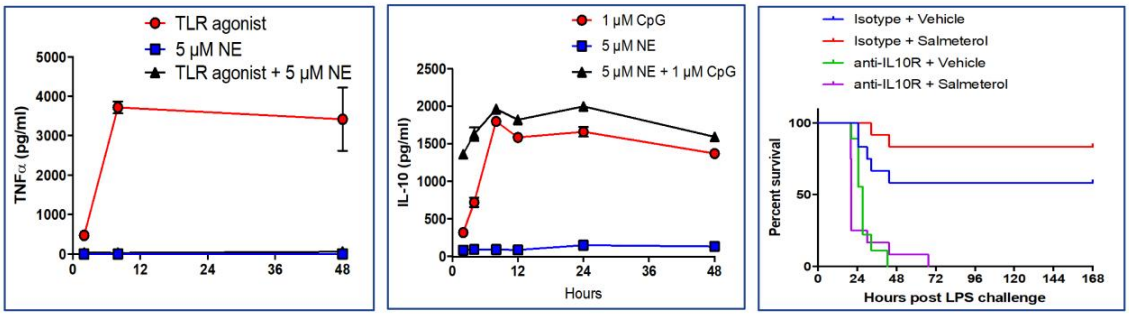


- Decreased serum concentrations of IL-1beta in septic patients following treatment with epinephrine
- Similar effects seen with other inflammatory cytokines
- Epinephrine increases serum concentrations of the anti-inflammatory cytokine, IL-10

1. Van Der Poll and Lowry, Am J Physiol., 1997, 273:R1829-R2137.

Epinephrine is a potent inhibitor of inflammatory cytokines in mouse models[1]

The β2-adrenergic receptor controls inflammation by driving rapid IL-10 secretion



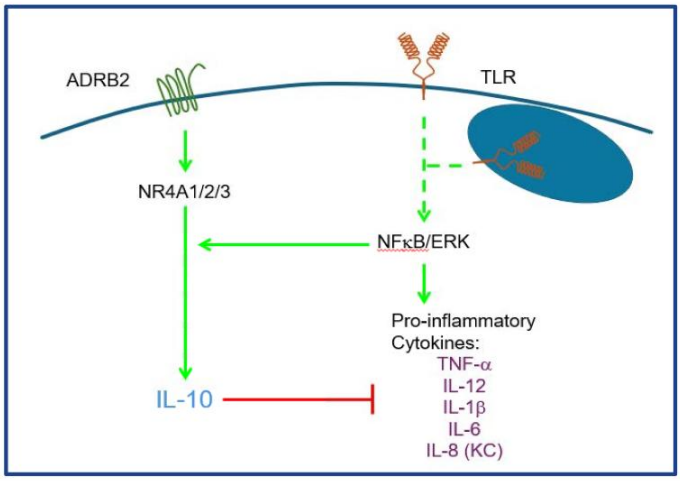
Norepinephrine (NE) potently suppresses TNFa while inducing rapid IL-10 secretion

1. Brain, Behav. Immun., 2018, Didem Agac, Leonardo D. Estrada, Robert Maples, Lora V. Hooper, J. David Farrar.

Adrenergic receptor beta 2 (ADRB2)-mediated suppression of inflammation

Adrenergic regulation of immune cell function and inflammation[1]

Unlike JAK inhibitors, which temporarily block inflammatory cytokine signaling, adrenergic signaling converts an inflammatory environment to an anti-inflammatory pathway.



1. Drashya Sharma, J. David Farrar , Seminars in Immunopathology (2020) 42:709-717; https://doi.org/10.1007/s00281-020-00829-6.

Key takeaways

- Epinephrine and Norepinephrine are natural immune modulators that act both systemically and locally to inhibit the magnitude of normal inflammation
- Pharmacological application of epinephrine inhibits inflammatory activities of both innate and adaptive arms of the immune system


Aquestive
Adrenaverse™ Prodrug Platform
R&D Overview
Stephen Wargacki, Ph.D.
Chief Science Officer

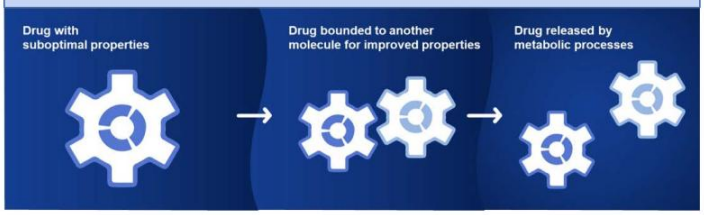
Stephen Wargacki, PhD

Chief Science Officer

- PhD, Polymer Chemistry
  University of Tennessee
- Postdoctoral Fellow
  Air Force Research Laboratory
- 15+ years experience in alternative drug delivery
- 29 publications (414 citations)
- 122 patents/applications (26 patent families)

Adrenaverse™: A robust and versatile prodrug platform

Adrenaverse consists of over 20 identified prodrug compounds

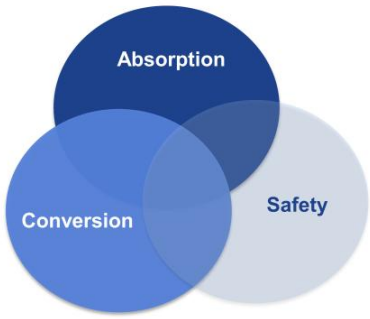


Aquestive's topical platform allows for:

- **Simple fast drying formulations**
- **Ability to accommodate single or multiple prodrugs**
- **Ability to include additional components without impacting performance**
- **Robust stability through six months accelerated conditions**

Allows for different critical profiles of key properties

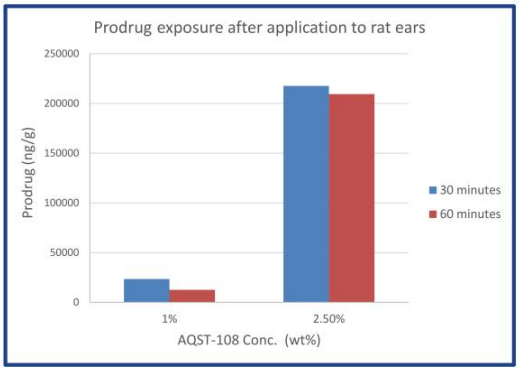
Enables the development of patient centric formulations tailored to the needs of the indication

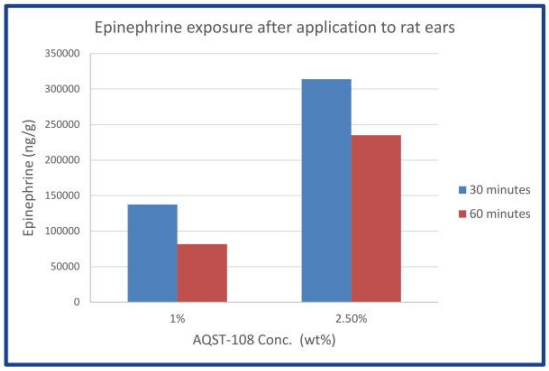


Aquestive

Non-clinical results (pharmacokinetics in rat ears)[1]

AQST-108 (epinephrine) Topical Gel demonstrates significant local absorption for over one hour without systemic exposure



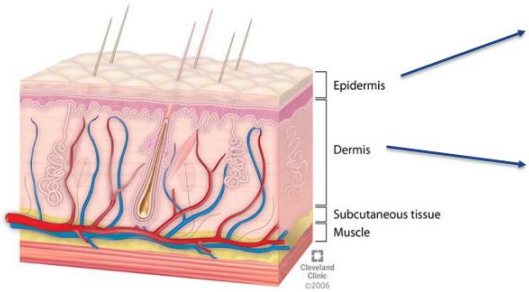


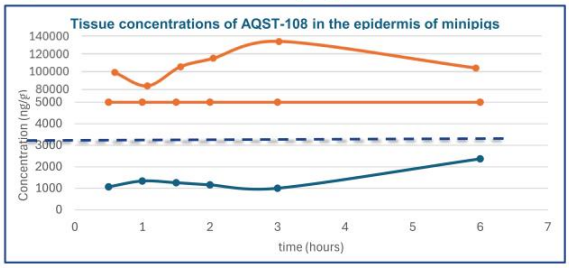
1. Aquestive Therapeutics data on file.

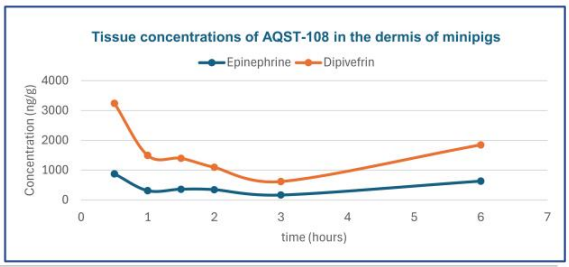
Aquestive

Non-clinical pharmacokinetic (PK) results in minipigs[1]

Results show high exposure in both dermis and epidermis lasting > 6 hours and no systemic exposure even at high body surface area coverage







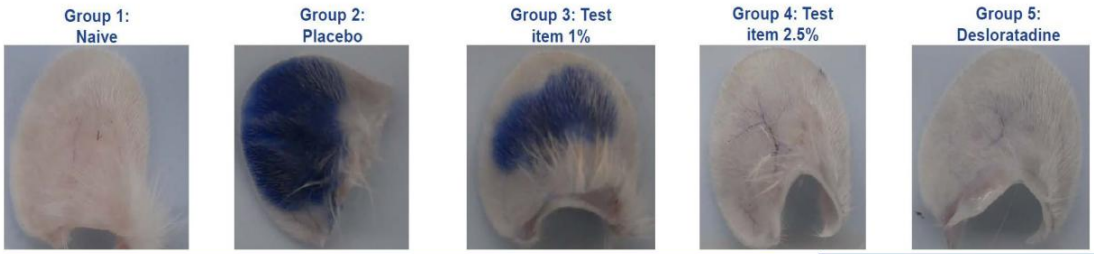
2.5% topical gel applied at 30mg/cm2
7, 10, and 12% Body Surface Area (BSA) coverage[2]

1. Aquestive Therapeutics data on file. 2. Single (2.5hr) timepoint detected systemic 108 at 12.5% BSA.

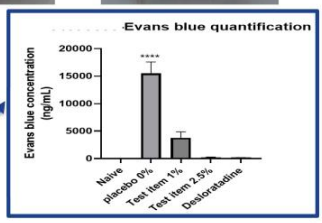
Aquestive

Non-clinical results - passive cutaneous anaphylaxis in rat ears[1]

AQST-108 resolves cutaneous anaphylaxis in rat ears, preventing dye profusion



- N=10 rats per group (except N=5, naïve control) were given either topical application of: Placebo, 1% or 2.5% AQST-108 was applied, high dose oral histamine (desloratadine) as positive control
- Injection of 2,4-dinitrophenol (DNP), an immunoglobulin E (IgE) specific antibody, which induces mast cell degranulation releasing histamine and proinflammatory cytokines
- Evans Blue dye was also injected to observe increased capillary profusion (see chart)

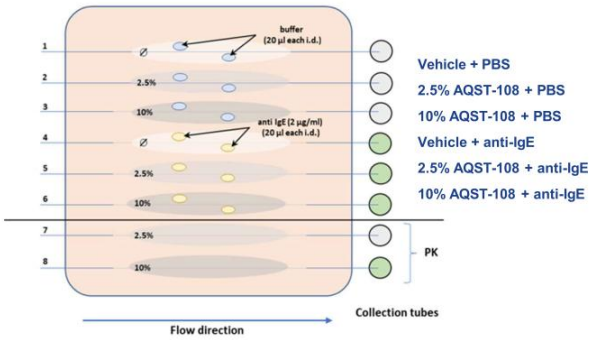


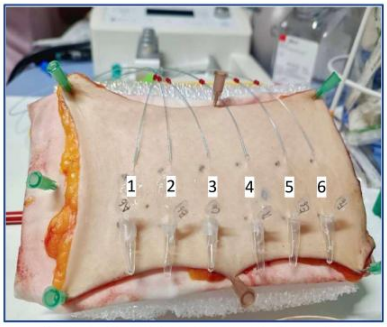
1. Aquestive Therapeutics data on file.

Aquestive

Ex-Vivo human skin microdialysis

Design: Freshly excised human skin used for microdialysis of interstitial fluid across multiple treatment groups[1]





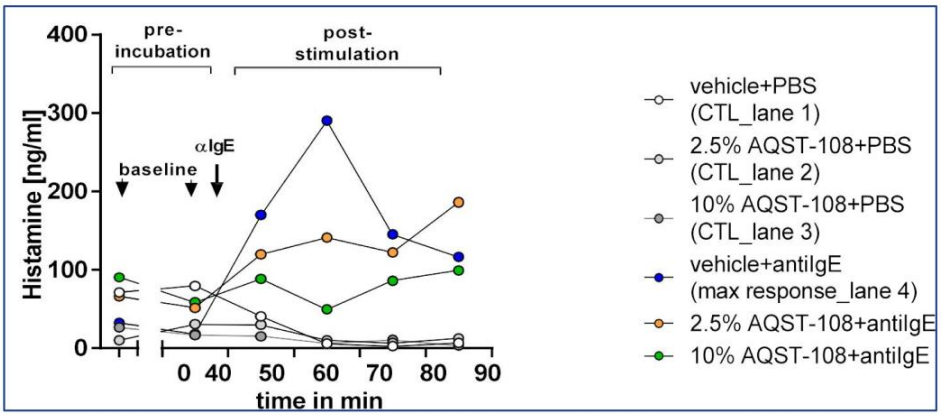
Ex vivo skin explant with sampling lanes 1– 6

1. Aquestive Therapeutics data on file.

Aquestive®

Topical AQST-108 human skin microdialysis results[1]

AQST-108 demonstrates that histamine release is inhibited through mast cell stabilization in ex-vivo human skin provoked with IgE antibodies

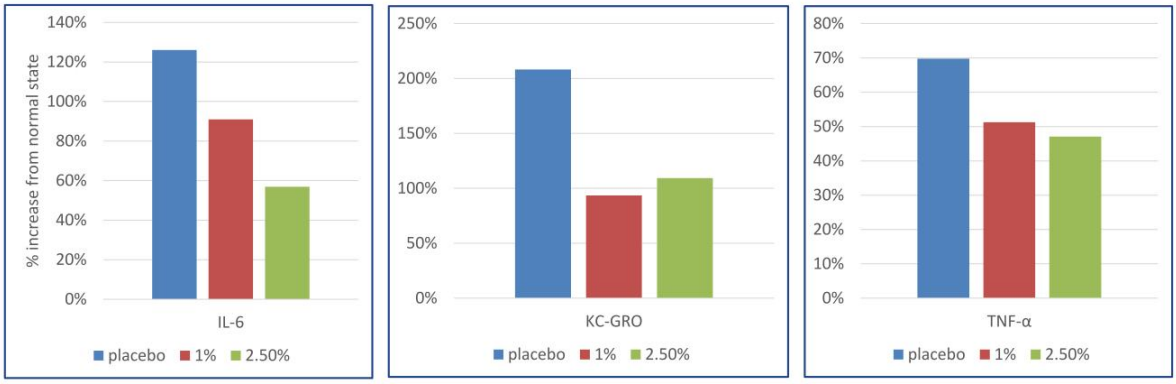


1. Aquestive Therapeutics data on file.

Aquestive

Cytokine analysis from passive cutaneous anaphylaxis (PCA) model[1]

AQST-108 demonstrates immunomodulation across multiple cytokines monitored in the PCA model. Graphs represent % cytokine presence during PCA relative to the naive state[2]

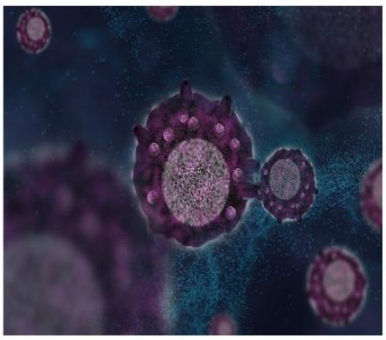


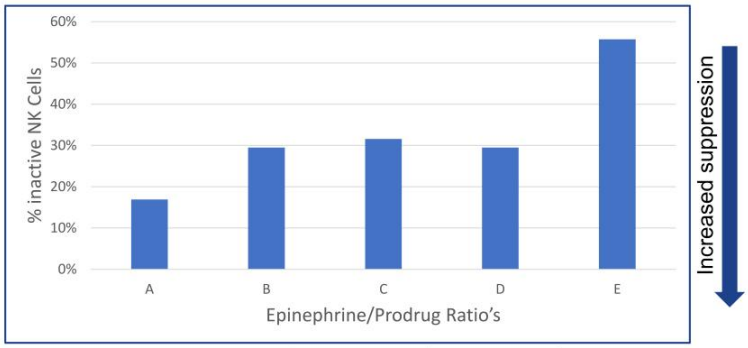
1. Aquestive Therapeutics data on file. 2. p<0.01compared to Placebo; Utilized One way ANOVA; Dunnett's test for multiple comparisons.

Aquestive

Modulation of NK cell activity[1]

AQST-108 suppressed NK cell activation across of range of concentrations exceeding the half-maximal inhibitory concentration (IC50) above a 750nM [2]





	ritlecitinib[3]	cortisol	108
Inhibition (IC50) - NK cells	509nM	200nM	750nM

1. Aquestive Therapeutics data on file. 2. IC50 is a measurement of how much of a drug is needed to inhibit a biological process by half. 3. ritlecitnib IC50 extracted from FDA summary basis of approval for Litfulo™, results shown are a cross-study comparison.

Aquestive

AQST-108 patent applications potentially extending into 2046[1]

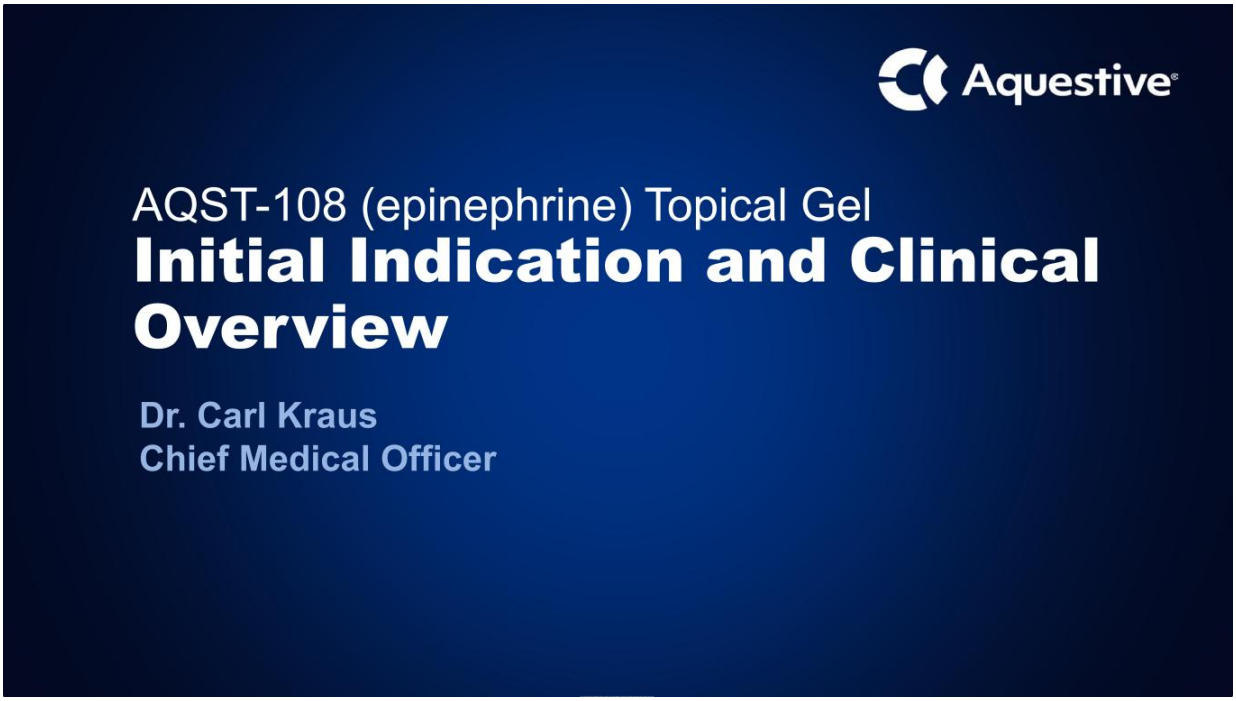
TITLE	PATENT STATUS
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	▶ **Priority date: May 5, 2016** ▶ Possible patent term to 2037
ENHANCED DELIVERY EPINEPHRINE AND PRODRUG COMPOSITIONS	▶ **Priority date:** May 4, 2017 ▶ Possible patent term to 2037
PRODRUG COMPOSITIONS AND METHODS OF TREATMENT	▶ **Priority date:** Late 2019 ▶ Possible patent term to 2040
TOPICAL DELIVERY OF EPINEPHRINE AND PRODRUG COMPOSITIONS	▶ **Priority date:** March 2025 ▶ Possible patent term to 2046

1. If the current patents applications are issued by the U.S. PTO, patent coverage would be extended to 2046.

Key takeaways

- AQST-108 non-clinical development demonstrates valuable proof points about absorption and conversion potentially resulting in durable local exposure in the skin without undesirable systemic exposure

- Models successfully demonstrated desired pharmacology and immunomodulation that can be harnessed clinically and is patent-protected


Aquestive
AQST-108 (epinephrine) Topical Gel
Initial Indication and Clinical Overview
Dr. Carl Kraus
Chief Medical Officer

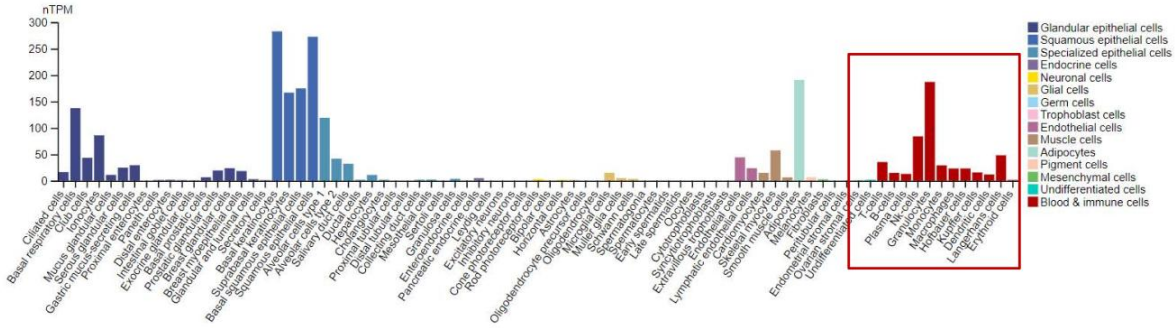
Carl Kraus, MD

Chief Medical Officer

- M.D., Washington University in St. Louis
- Residency, University of Chicago
- Fellowship, National Institutes of Health
- Clinical Reviewer, CDER, FDA
- 18+ years experience in multiple therapeutic development programs from preclinical – Phase IV

The Human Protein Atlas: clues from receptor expression

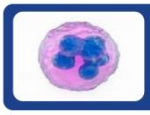
In addition to high expression on skin tissue, ADRB2 has high expression on immune cells[1]



33 1. Single cell type - ADRB2 - The Human Protein Atlas, ADRB2 – adrenergic receptor beta 2.

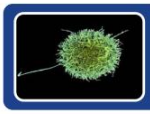
Aquestive

Skin disorders potentially addressable by adrenergic receptor-mediated immune cell targeting



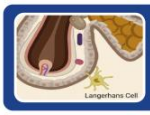
Granulocytes

- Mast cells – Cutaneous mastocytosis, MCAS[1], Alopecia areata
- Neutrophils – Chronic granulomatous disease, Leukocyte adhesion deficiencies



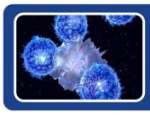
Natural Killer Cells

- Increased activity – Alopecia areata, Lupus, Rheumatoid Arthritis
- Decreased activity – Viral infections, proliferative diseases including cancers



Langerhans Cells[2]

- Alopecia areata
- Langerhans cell histiocytosis – Skin manifestations are common and mimic other conditions

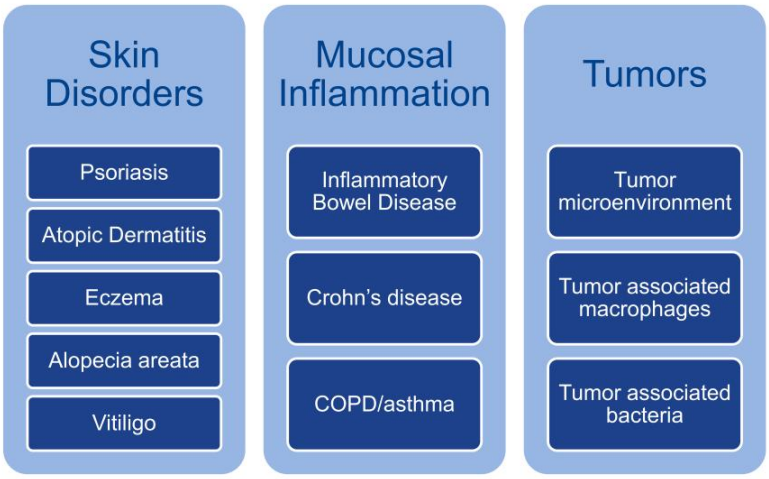


T-cells

- Cytotoxic – Autoimmune diseases (Alopecia areata), viral infections
- Helper – Atopic Dermatitis, mycobacterial infections, Asthma

 1. MCAS – mast cell activation syndrome.

Potential indications for Adrenaverse™ technology[1]

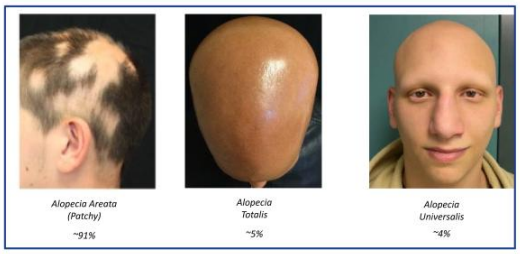


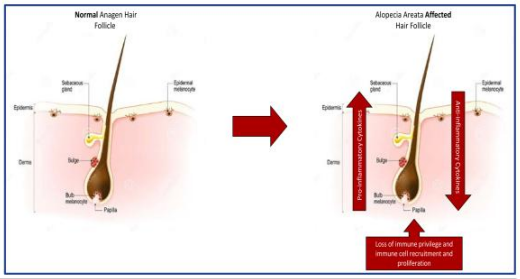
1. Not yet in development; assumes successful clinical development and approval by FDA.

Aquestive

Alopecia areata (AA) background[1]

- AA is an autoimmune disease leading to hair loss on the scalp, face, and in more severe cases, other body areas
- The mechanisms leading to AA are multifactorial, including an autoimmune response that results in the loss of hair follicle immune privilege
- The patient will begin treatment based on disease severity (> 50% involvement – JAK inhibitors; < 50% involvement – corticosteroids)

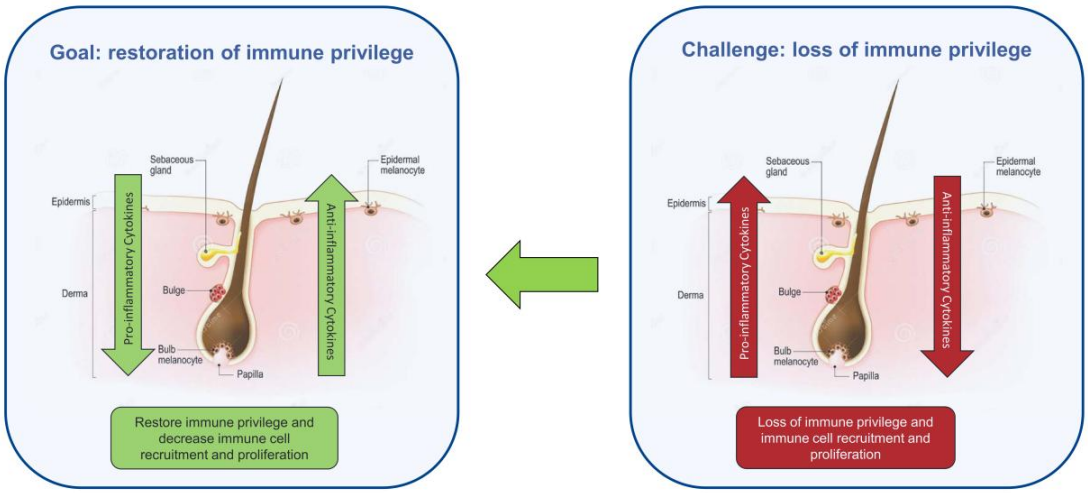




1. UpToDate; NAAF.org; BioMedTracker; Benigno et al. A large cross-sectional survey study of the prevalence of AA in the US. 2020; Litfulo Pfizer HCP Page. SALT Evaluation; King et Defining severity in Alopecia areata: current perspectives and a multidimensional framework. 2022, accessed January 2024.

Aquestive

Adrenergic receptor agonism may address early AA pathology[1]

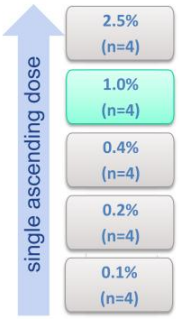


1. Hair follicle immune privilege and its collapse in Alopecia areata - Bertolini - 2020 - Experimental Dermatology - Wiley Online Library.

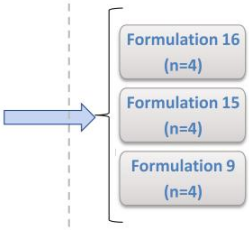
Aquestive

Completed first in human (FIH) two-part study[1]

Part 1 – single ascending doses of a single formulation of AQST-108



Part 2 – a single dose of 1 of 3 formulations of 1.0% AQST-108



Part 1 outcomes:

- No serious adverse events (SAE) or topical adverse events (AE)
- Calculated % AQST-108 in skin remained relatively consistent, between 9-14%
- No AQST-108 concentration in plasma observed
- Systemic epinephrine concentrations remained within normal physiologic range for all doses

1.0% AQST-108 strength down-selected to Part 2

Part 2 outcomes:

- No SAEs or topical AEs
- Calculated % AQST-108 in skin remained relatively consistent across formulations (11-12%)
- No AQST-108 concentration in plasma observed

1. Aquestive Therapeutics data on file.

Aquestive

AQST-108 planned Phase 2 Alopecia areata clinical study[1]

A Phase 2, multi-center, double-blind, placebo-controlled, dose-ranging, adaptive study to evaluate the safety and efficacy of AQST-108 in mild to moderate Alopecia areata patients

Phase 2a	Phase 2b Continuation
• N=48, 3 doses and placebo • 12 weeks • Trichoscopy evaluations and labs at baseline, 2, 4, 6, 8 & 12 weeks	• Additional subjects • 12 additional weeks for Ph2a subjects • 24 weeks for additional subjects • SALT, trichoscopy and labs

Objectives of Phase 2a Study

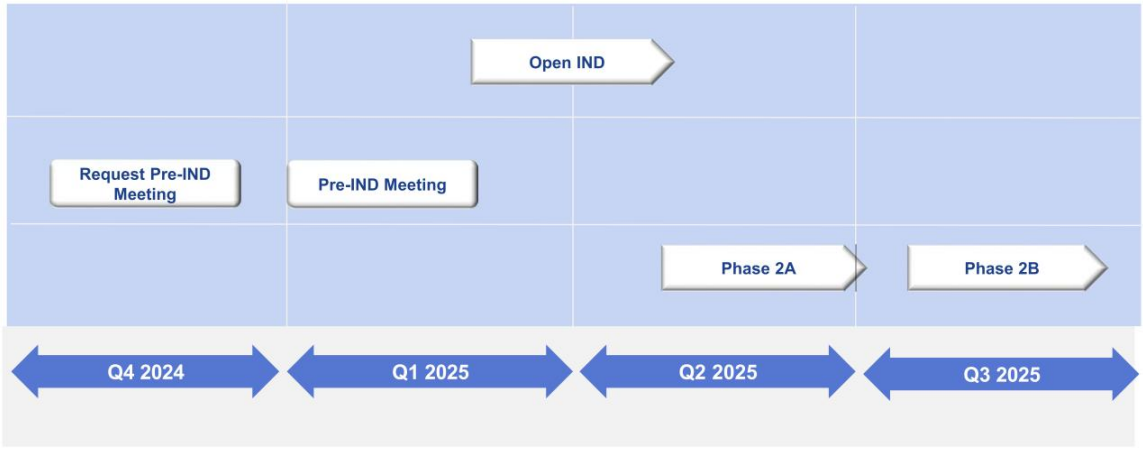
Assess the safety and efficacy of AQST-108 in Alopecia areata patients following 12 weeks of treatment as determined by digital imagery (Canfield)

Objectives of Phase 2b Study

To evaluate the safety and efficacy of AQST-108 compared to placebo in AA patients with less than 50% scalp hair loss, on regrowth of lost hair (as measured by change from baseline in Severity of Alopecia Tool (SALT) Score) at week 24

1. Plan on commencing study after alignment with the FDA.

Planned AQST-108 clinical and regulatory pathway[1]



1. End of phase 2 meeting with the FDA is planned for the fourth quarter of 2025 or the first quarter of 2026.

Aquestive

Key takeaways

- AQST-108 demonstrated no serious adverse events or topical adverse events
- Lack of plasma concentration after application of AQST-108 may indicate conversion in the dermis at the targeted site of action
- Plan to hold pre-IND meeting and advance AQST-108 into a Phase 2 clinical study for mild to moderate Alopecia areata

Aquestive®

Alopecia areata

Market Potential

Dan Barber

Patient unmet needs in moderate to severe Alopecia areata[1]

Existing JAK inhibitor therapies

- are systemic and have known side effects
- have a black box warning
- only show significant improvement in approximately one out of three cases
- have an unacceptable relapse rate
- are expensive

1. Aquestive Therapeutics data on file.

Alopecia areata represents a potential opportunity[1]

Reasons to Believe

- Patient unmet need is well-documented and understood
- Planned development endpoints that are potentially achievable
- Competitive landscape indicates pricing will continue to be reasonable (severe is high)
- Commercial opportunity can fit within a growing Aquestive commercial infrastructure

Initial Target Product Profile[2]	
Description	• Topical gel form of AQST-108
Indication	• Moderate and severe Alopecia areata patients
Dosage and Administration	• Apply once in the morning and once at night
Safety	• Potential for no black box warning • No systemic effect may limit side effects
Value Proposition	• May be an alternative to using JAK inhibitors • May improve treatment for the two-thirds of severe patients who see no improvement with JAK inhibitors • May improve treatment in conjunction with JAK inhibitors

1. Aquestive Therapeutics data on file. 2. Dependent on final clinical and regulatory outcomes.

Alopecia areata occurs in ~2% of the population

Alopecia areata by the Numbers

- Estimated 6.7M people in the U.S. have been affected by Alopecia areata[1]
- Equally prevalent between male and females[2] (average age of diagnosis is 31 years for males and 36 years for females)[3]
- Evidence suggests there may be a genetic link for some patients[4]
- ~39% of patients with Alopecia areata also have atopic dermatitis[5]
- ~43% of Alopecia areata patients are considered severe[6]

1. National Alopecia Areata Foundation, What you need to know about Alopecia areata, https://www.naaf.org/alopecia-areata, Accessed August 2024; 2. National Organization for Rare Disorders, Alopecia areata, https://rarediseases.org/rare-diseases/alopecia-areata/, Last Updated July 12, 2022; 3. Mirzoyev S., et al., Lifetime incidence risk of Alopecia areata estimated at 2. 1% by Rochester epidemiology project, 1990–2009, Journal of Investigative Dermatology, April 2014; 4. Lepe K., et al., Alopecia Areata, StatPearls, National Library of Medicine, Updated March 7, 2023; 5. Kolb L., et al., Atopic Dermatitis, StatPearls, National Library of Medicine, Updated August 8, 2022; 6. Benigno et al. A large cross-sectional survey study of the prevalence of AA in the US. 2020.

Aquestive®

Currently marketed products for severe AA are JAK inhibitors

Alopecia areata Treatment Landscape[1]

	Product/ Generic	Company	Mechanism of Action[2]	Route of Administration[2]	Dosing Frequency[5]	Approval Year (Indication)[3]	Monthly Treatment Cost (WAC)[4]
On-Label Branded Therapies	olumiant (baricitinib tablets)	Lilly	JAK1/2 inhibitor	Oral	Once daily	2022	$2,740 (2mg) – $5,480 (4mg)
	Litfulo (ritlecitinib)	Pfizer	JAK3 inhibitor	Oral	Once daily	2023	$4,240 (50mg)
	LEQSELVI (deuruxolitinib) tablets 8mg	SUN PHARMA	JAK1/2 inhibitor	Oral	Twice daily	2024	*Not yet announced by Sun Pharma*
Corticosteroids	Triamcinolone acetonide	Generic Rx	Steroid	Topical / Intralesional	Twice daily / Every 4-6 weeks until regrowth or failure	N/A	$50†
	Betamethasone	Generic Rx	Topical	Topical / Intralesional	Twice daily / Every 4-6 weeks until regrowth or failure	N/A	$50††
	Desoximetasone	Generic Rx	Topical	Topical / Intralesional	Twice daily / Every 4-6 weeks until regrowth or failure	N/A	$20††
Non-Steroidals	DPCP*	Generic Rx	Calcineurin inhibitor	Topical	Once weekly	N/A	-§
	SADBE**	Generic Rx	IL-13 & IL-4 antagonist	Topical	Once weekly	N/A	-§
	Methotrexate	Generic Rx	JAK1 inhibitor	Oral	Once weekly	N/A	$10
	Minoxidil	Generic Rx	Anti-hypertensive	Oral / Topical	Twice daily	N/A	$30
	Dupixent	Sanofi	IL-13 & IL-4 antagonist	SQ Injection	Every 2-4 weeks	N/A	$3,800

1. Aquestive Therapeutics data on file.

JAK inhibitors pricing for severe AA remains high

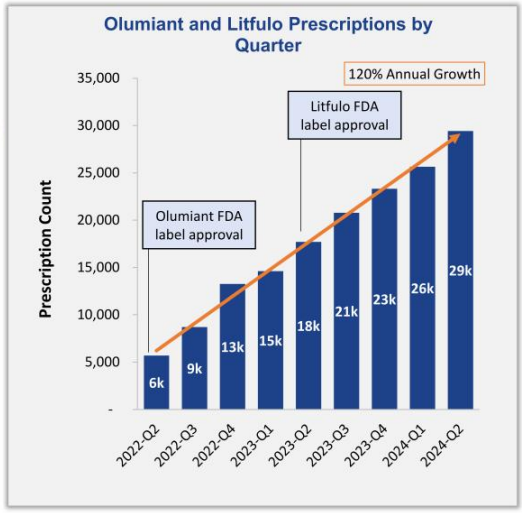
olumiant® (baricitinib) tablets 4mg, 2mg, 1mg	Litfulo® (ritlecitinib) capsules 50mg	LEQSELVI™ (deuruxolitinib) tablets 8mg
Lilly	Pfizer	
List Price (WAC, 4mg tablets): **$5,480/ month[1,2]**	List Price (WAC, 50mg tablets): **$4,240/ month[2]**	List Price (WAC, 50mg tablets): ***Not yet announced by Sun Pharma***
Indication(s): Adults with Severe Alopecia; Moderate-to-Severe RA*	Indication(s): Adults and Pediatric Patients >17 YoA with Severe Alopecia	Indication(s): Adults with Severe Alopecia
Black Box Warning on Label	Black Box Warning on Label	Black Box Warning on Label

*Rheumatoid Arthritis; following inadequate response to anti-TNF therapy

1. Lilly, How much should I expect to pay for Olumiant?; https://pricinginfo.lilly.com/Olumiant, accessed August 2024; 2.Redbook, Accessed August 2024.

Estimated $1 billion+ opportunity for JAK inhibitors[1]

- Olumiant label for AA granted in June 2022
- Litfulo label for AA granted in June 2023
- Combined prescriptions for Olumiant and Litfulo in 2nd quarter of 2024 totaled ~30K, representing a small fraction of the severe AA patient population
- This still represents a small fraction of the patient prevalence for severe AA, for which awareness is building



1. Aquestive Therapeutics data on file.

Aquestive

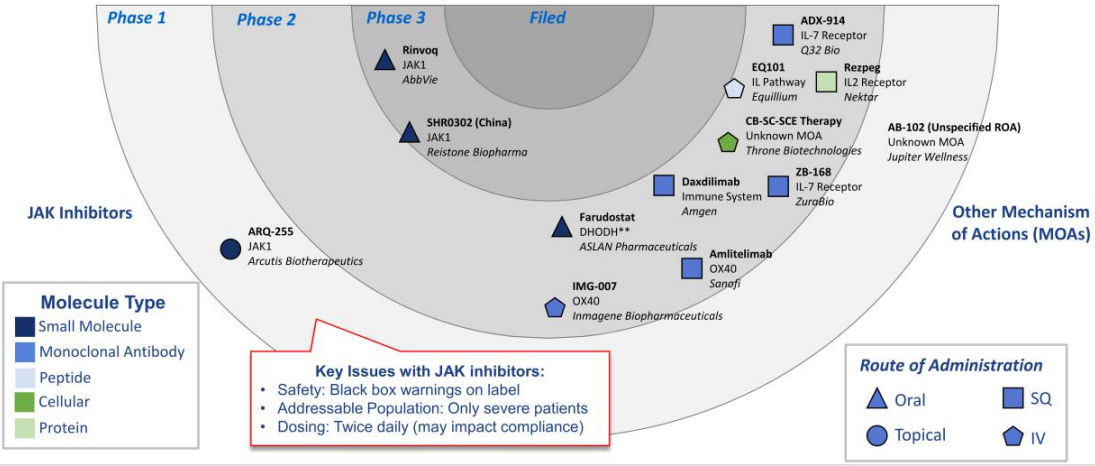
AQST-108 – potential annual peak net sales[1]

1. Aquestive Therapeutics data on file; potential revenues are Aquestive Therapeutics estimates based on current information; peak year sales are assumed ~5 years post launch.

Aquestive

Late-stage pipeline assets of competitors include multiple JAK inhibitor products, creating a unique space for AQST-108, if approved by FDA

Alopecia areata competitive pipeline[1]

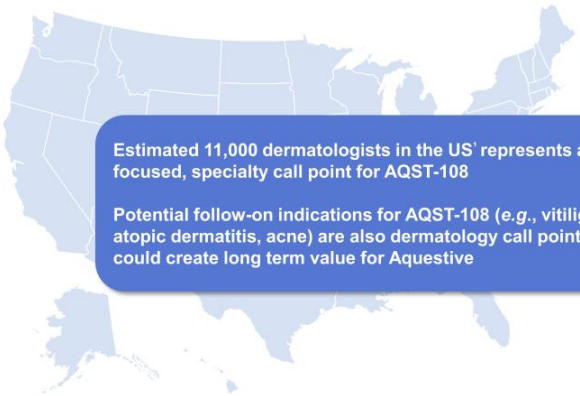


1. Aquestive Therapeutics data on file.

Aquestive

Planned commercialization efforts would focus on a derm call point

Focused commercialization effort with a dermatology call point



Estimated 11,000 dermatologists in the US[1] represents a focused, specialty call point for AQST-108

Potential follow-on indications for AQST-108 (*e.g.*, vitiligo, atopic dermatitis, acne) are also dermatology call points – could create long term value for Aquestive

Dermatologist-Expressed Level of **Unmet Need** for **severe** Alopecia areata patients[1] and **Receptivity to AQST-108**

"Product X* [AQST-108], *due to its superior safety profile, could likely be used for extended durations [compared to topical corticosteroids], given its lack of systemic absorption or local side effects. I think that's very beneficial."

- Dermatologist

"If Product X's efficacy is comparable to that of class I topical steroids, then it's going to be very desirable. And I could see this being first-line therapy."

- Dermatologist

1. Aquestive Therapeutics data on file.

Aquestive

Final key takeaways

- The Adrenaverse™ platform opens a new development pipeline for the Company
- AQST-108 for Alopecia areata has the potential to be an important opportunity


Aquestive
Closing Remarks and Q&A


Aquestive
Thank You

Aquestive®

Corporate Presentation

September 2024

Advancing medicines.
Solving problems.
Improving lives.

Disclaimer

This presentation and the accompanying oral commentary have been prepared by Aquestive Therapeutics, Inc. ("Aquestive", the "Company", "our" or "us") and contains 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™ (epinephrine) Sublingual Film through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the timing of submission of supporting and pediatric clinical studies, holding a pre-New Drug Application (NDA) meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; 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 expected growth of the U.S. epinephrine market including in value and the opportunity such growth presents to the Company should Anaphylm be approved by the FDA; the advancement and related timing of our Adrenaverse pipeline epinephrine prodrug product candidates, including AQST-108, through clinical development and FDA regulatory approval process, including holding a pre-IND meeting with the FDA for AQST-108 and the following launch of AQST-108, if approved by the FDA; the advancement and related timing of our product candidate Libervant® (diazepam) Buccal Film for the indicated epilepsy patient population aged between six and eleven years through clinical development and FDA regulatory approval and the following launch of Libervant for this patient population if approved by the FDA; the approval for U.S. market access of Libervant for this patient population aged six years and older and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for Libervant for these epilepsy patients six years of age and older; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel, through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of Alopecia areata for AQST-108, and holding a pre-investigational new drug application meeting (IND) with the FDA, and the following launch of AQST-108, if approved by the FDA; the commercial opportunity of Libervant, Anaphylm, AQST-108 and our other product candidates, including potential revenues (including projected peak annual sales) generated from commercialization of these products and product candidates should these product candidates be approved by the FDA; the potential growth of our patent portfolio including the extension of patent protection for Anaphylm should the pending patents be approved by the U.S. Patent and Trademark Office (PTO); the potential benefits our products and product candidates could bring to patients; our cash and financial position, including with respect to our 2024 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts.

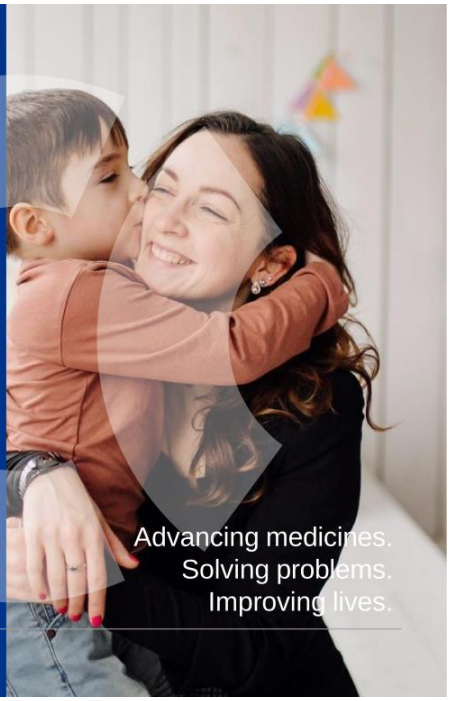
These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited 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 (including for pediatric patients), AQST-108, and the Company's other product candidates; risks associated with the Company's distribution work for Libervant, including any delays or changes to the timing, cost and success of Company's distribution activities and expansion of market access to patients aged two to five for Libervant; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm, AQST-108, Libervant for patients aged between six and eleven and other product candidates, or failure to receive FDA approval at all of any of these product candidates; risk of the Company's ability to generate sufficient clinical data for approval of our product candidates, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's future clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risk that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients aged six years and older until the expiration of the orphan drug market exclusivity period of the nasal spray product due to expire in January 2027, or for other reasons; risk of loss of U.S. market approval of Libervant for patients aged between two and five resulting from a legal challenge relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA's approval for U.S. market access of Libervant for this pediatric patient population, or for other reasons; 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 Libervant and other product candidates, including Anaphylm and AQST-108; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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 fund commercialization activities relating to Libervant for patients between two and five years of age and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, AQST-108 and Libervant for patients aged between six and eleven, should these product candidates be approved by the FDA, and for Libervant patients of six years and older upon expiration of the orphan drug marketing exclusivity period of the nasal spray product; risk that our manufacturing capabilities will be sufficient to support demand for Libervant for patients between two and five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the 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 for epilepsy patients between two and five years of age, and for older epilepsy patients if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant and Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the PTO; 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in the Company's 2023 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 presentation 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.

Aquestive®

Who we **are…**

A publicly traded pharmaceutical company (NASDAQ: AQST) focused on advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies



Drug delivery technologies

PharmFilm®

Adrenaverse™ Prodrug Platform

Adrenaverse platform contains a library of over 20 epinephrine prodrugs that demonstrate control of absorption and conversion rates across a variety of dosage forms and delivery sites, including allergy, topical (dermatological), and more.

Our products

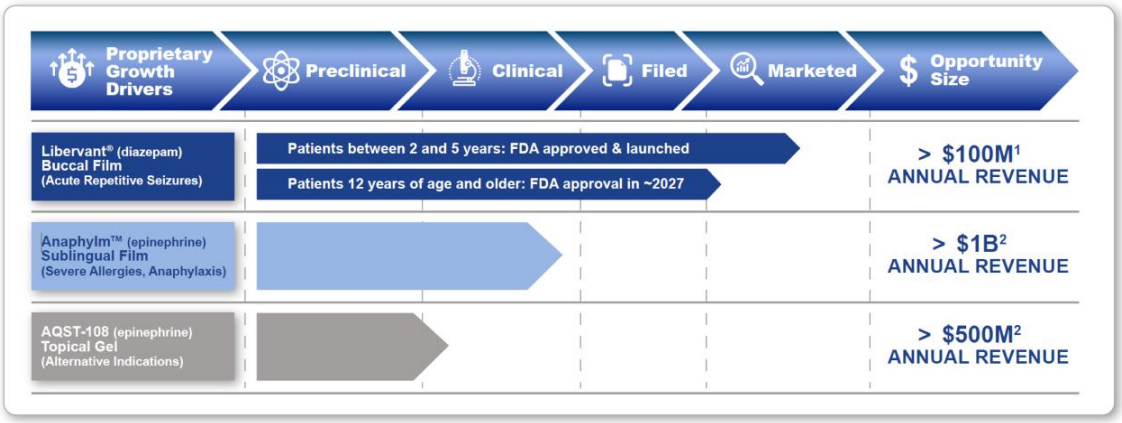
Aquestive is the go-to formulation development and commercial manufacturing partner for oral thin film products worldwide

Validation from 5 proprietary and licensed commercial products, supplying over 95% of the ***world's*** prescription oral thin films

1. Ondif collaboration with Hypera-Pharma (Brazil). 2. Sympazan collaboration with Otter Pharmaceuticals. 3. Libervant FDA Approval. 4. Libervant collaboration with Pharmanovia (Ex-US). 5. Emylif collaboration with Zambon (EU). 6. Suboxone collaboration with Indivior.

Aquestive

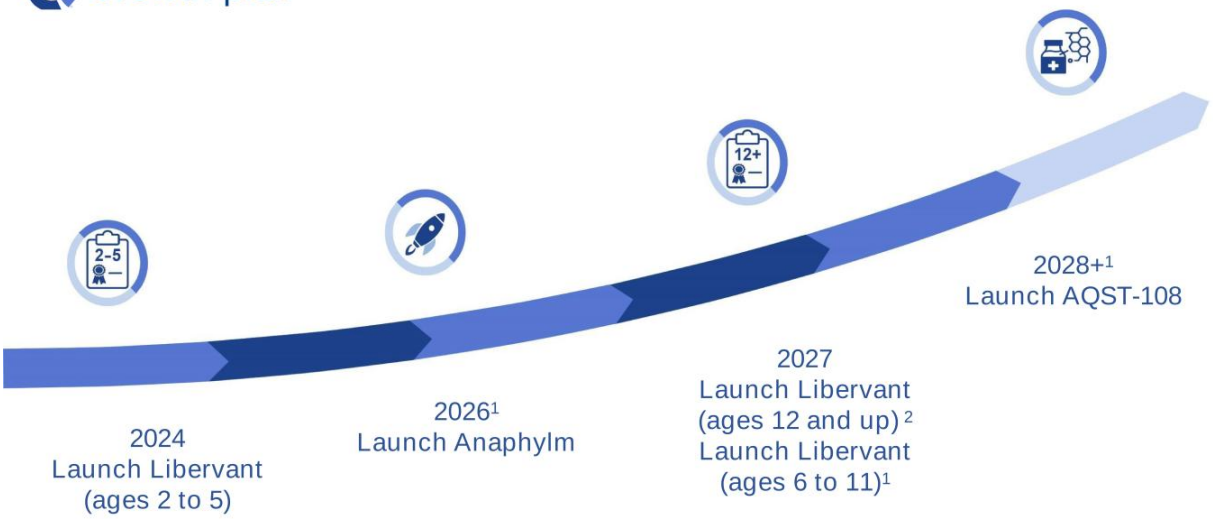
Diversified pipeline



1. Annual revenue includes revenue for patients 12 and up after launch in 2027. 2. Aquestive Therapeutics data on file.

Aquestive

Growth plan



1. Assumes satisfaction of all predetermined clinical endpoints and approved by U.S. Food and Drug Administration (FDA). 2. Estimate is based on an orphan drug market exclusivity block until January of 2027 by an FDA approved nasal spray product.

Aquestive

Our end-to-end capabilities

Development

- Formulation & analytical chemistry (CMC) leaders
- Regulatory experts with 6 FDA approvals
- Clinical trial design and execution
- Intellectual property know-how with 150+ patents worldwide

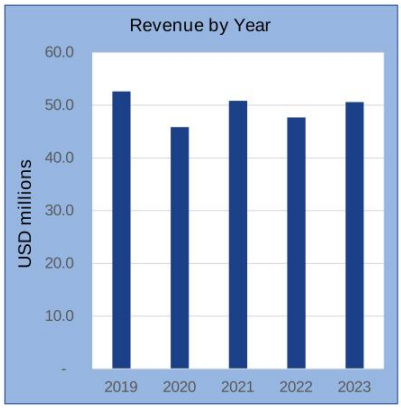
Production

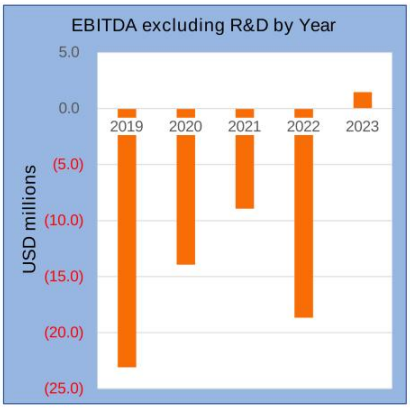
- Leading manufacturer of oral thin film technology (over 2 billion doses distributed for patient use)
- Two manufacturing and packaging facilities located in Indiana
- Comprehensive supply chain sourcing expertise

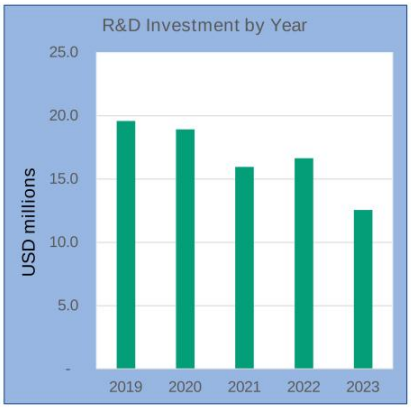
Commercialization

- Sales, marketing, and market access
- Direct to consumer capabilities
- Licensing and collaboration expertise

Financial snapshot







Dedicated and experienced leadership team

Daniel Barber
President, CEO & Director

Peter Boyd
SVP, HR & IT

Lori J. Braender
Chief Legal Officer, Chief Compliance Officer, Corporate Secretary

Cassie Jung
Chief Operating Officer

Sherry Korczynski
SVP, Sales & Marketing

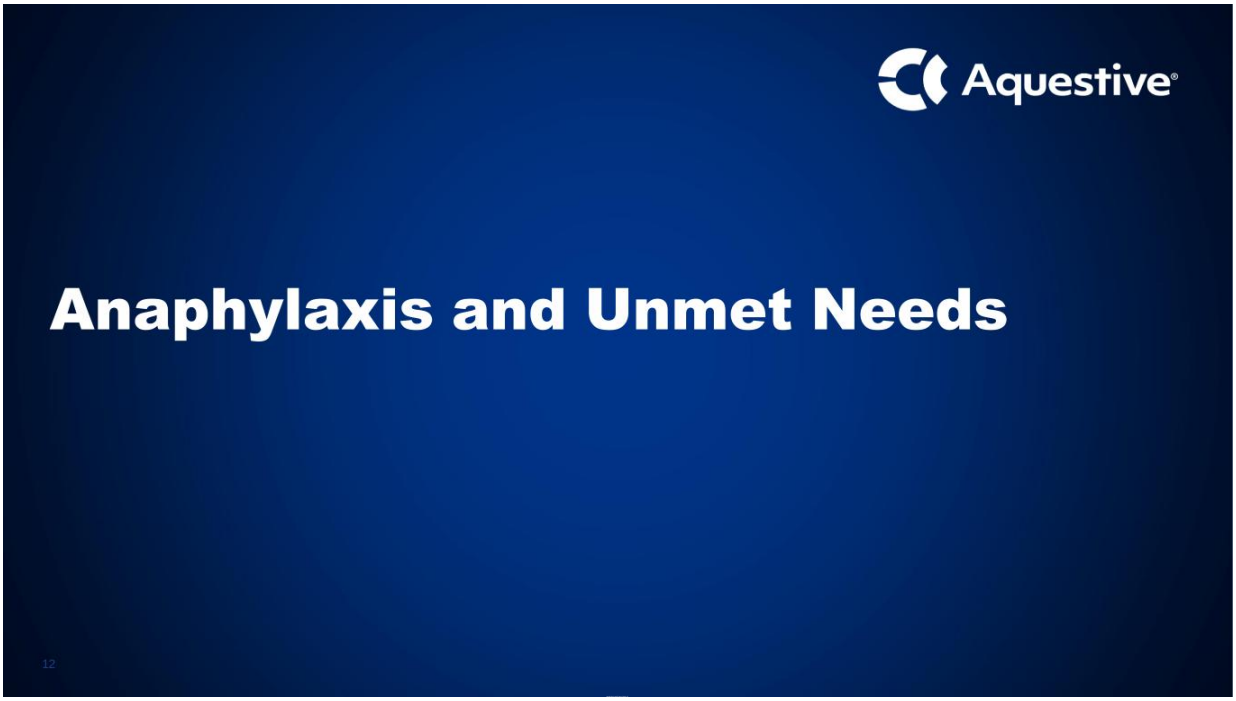
Carl Kraus
Chief Medical Officer

Mark Schobel
Chief Innovation & Technology Officer

Ernie Toth
Chief Financial Officer

Steve Wargacki
Chief Science Officer


6
FDA
drug approvals
More than
2 billion
PharmFilm® doses shipped worldwide
PharmFilm
19+
years since the company was founded
Aquestive®
(NASDAQ: AQST)
$50M+
of revenue in 2023
150+
employees based in Indiana and New Jersey
Products are available on
6
continents
2
Product launches are expected in the U.S. by 2027
Over
$1.5 billion1
in potential peak annual net sales from pipeline assets
1. Aquestive Therapeutics data on file.


Aquestive
Anaphylaxis and Unmet Needs
12

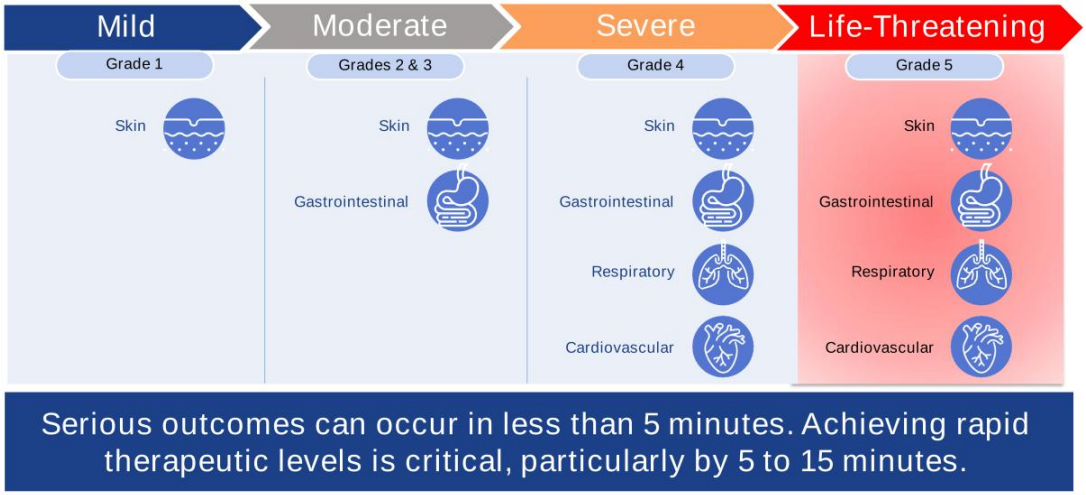
Anaphylaxis: a potentially fatal allergic reaction[1]

Severe systemic hypersensitivity allergic reaction
that is rapid in onset and can cause death

- Poses serious consequences for at-risk patients
- Often occurs in the community setting
- Patients at risk for anaphylaxis should have a long-term allergy-management plan

1. Turner PJ, et al. World Allergy Org J. 2019;12100066.

Stages of anaphylaxis: early intervention is critical[1]



Serious outcomes can occur in less than 5 minutes. Achieving rapid therapeutic levels is critical, particularly by 5 to 15 minutes.

1. Dribin et al., J Allergy Clin Immunol, 2021; Xu et al., Allergy Asthma Clin Immunol. 2014.

Aquestive

What is happening in the allergy rescue space

Multiple epinephrine medical devices (EMDs)

- Epinephrine, the only medication proven to stop a life-threatening allergic reaction, is the first-line treatment for anaphylaxis
- No oral products are available
- By nature, EMDs would be put in a carrying case

Aquestive

Several factors influence epinephrine administration during anaphylaxis

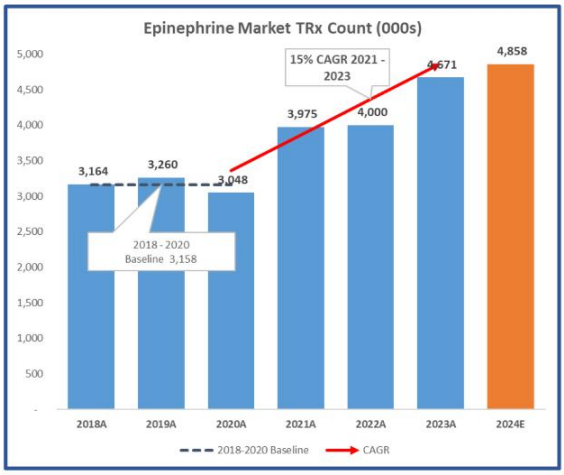
- Comorbidities
  - Rhinitis: 10% - 30%[1,2]
  - Chronic rhinosinusitis: 12%[3]
- Mental issues
  - Needle phobia: 50%[4,5,6]

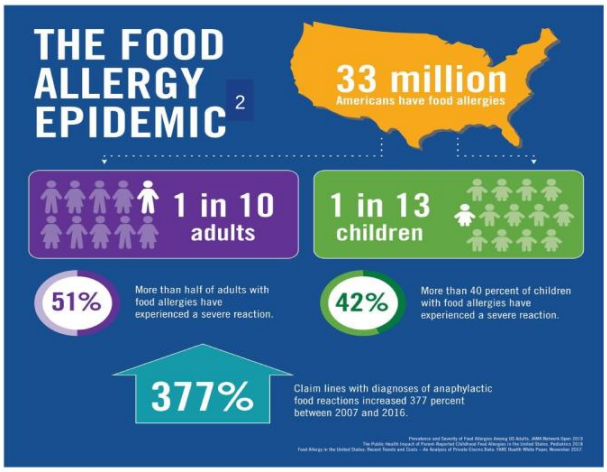
- Anaphlym™ has the potential to address these issues:
  - Orally administered – not affected by rhinitis
  - No needle or device

1. Nature Reviews Disease Primers on Allergic Rhinitis (2020). 2. Decker et. al. J All Clin Imm (2008). 3. Palmer et. al. All Asthma Proc (2019). 4. Warren et. al. Ann All Asthma Imm (2018). 5. Brooks et. al. Ann All Asthma Imm (2017). 6. Asthma and Allergy Foundation of America Patient Survey Report (2019).

Aquestive®

U.S. market has the potential to grow to ~$2B in value by 2031[1]





1. Aquestive Therapeutics data on file, scripts written for epinephrine autoInjectors have increased at a 15% compound annual growth rate (CAGR) from 2021- 2023.
2. https://foodallergy.org/resources/epidemic-infographic.

Aquestive

Lead Asset Anaphylm™ (epinephrine) Sublingual Film

Anaphylm executive summary

Anaphylm meets all predetermined primary and secondary endpoints of program clinical studies to support NDA submission

Large Market Opportunity

- ~$2B anaphylaxis market in value by 2031 with high unmet meet[1]

Novel Oral Product

- First and only oral epinephrine product candidate in development for anaphylaxis, with patent protection potentially into 2044
- World leader in oral thin film delivery, with proprietary PharmFilm® technology having been commercialized across six FDA approved products

Path to Launch

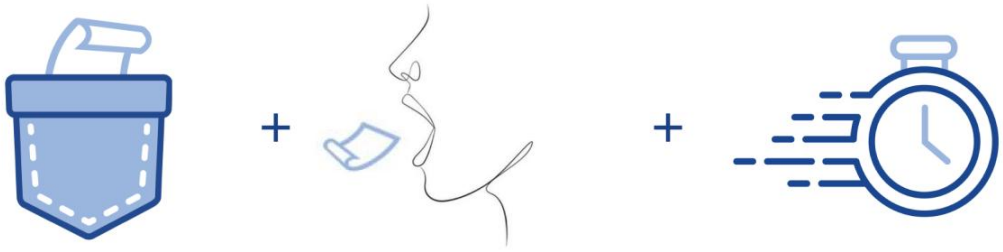
- Recently completed adult pivotal studies and met all predetermined primary and secondary endpoints[1]
- Positive FDA Type C meeting provided clear path to NDA submission by Q1 **'25**

1. Aquestive Therapeutics data on file.

Aquestive

Anaphylm (epinephrine) Sublingual Film

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



Easy To Carry	Easy To Administer	Works Quickly[1]

1. Aquestive Therapeutics data on file.

Aquestive

Most common reasons that people **don't** carry their epinephrine medical devices (EMDs)[1]

- Inconvenience
- Forgetfulness
- Cost
- Availability at other places, such as the home, car or school
- Expiration of the previous prescription
- Complacency if there has been no accidental exposure in a long time
- Did not understand that they were supposed to carry it at all times

1. https://community.kidswithfoodallergies.org/blog/new-epinephrine-study-shows-alarming-results; survey result reflect autoinjectors only.

Incorporating Anaphylm into **patients'** daily lifestyle routine

Anaphylm, if approved by the FDA, has the potential to be carried on the back of a phone.

1. https://www.reviews.org/mobile/cell-phone-addiction; July 2023.

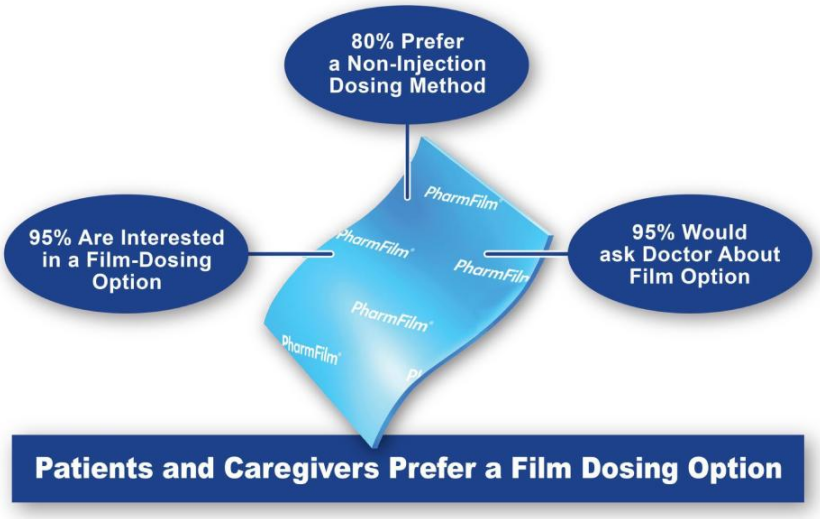
Aquestive

High epinephrine prescribing physicians have spoken[1]

~90%	expressed concern that their at-risk patients **don't** consistently have an epinephrine auto injector (EAI) with them when away from home
85%	articulated that **"A** sublingual film is more likely to be carried, thereby protecting more at-risk **patients"**
>75%	believe their at-risk patients too often and inappropriately carry oral antihistamines as a first-line treatment for a severe allergic reaction
55%	stated that **"My** overall **Rx'ing** of epinephrine would increase if the film were **available."** Average anticipated increase: >30%

1. Aquestive Therapeutics 2024 Survey data on file.

Patients and caregivers have spoken[1]



1. Aquestive Therapeutics 2024 Survey data on file.

Aquestive


Aquestive
Intellectual Property
25

Anaphylm's patented technology is broad, deep and constantly evolving with patent protection potentially extending into 2044[1]

ANAPHYLM Patent Title	Status
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	▸ 2 US patents granted ▸ 2 US applications ▸ 3 Foreign patents ▸ 8 Foreign applications ▸ **Priority date:** May 5, 2016 ▸ Possible patent term to 2037
ENHANCED DELIVERY EPINEPHRINE AND PRODRUG COMPOSITIONS	▸ 2 US applications ▸ 8 Foreign applications ▸ **Priority date:** May 5, 2016 ▸ Possible patent term to 2037
PRODRUG COMPOSITIONS AND METHODS OF TREATMENT	▸ 1 US application ▸ 10 Foreign applications ▸ **Priority date:** November 1, 2019 ▸ Possible patent term to 2040
PHARMACEUTICAL COMPOSITIONS WITH ENHANCED STABILITY PROFILES	▸ 1 US application ▸ 8 Foreign applications ▸ **Priority date:** October 22, 2021 ▸ Possible patent term to 2042
ENHANCED DELIVERY EPINEPHRINE COMPOSITIONS	▸ 1 US application ▸ 1 Foreign application ▸ **Priority date:** July 20, 2023 ▸ Possible patent term to 2044

1. The issued patents have a current expiry of 2037 and 2042. If the current patents applications are issued, patent coverage would be extended to 2044.

Aquestive

Anaphylm Clinical Program

Anaphylm program overview

Pivotal Study meets predetermined endpoints for single dose and repeat dose

Temperature/pH Study and Self-Administration Study meet predetermined endpoints; Oral Allergy Syndrome Study underway

Continue to anticipate a pre-NDA meeting with FDA prior to filing

Anaphylm is fast-acting and well-tolerated, with a safety profile comparable to standard of care (SOC)[1]

1 Rapid absorption as demonstrated by:

- Consistent time to peak drug concentration (Tmax) of 12-15 minutes
- Onset of pharmacodynamics (PD) effects within 2-5 minutes

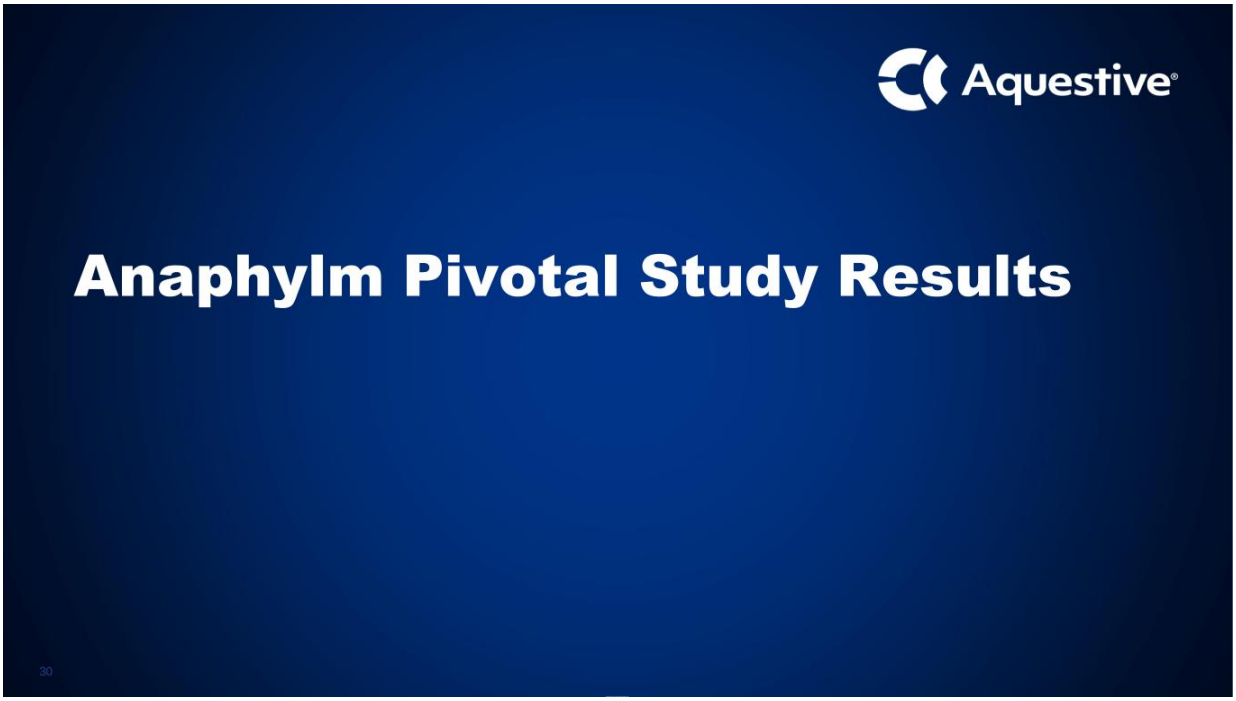
2 Consistent pharmacokinetics (PK) demonstrated across 5 administration procedures:

- Performed consistently in the presence of food (clinically), drink, temperature, and local swelling (non-clinically)
- Same peak concentration levels as autoinjectors of epinephrine

3 Safety and tolerability:

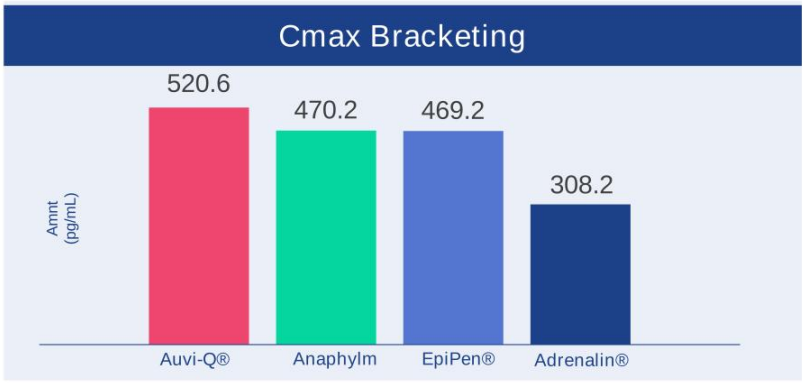
- Adverse events **(AE's)** were generally mild, all were transient and resolved without intervention

1. Aquestive Therapeutics data on file.


Aquestive
Anaphylm Pivotal Study Results
30

12mg single dose study meets primary endpoints of Cmax, demonstrating biocomparability to current SOC[1]

Primary endpoints predefined as Anaphylm values bracketed between injectable products for (1) maximum drug concentration (Cmax) and (2) area under the curve (AUC)0-10min, AUC0-20min, AUC0-30min, AUC0-45min

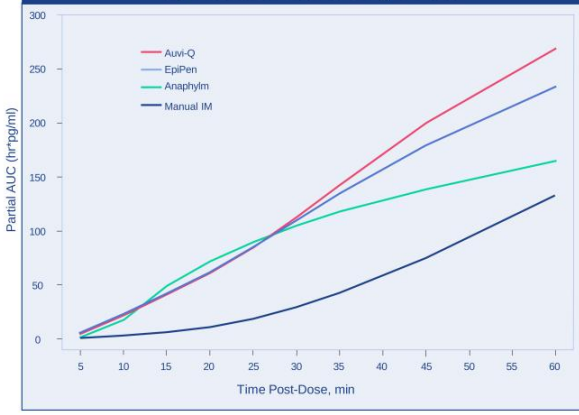


1. All figures are baseline corrected (removal of baseline effect) and geometric means; $pAUC_{0\text{-}20min}$ not statistically different ($p > 0.05$) (comparison to EpiPen); Aquestive Therapeutics data on file.

Aquestive®

Primary predetermined endpoint of pAUC, demonstrating biocomparability to SOC[1]

Geometric Mean Epinephrine Exposure Levels (pAUC) by Product After a Single Dose

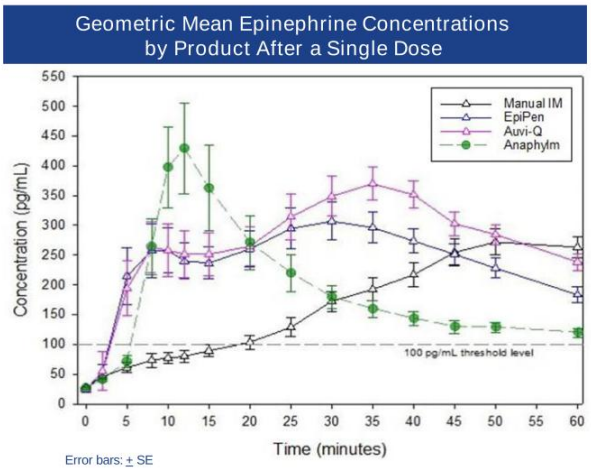


Anaphylm's partial AUC values demonstrate comparability to autoinjectors for 30 minutes post-dosing and remain bracketed beyond 60 minutes after dosing

1. Aquestive Therapeutics data on file.

Aquestive

Anaphylm demonstrated a rapid and robust PK profile[1]



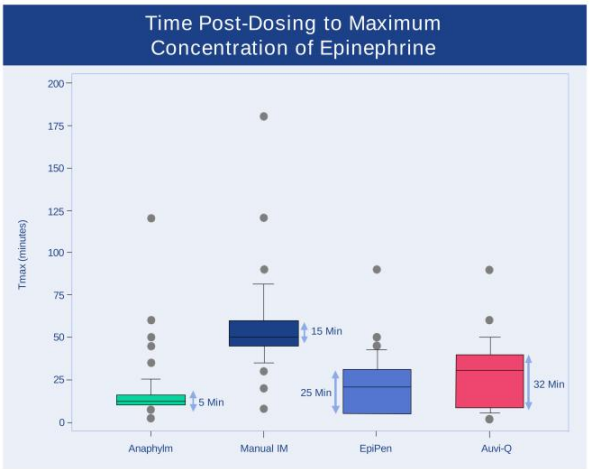
Anaphylm's epinephrine concentration:

- Exceeds Adrenalin beginning at 2 minutes
- Matches **EAI's** by 10 minutes
- Sustains levels above Adrenalin intramuscular out to 35 minutes
- Remains above 100 pg/mL for the relevant period of time, which is 60 minutes

1. Aquestive Therapeutics data on file.

Aquestive

Time to maximum concentration of Anaphylm demonstrates more consistency[1]



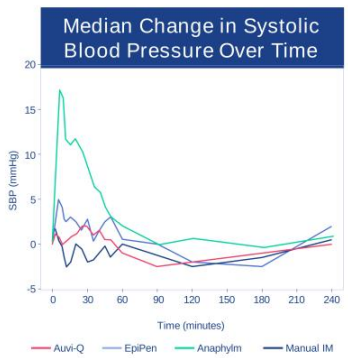
- Tmax is a surrogate for speed of absorption, a critical factor in treating Anaphylaxis
- Tmax consistency is an important measure of clinical performance
- Anaphylm Tmax interquartile range (5 min) is more consistent than EpiPen, Auvi-Q, and Adrenalin
- Anaphylm median Tmax of 12 minutes is faster than EpiPen (20 mins), Auvi-Q (30 mins), and Adrenalin (50 mins)

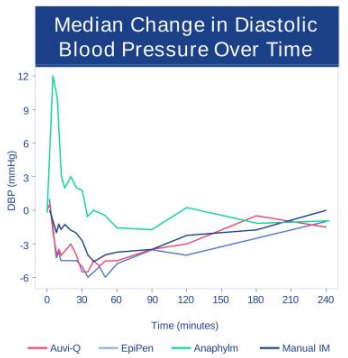
1. Aquestive Therapeutics data on file.

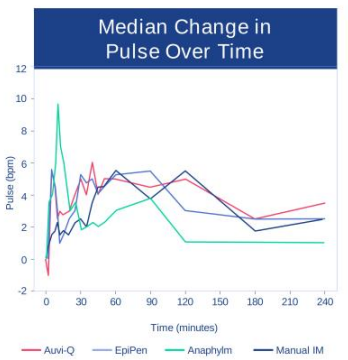
Aquestive

Anaphylm demonstrates rapid pharmacodynamic (PD)

- Epinephrine is administered during anaphylaxis to quickly raise heart rate and blood pressure to normal levels
- PD results were consistent with previous clinical study results







1. Aquestive Therapeutics data on file.

Aquestive®

Supportive Studies and Clinical Timeline

Anaphylm temperature/pH study results[1]

Test Condition	Cmax (Test Condition/Room Temperature Water)	AUC0-60min (Test Condition/Room Temperature Water)
Cold water	106%	98%
Hot water	104%	107%
Lemon water (target pH: 3)	98%	99%
Baking soda water (target pH:8)	123%	132%

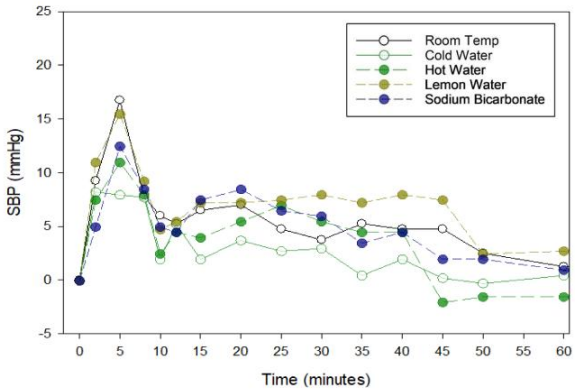
Key Takeaways:

- No significant difference in PK results based on changes in temperature and pH

1. Aquestive Therapeutics data on file.

Anaphylm temperature/pH study PD results[1]

Median Change in Systolic Blood Pressure Over 60 Minutes Following Administration of Anaphylm (epinephrine) Sublingual Film



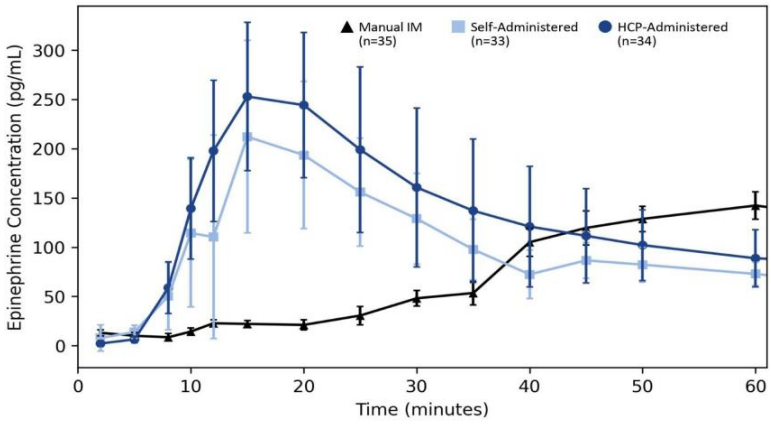
Key Takeaways:

- Topline results demonstrate no statistically significant difference in the maximum increase in systolic blood pressure due to temperature/pH conditions
- PD results for this study are in alignment with prior study results

1. Aquestive Therapeutics data on file.

Aquestive

Anaphylm self-administration PK study results[1]



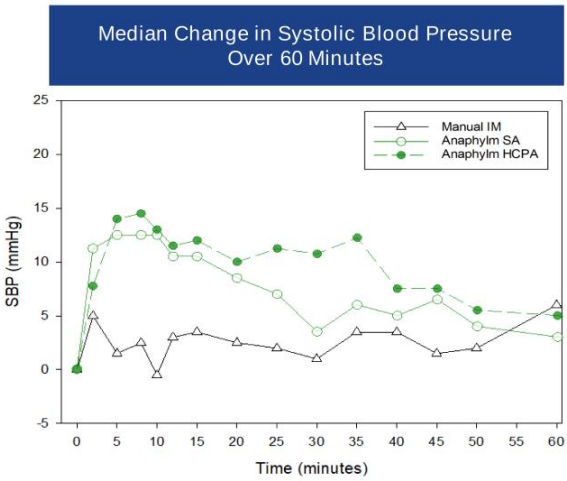
Key Takeaways:

- Cmax was not statistically different whether Anaphylm was self-administered or administered by an HCP
- Median Tmax was 15 minutes for Anaphylm whether self-administered or administered by an HCP
- Median Tmax for the Adrenalin intramuscular (IM) injection was 50 minutes after dosing

1. Aquestive Therapeutics data on file.

Aquestive

Anaphylm self-administration study PD results[1]



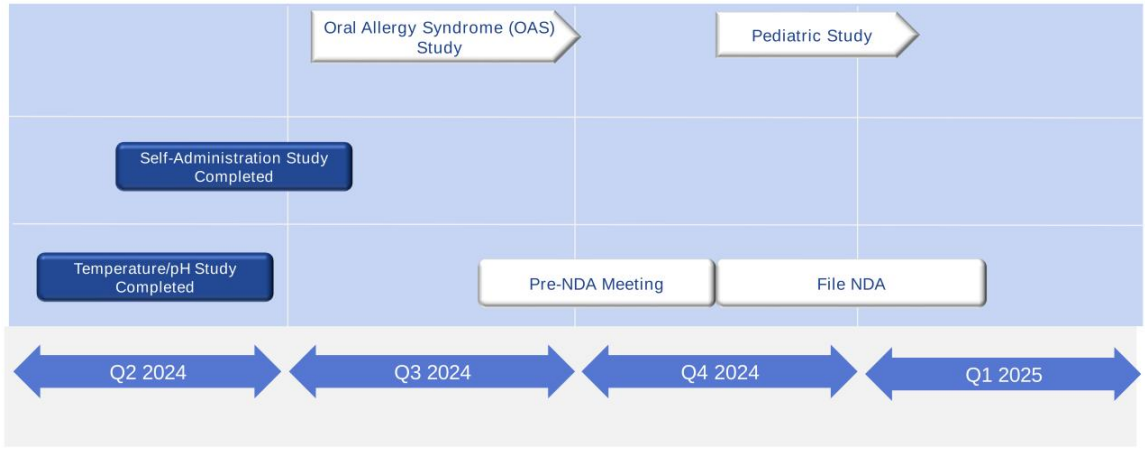
Key Takeaways:

- Topline PD results demonstrate no significant difference in the median increase in systolic blood pressure whether Anaphylm is self-administered or HCP-administered
- PD results for this study are in alignment with prior study results

1. Aquestive Therapeutics data on file.

Aquestive

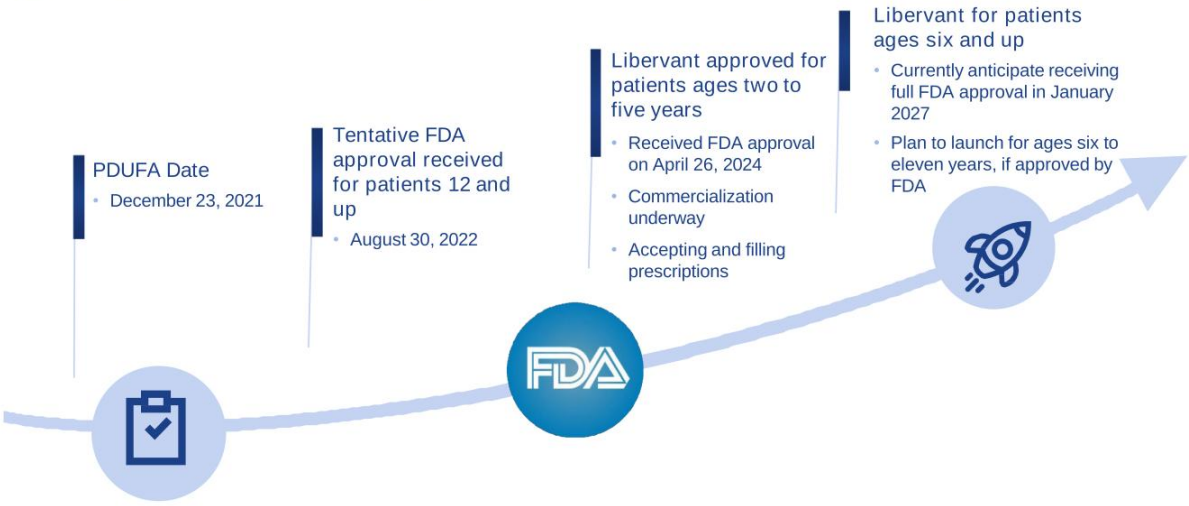
Expected clinical and regulatory timeline for Anaphlym



Aquestive

Pipeline Products

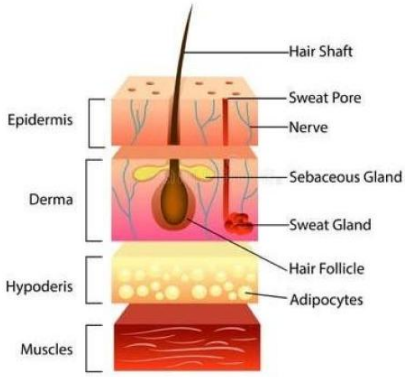
Expected full launch path for Libervant® (diazepam) Buccal Film



Aquestive

AQST-108 (epinephrine) Topical Gel

Human Skin Structure



- The utility of exogeneous epinephrine for the treatment of medical conditions has **been limited due to the molecule's five-**minute half-life as well as poor absorption capabilities[1]
- **Aquestive's** Adrenaverse technology unlocks the potential of epinephrine by addressing both problems[2]
- Completed First-in-Human Study (FIH)
- Pursing Alopecia areata as an initial indication[3]

1. Jeong, W.Y., Kwon, M., Choi, H.E. et al. Recent advances in transdermal drug delivery systems: a review. Biomater Res 25, 24 (2021). 2. Aquestive Therapeutics data on file.
3. See Investor Day Presentation dated September 27 located at Aquestive.com/investors/eventsandpresentations for more detail on clinical development and the commercial overview.

Aquestive

AQST-108 planned Phase 2 Alopecia areata clinical study[1]

A Phase 2, multi-center, double-blind, placebo-controlled, dose-ranging, adaptive study to evaluate the safety and efficacy of AQST-108 in mild to moderate Alopecia areata patients

Phase 2a	Phase 2b Continuation
• N=48, 3 doses and placebo • 12 weeks • Trichoscopy evaluations and labs at baseline, 2, 4, 6, 8 & 12 weeks	• Additional subjects • 12 additional weeks for Ph2a subjects • 24 weeks for additional subjects • SALT, trichoscopy and labs

Objectives of Phase 2a Study

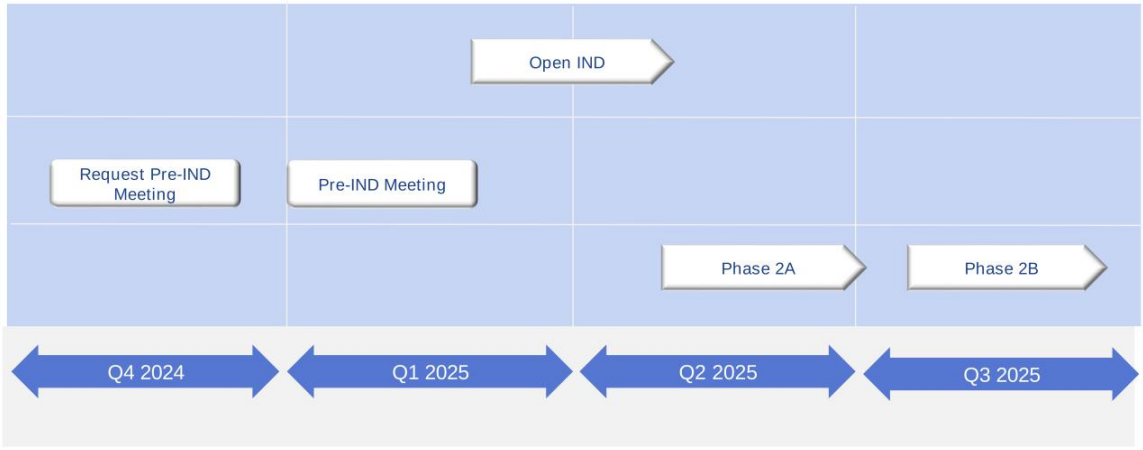
Assess the safety and efficacy of AQST-108 in Alopecia Areata patients following 12 weeks of treatment as determined by digital imagery (Canfield)

Objectives of Phase 2b Study

Evaluate the safety and efficacy of AQST-108 compared to placebo in AA patients with less than 50% scalp hair loss, on regrowth of lost hair (as measured by change from baseline in Severity of Alopecia Tool (SALT) Score) at week 24

1. Plan on commencing study after alignment with the FDA.

Planned AQST-108 clinical and regulatory pathway[1]

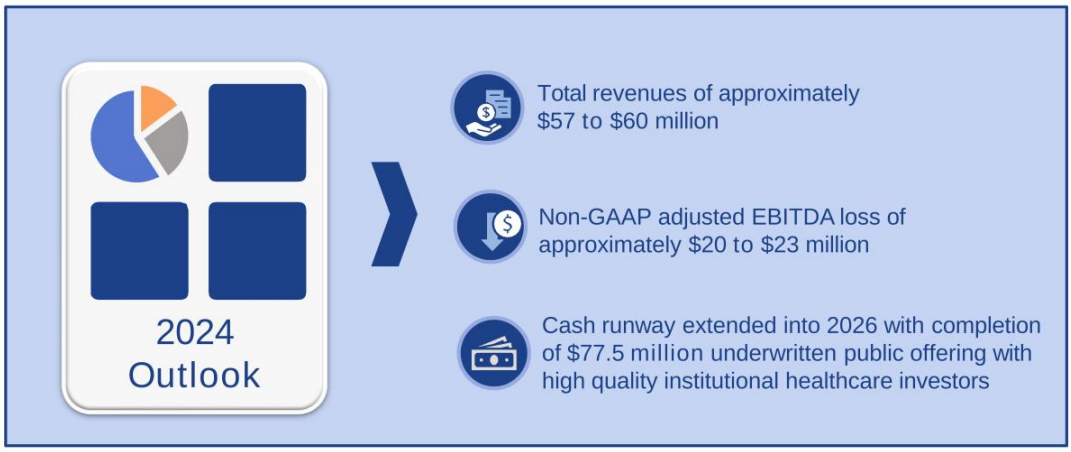


1. End of phase 2 meeting with the FDA is planned for the fourth quarter of 2025 or the first quarter of 2026.

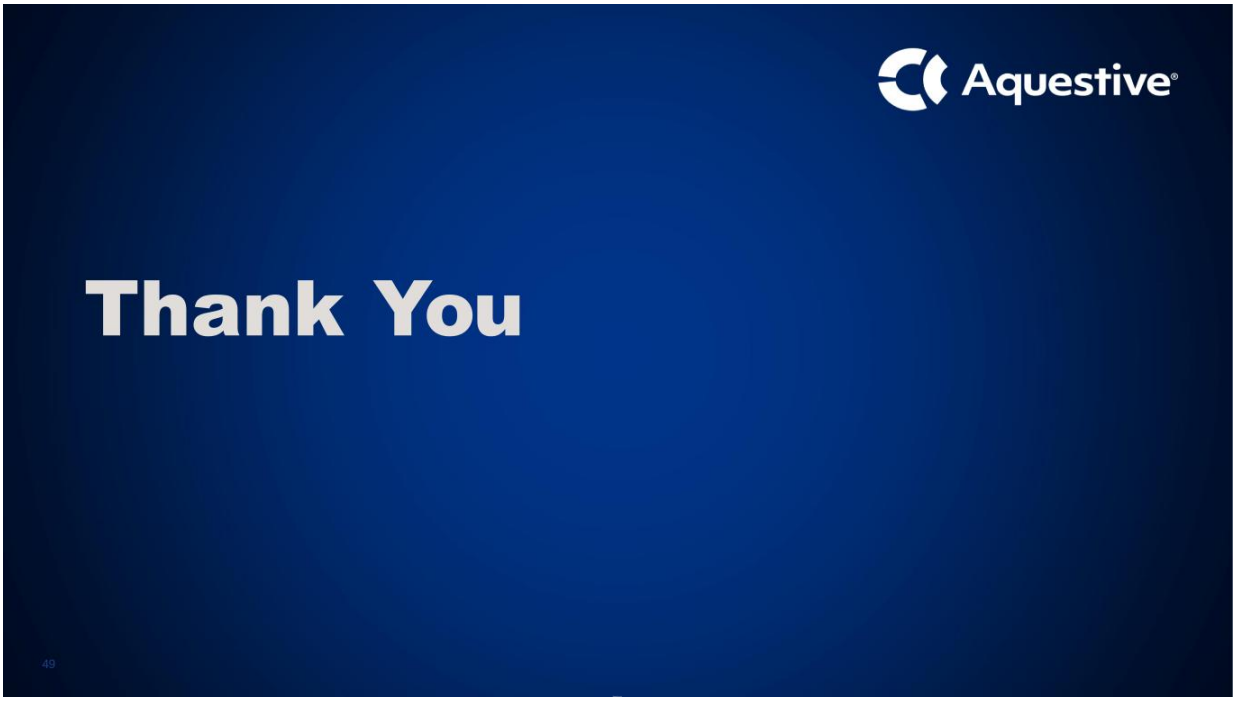
Aquestive


Aquestive
Financial Guidance
47

2024 expected outlook as of August 6, 2024



Aquestive


Aquestive
Thank You
49

Aquestive Therapeutics Spotlights its Innovative Epinephrine Delivery Pipeline at Virtual Investor Day

- Announces completion of enrollment in its oral allergen challenge study for the development of its late-stage pipeline program, Anaphylm™ (epinephrine) Sublingual Film
- Outlines the development strategy for the Company's next pipeline product candidate, AQST-108 (epinephrine) Topical Gel for the treatment of Alopecia areata
- Holds virtual investor day

WARREN, N.J., September 27, 2024 -- 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 hosted a virtual investor day highlighting the Company's pipeline inclusive of Anaphylm™ (epinephrine) Sublingual Film and AQST-108 (epinephrine) Topical Gel, both product candidates emerging from the Company's Adrenaverse™ epinephrine prodrug platform. The event included presentations by members of the Aquestive management team and by distinguished key opinion leader J. David Farrar, PhD, Associate Professor, Immunology/Molecular Biology, UT Southwestern Medical Center.

"Our pipeline is progressing, and we are excited about the next chapter for growth. We recently submitted our pre-NDA meeting request to the FDA for Anaphylm and are on track to report topline data from our oral allergy challenge study in the coming weeks," remarked Daniel Barber, President and Chief Executive Officer of Aquestive. "This is an exciting time for the Company and for our stakeholders, most importantly the patients we seek to help. As our next step for the Adrenaverse platform, we will focus on developing AQST-108 for the treatment Alopecia areata, based on our candidate's differentiated therapeutic profile and significant unmet need in this indication."

"Epinephrine plays a critical role in immune suppression but, until now, its role has been limited due to issues in the absorption and conversion of epinephrine," said Carl Kraus, MD, Chief Medical Officer of Aquestive. "Our Adrenaverse platform has demonstrated the ability to harness the therapeutic potential of epinephrine through highly differentiated prodrug formulations, which can achieve absorption, provide sustained local exposure and avoid systemic exposure. The platform makes it possible to deliver epinephrine locally across mucosal surfaces and the skin and, therefore, we believe that it has the potential to yield multiple product candidates focused on treating a range of diseases. AQST-108 for the treatment of Alopecia areata is a natural next step in the evolution of this platform."

Anaphylm™ (epinephrine) Sublingual Film
Aquestive outlined today that it has completed enrollment in its remaining supportive study for Anaphylm, the oral allergy syndrome (OAS) challenge study, which is expected to be completed in the fourth quarter of 2024 following the completion of dosing. The Company remains on track to hold the pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2024 as it has recently submitted a meeting request letter to the FDA. Aquestive remains focused on completing an NDA submission with the FDA in the first quarter of 2025 and initiating a full product launch of Anaphylm, if approved by the FDA, at the end of 2025 or in the first quarter of 2026.

AQST-108 (epinephrine) Topical Gel
The Company completed its first human clinical study for AQST-108. The two-part study 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 pharmacokinetics of five different dose levels. The 1.0% dose of AQST-108 was chosen based on the highest dose found with no appreciable transdermal absorption in order 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.

Aquestive unveiled in the event its plan to develop AQST-108 for the treatment of Alopecia areata, which impacts as many as 6.7 million people in United States. AQST-108, a topically delivered adrenergic agonist prodrug, has the potential to support immune privilege in the hair follicle. The Company outlined the design of its planned Phase 2 study to assess the safety and efficacy of AQST-108 in mild to moderate Alopecia areata patients. The Company expects to hold a pre-Investigational New Drug (IND) meeting with the FDA in the first quarter of 2025 and to commence the Phase 2 study in the second half of 2025, pending alignment with the FDA.

The Investor Day webcast and accompanying written presentation (including discussion on the planned clinical and regulatory pathway and potential commercial opportunity) may be accessed through the Events & Presentations page in the Investors section of the Company's website at https://investors.aquestive.com/events-and-presentations. The webcast will be archived for 30 days.

About Anaphylm™ (epinephrine) Sublingual Film

Anaphylm™ (epinephrine) 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 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 AQST-108 (epinephrine) Topical Gel

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 and without any serious or topical adverse events. 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.

About Aquestive Therapeutics

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 five 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 earlier stage epinephrine prodrug topical gel for various dermatology conditions including Alopecia areata. For more information, visit Aquestive.com and follow us on LinkedIn.

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™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of supporting and pediatric clinical studies, holding a pre-NDA meeting with the FDA and filing the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; that the results of the Company's clinical studies for Anaphylm are sufficient to support submission of the NDA for approval of Anaphylm by the FDA; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel (and potential alternative indications), through clinical development including design and timing of clinical studies including those necessary to support the targeted indication of Alopecia areata for AQST-108, and holding a pre-IND meeting with the FDA, and the following launch of AQST-108, if approved by the FDA; the potential indications and potential benefits our products and product candidates could bring to patients; 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 (including for pediatric patients), AQST-108, and the Company's other product candidates; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, including for Anaphylm and AQST-108, or the failure to receive FDA approval at all of any of these product candidates; 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 comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of the success of any competing products; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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 fund commercialization activities relating to fund future clinical development and commercial activities for our product candidates, including Anaphylm and AQST-108, should these product candidates be approved by the FDA; risk of eroding market share for Suboxone® and risk as a sunsetting product, which accounts for the 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. of Anaphylm and AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk of the success of any competing products including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to 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 PTO; 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against Aquestive 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; 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; 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.

Investor Inquiries
ICR Westwicke
Stephanie Carrington
stephanie.carrington@westwicke.com
646-277-1282