Aquestive Therapeutics Reports Third Quarter 2026 Financial Results and Provides Business Update

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- *Anaphylm resubmission accepted with PDUFA goal date of March 16, 2027*
- *Anaphylm would be the first and only oral rescue medication for the treatment of severe allergic reactions, including anaphylaxis, if approved*
- *Commercial preparations remain on track to support a potential U.S. launch of Anaphylm following FDA approval*
- *Ex-U.S. Anaphylm strategy progressing, with Health Canada submission expected in Q4 2026 and an EU filing planned for Q1 2027*
- *Company to host investor call on November 4, 2026, at 8:00 a.m. ET*

WARREN, N.J., Nov. 03, 2026 (GLOBE NEWSWIRE) -- Aquestive Therapeutics, Inc. (NASDAQ: AQST) ("Aquestive" or the "Company"), a biopharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science, today announced financial results for the third quarter ended September 30, 2026, and provided a strategic business update.

“With a PDUFA goal date of March 16, 2027, we believe we have a clear path to making Anaphylm available to patients and caregivers, if approved,” said Daniel Barber, President and Chief Executive Officer of Aquestive. “For decades, people at risk of anaphylaxis have had limited treatment options. We believe Anaphylm - designed to be easy to carry and use confidently whenever and wherever it may be needed - has the potential to address important unmet needs. As we work with the FDA to support an efficient review, we continue to advance our commercial preparations, including building our field sales organization to engage allergists following approval. These efforts are intended to position us to move quickly toward launch following potential FDA approval.”

Anaphylm™ (dibutepinephrine) sublingual film
Anaphylm is an oral epinephrine product candidate being developed for the treatment of type I allergic reactions, including anaphylaxis. The Company believes Anaphylm has the potential to be the first and only non-invasive, orally delivered epinephrine product for the treatment of type I allergic reactions, including anaphylaxis, if approved by the U.S. Food and Drug Administration (FDA).

On September 16, 2026, the Company resubmitted its New Drug Application (NDA) for Anaphylm to the U.S. Food and Drug Administration (FDA). The FDA acknowledged the resubmission as complete, classified it as a Class 2 response and assigned a Prescription Drug User Fee Act (PDUFA) goal date of March 16, 2027.

Outside the U.S., the Company expects to submit a New Drug Submission to Health Canada in Q4 2026 and plans to file in the European Union in Q1 2027.

Aquestive continues to advance commercial readiness in anticipation of a potential Anaphylm launch. The Company's Medical Affairs team is driving healthcare professional awareness and maintains active partnerships with leading allergy-focused patient advocacy organizations. In parallel, the commercial team continues to refine launch execution and market access strategies. These efforts are supported by the Company's experienced commercial team and its established infrastructure, enabling Aquestive to execute a focused and disciplined launch strategy, if Anaphylm is approved by the FDA.

AQST-108 (epinephrine) topical gel
AQST-108 is a topical epinephrine prodrug candidate being developed for potential dermatologic indications. Following completion of a first-in-human study in which no serious or topical adverse events were observed, Aquestive is advancing the program in atopic dermatitis. The Company expects to conduct additional clinical work beginning in the first quarter of 2027. The Company continues to evaluate additional potential dermatologic indications.

Atopic dermatitis affects approximately 7%–10% of U.S. adults and 10%–20% of children, making it one of the most common chronic inflammatory skin diseases in the U.S.

Aquestive’s AdrenaVerse platform comprises approximately 20 epinephrine prodrugs designed to enable control of absorption and conversion rates of epinephrine across a range of dosage forms and delivery sites. The Company continues to analyze the AdrenaVerse platform’s long-term potential to address multiple indications.

Commercial Collaborations and Other
Aquestive manufactures products for its licensing and supply partners, including Indivior’s Suboxone® Sublingual Film, Sympazan® (clobazam) oral film for Cosette Pharmaceuticals, Inc. in the U.S., Ondif® (ondansetron) oral film for Hypera Pharma

in Brazil and Emylif® (riluzole) oral film for Zambon S.p.A. in Europe. The Company manufactured approximately 26 million doses in the third quarter 2026, compared to approximately 44 million doses in the third quarter 2025. On a year-to-date basis through September, the Company manufactured approximately 107 million doses in 2026 compared to approximately 108 million doses in the same period in 2025.

In October 2026, Aquestive granted Eton Pharmaceuticals, Inc. (Nasdaq: ETON) exclusive U.S. commercialization rights to Libervant. Eton will be responsible for U.S. commercialization, while Aquestive received a $10 million upfront payment and is eligible to receive up to $47.5 million in contingent regulatory and sales-based milestone payments and mid-teens royalties on net sales. Aquestive will remain the exclusive manufacturer and supplier of Libervant under a 20-year supply agreement.

Libervant® has received tentative FDA approval for patients two to five and twelve years of age and older. Final FDA approval for patients twelve years of age and older is subject to expiration of the orphan drug exclusivity for Valtoco® on January 10, 2027, and final FDA action, with a PDUFA goal date of March 23, 2027. The Company has also submitted a Type 9 NDA seeking to add patients six to eleven years of age to the label, with a PDUFA goal date of March 29, 2027.

The Company, being a U.S. based manufacturer with intellectual property domiciled in the U.S., confirms that its supply chain currently remains largely unaffected by government tariffs currently in effect. The Company continues to monitor proposed tariffs and other trade restrictions.

Third Quarter 2026 Financials
Total revenues decreased to $7.6 million in the third quarter 2026 from $12.8 million in the third quarter 2025. The 41% decrease was primarily driven by the quarterly fluctuation of Suboxone product orders.

Manufacture and supply revenue decreased to $6.7 million in the third quarter 2026 from $11.5 million in the third quarter 2025, primarily due to decreases in Suboxone revenues due to timing of product orders, partially offset by higher Ondif revenues.

License and royalty revenue decreased to $0.8 million in the third quarter 2026 from $1.0 million in the third quarter 2025, primarily due to lower estimated royalty revenues.

Research and development expenses decreased to $4.3 million in the third quarter 2026 from $4.5 million in the third quarter 2025. The decrease in research and development expenses was primarily due to lower share-based compensation, partially offset by higher clinical trial costs due to the human factors validation study and PK study completed for the Anaphylm NDA resubmission.

Selling, general and administrative expenses decreased to $14.2 million in the third quarter 2026 from $15.3 million in the third quarter of 2025. The decrease primarily represents lower legal fees of approximately $1.5 million, lower commercial spending of approximately $1.4 million, and lower regulatory expenses related to Anaphylm of approximately $0.6 million, partially offset by higher personnel costs of approximately $0.9 million, higher share-based compensation expenses of approximately $0.4 million and higher consulting and outside services expenses of approximately $0.4 million as well as other expenses.

Aquestive's net loss for the third quarter 2026 was $16.5 million, or $0.13 for both basic and diluted loss per share, compared to the net loss in the third quarter 2025 of $15.4 million, or $0.14 for both basic and diluted loss per share. The increase in net loss was primarily driven by decreases in revenues, partially offset by decreases in selling, general, and administrative expenses, manufacture and supply expenses, and interest expense, and increases in interest income.

Non-GAAP adjusted EBITDA loss was $12.2 million in the third quarter 2026, compared to non-GAAP adjusted EBITDA loss of $8.6 million in the third quarter 2025.

Cash and cash equivalents were $90.3 million as of September 30, 2026.

2026 Outlook
Aquestive's full-year 2026 financial guidance remains unchanged.

The Company expects:

	Guidance
Total revenue (in millions)	$46 to $50
Non-GAAP adjusted EBITDA loss (in millions)	$35 to $30

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, November 4, 2026.

In order to participate, please register in advance **here** to obtain a local or toll-free phone number and your personal PIN.

A live webcast of the call will be available on Aquestive's website at: **Third Quarter 2026 Earnings Call.**

About Anaphylm™
Anaphylm™ (dibutepinephrine) sublingual film is a polymer matrix-based epinephrine prodrug product candidate. Anaphylm is

similar in size to a postage stamp, weighs less than an ounce and begins to dissolve on contact. No water or swallowing is required for administration. The primary packaging for Anaphylm is thinner and smaller than an average credit card, can be carried in a pocket and is designed to withstand weather excursions such as exposure to rain and/or sunlight. If approved by the FDA, Anaphylm would be the first and only oral rescue medication for the treatment of severe allergic reactions, including anaphylaxis. 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
AQST-108 (epinephrine) topical gel is a topically delivered adrenergic agonist prodrug product candidate. Aquestive completed a first-in-human study for AQST-108 without any serious or topical adverse events observed. AQST-108 is based on Aquestive's AdrenaVerse™ platform which contains a library of over twenty epinephrine prodrugs intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites.

About Libervant®

Libervant® (diazepam) buccal film is a product candidate consisting of a buccally administered film formulation of diazepam, a benzodiazepine. If approved for U.S. market access, Libervant would be indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy. Libervant has received tentative FDA approval and is not currently available for U.S. market access.

About Aquestive Therapeutics, Inc.
Aquestive is a biopharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science. The worldwide leader in delivering trusted, quality medications on oral film, Aquestive operates as both a developer of its own proprietary products, with its headquarters in New Jersey and U.S.-based manufacturing facilities in Indiana. The Company is the exclusive manufacturer of four commercialized products marketed by its licensees across six continents using proprietary, best-in-class technologies like PharmFilm®. Aquestive's AdrenaVerse™ platform contains a library of more than 20 epinephrine prodrugs enabling the pursuit of various potential allergy and dermatological indications. The Company is advancing Anaphylm™ (dibutepinephrine) sublingual film for the treatment of severe allergic reactions, including anaphylaxis, and AQST-108 (epinephrine) topical gel for various potential dermatological conditions. For more information, visit Aquestive.com and follow us on LinkedIn.

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

Specifically, the Company adjusts net loss for certain non-cash expenses, including share-based compensation expenses; loss on extinguishment of debt; depreciation and amortization; and interest expense related to the sale of future revenue, interest income and other income, net and income taxes, with a result of adjusted EBITDA loss. Similarly, manufacture and supply expense, R&D expense, and selling, general and administrative expense were adjusted for certain non-cash expenses of share-based compensation expense and depreciation and amortization. Adjusted EBITDA loss and these non-GAAP expense categories are used as a supplement to the corresponding GAAP measures to provide additional insight regarding the Company's ongoing operating performance.

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

Non-GAAP Outlook
In providing the outlook for non-GAAP adjusted EBITDA and non-GAAP gross margin, we exclude certain items which are otherwise included in determining the comparable GAAP financial measures. In order to inform our outlook measures of non-GAAP adjusted EBITDA and non-GAAP gross margin, a description of the adjustments which have been applicable in determining non-GAAP Adjusted EBITDA and non-GAAP gross margin for these periods are reflected in the tables below. In providing outlook for non-GAAP gross margin, the Company adjusts for non-cash share-based compensation expense and depreciation and amortization. The Company is providing such outlook only on a non-GAAP basis because the Company is unable to predict with reasonable certainty the totality or ultimate outcome or occurrence of these adjustments for the forward-looking period such as share-based compensation expense, income tax, amortization, and certain other adjusted items, which can

be dependent on future events that may not be reliably predicted. Based on past reported results, where one or more of these items have been applicable, such excluded items could be material, individually or in the aggregate, to reported results.

Forward-Looking Statement

Certain statements in this press release include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the FDA's review of the accepted Class 2 resubmission of the NDA for Anaphylm™ (dibutepinephrine) sublingual film and potential approval by the March 16, 2027 PDUFA goal date; the Company's commercial launch strategy, launch readiness and potential launch of Anaphylm, if approved; potential international regulatory submissions and marketing authorizations for Anaphylm, including the anticipated timing of submissions in Canada and the European Union; the potential for Anaphylm, if approved, to be the first and only oral rescue medication for the treatment of severe allergic reactions, including anaphylaxis; the design, timing, and conduct of clinical studies for AQST-108 (epinephrine) topical gel, data and potential indications, and the advancement of the AdrenaVerse™ platform; the timing and outcome of FDA review of Libervant® (diazepam) buccal film, including potential final approval, label expansion and commercial availability; Eton Pharmaceuticals' commercialization of Libervant; the potential receipt by Aquestive of contingent milestone and royalty payments; Aquestive's manufacture and supply of Libervant; the Company's 2026 financial outlook, liquidity, cash requirements, funding and operating results; and other statements that are not historical facts. Such forward-looking statements also include statements regarding anticipated timelines, milestones and guidance relating to regulatory submissions, clinical studies, regulatory interactions, and potential approvals, which are inherently uncertain and subject to change based on regulatory feedback, protocol alignment, data sufficiency and other factors outside the Company's control.

These forward-looking statements are based on the Company's current expectations and beliefs and are subject to risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the possibility that the FDA may disagree with the Company's interpretation of study results, findings or conclusions, determine that the Anaphylm NDA resubmission does not adequately address the deficiencies identified in the January 30, 2026 Complete Response Letter, request additional information, analyses, human factors studies, clinical studies or inspections, consider issues raised in citizen petitions or similar submissions, or otherwise delay or decline approval; risks associated with launch readiness and the potential commercial launch, reimbursement, market acceptance, manufacturing and supply of Anaphylm, if approved; risks associated with obtaining regulatory approvals outside the United States, including that foreign authorities may require different, additional or more extensive clinical, nonclinical, human factors, pharmacokinetic or manufacturing data than anticipated or may not accept data generated for U.S. regulatory purposes; risks of delays or changes to the timing, design, cost, conduct, data or success of clinical studies for AQST-108 and uncertainty regarding its potential indications; delays in or failure to obtain final FDA approval or label expansion for Libervant; changes in regulatory requirements or the effect of competing products' exclusivity; Eton's commercialization costs and execution; whether and when contingent milestone events are achieved, which depend on FDA actions and Eton's commercialization efforts; the amount of any royalties, which depends on net sales; Eton's right to terminate the license agreement; Aquestive's ability to meet its manufacture and supply obligations; competition, pricing, reimbursement and market acceptance; risks associated with the Company's cash requirements, funding, cash burn, projected cash runway, liquidity and access to debt and equity financing; risks that the Company's manufacturing capabilities may be insufficient to support demand for its product candidates and licensed products; eroding market share for Suboxone®; the Company's obligations under its Purchase Agreement and Royalty Rights Agreement; regulatory, legal, intellectual property, cybersecurity, economic, political and market risks; and the other uncertainties described in the "Risk Factors" section and elsewhere in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, readers 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.

Libervant®, PharmFilm®, Sympazan® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 90,349	$ 121,169
Trade and other receivables, net	5,254	17,763
Inventories	7,309	6,169
Prepaid expenses and other current assets	2,913	4,168
Total current assets	105,825	149,269
Property and equipment, net	4,358	3,893
Right-of-use assets, net	7,451	4,621
Other non-current assets	1,693	2,642
Total assets	$ 119,327	$ 160,425
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 8,818	$ 29,862
Accrued expenses	5,576	5,029
Lease liabilities, current	623	631
Deferred revenue, current	1,092	1,092
Liability related to the sale of future revenue, current	1,000	1,000
Royalty obligations, current	157	—
Debt, current	33	9,994
Total current liabilities	17,299	47,608
Debt, long-term, net	50,757	27,519
Royalty obligations, net	28,702	25,941
Liability related to the sale of future revenue, net	61,192	62,023
Lease liabilities	7,359	4,337
Deferred revenue, net of current portion	18,573	19,390
Other non-current liabilities	6,269	7,269
Total liabilities	190,151	194,087
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 125,687,705 and 122,044,299 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	126	122
Additional paid-in capital	423,465	413,214
Accumulated deficit	(494,415)	(446,998)
Total stockholders' deficit	(70,824)	(33,662)
Total liabilities and stockholders' deficit	$ 119,327	$ 160,425

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenues	$ 7,557	$ 12,807	$ 35,822	$ 31,530
Costs and expenses:				
Manufacture and supply	3,606	4,506	11,092	12,719
Research and development	4,251	4,530	12,417	13,996
Selling, general and administrative	14,169	15,250	39,209	47,027
Total costs and expenses	22,026	24,286	62,718	73,742

Loss from operations	(14,469)	(11,479)	(26,896)	(42,212)
Other income/(expenses):				
Loss on extinguishment of debt	—	—	(11,683)	—
Interest expense	(1,845)	(2,779)	(7,555)	(8,342)
Interest expense related to royalty obligations	(973)	(1,433)	(2,918)	(4,304)
Interest expense related to the sale of future revenue	(62)	(61)	(183)	(181)
Interest income and other income, net	853	306	1,818	3,115
Net loss before income taxes	(16,496)	(15,446)	(47,417)	(51,924)
Net loss	$ (16,496)	$ (15,446)	$ (47,417)	$ (51,924)
Comprehensive loss	$ (16,496)	$ (15,446)	$ (47,417)	$ (51,924)
Loss per share attributable to common stockholders:				
Basic and diluted (in dollars per share)	$ (0.13)	$ (0.14)	$ (0.38)	$ (0.51)
Weighted average common shares outstanding:				
Basic and diluted (in shares)	125,548,783	110,584,371	124,395,079	101,857,974

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
GAAP net loss	$ (16,496)	$ (15,446)	$ (47,417)	$ (51,924)
Share-based compensation expense	2,126	2,777	7,339	6,248
Interest expense	1,845	2,779	7,555	8,342
Interest expense related to royalty obligations	973	1,433	2,918	4,304
Interest expense related to the sale of future revenue	62	61	183	181
Interest income and other income, net	(853)	(306)	(1,818)	(3,115)
Loss on extinguishment of debt	—	—	11,683	—
Depreciation and Amortization	156	139	405	418
Total non-GAAP adjustments	$ 4,309	$ 6,883	$ 28,265	$ 16,378
Non-GAAP adjusted EBITDA	$ (12,187)	$ (8,563)	$ (19,152)	$ (35,546)
Excluding Non-GAAP adjusted R&D expenses	(3,916)	(3,204)	(11,505)	(11,901)
Non-GAAP adjusted EBITDA excluding Non-GAAP adjusted R&D expenses	$ (8,271)	$ (5,359)	$ (7,647)	$ (23,645)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Total costs and expenses	$ 22,026	$ 24,286	$ 62,718	$ 73,742
Non-GAAP adjustments:				
Share-based compensation expense	(2,126)	(2,777)	(7,339)	(6,248)
Depreciation and amortization	(156)	(139)	(405)	(418)
Non-GAAP adjusted costs and expenses	$ 19,744	$ 21,370	$ 54,974	$ 67,076
Manufacture and Supply Expenses	$ 3,606	$ 4,506	$ 11,092	$ 12,719

Gross Margin on total revenue	*52%*	*65%*	*69%*	*60%*
Non-GAAP adjustments:				
Share-based compensation expense	(84)	(130)	(219)	(358)
Depreciation and amortization	(127)	(111)	(322)	(338)
Non-GAAP adjusted manufacture and supply expenses	$ 3,395	$ 4,265	$ 10,551	$ 12,023
Non-GAAP Gross Margin on total revenue	*55%*	*67%*	*71%*	*62%*
Research and Development Expenses	$ 4,251	$ 4,530	$ 12,417	$ 13,996
Non-GAAP adjustments:				
Share-based compensation expense	(319)	(1,310)	(868)	(2,048)
Depreciation and amortization	(16)	(16)	(44)	(47)
Non-GAAP adjusted research and development expenses	$ 3,916	$ 3,204	$ 11,505	$ 11,901
Selling, General and Administrative Expenses	$ 14,169	$ 15,250	$ 39,209	$ 47,027
Non-GAAP adjustments:				
Share-based compensation expense	(1,723)	(1,337)	(6,252)	(3,842)
Depreciation and amortization	(13)	(12)	(39)	(33)
Non-GAAP adjusted selling, general and administrative expenses	$ 12,433	$ 13,901	$ 32,918	$ 43,152