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): March 5, 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 2.02 Results of Operations and Financial Condition

On March 5, 2024, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the quarter and fiscal year ended December 31, 2023 and provided an update on recent developments in its business. A copy of the Company's press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated in this Item 2.02 by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "33 Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 7.01 Regulation FD Disclosure.

The Company is furnishing this Current Report on Form 8-K in connection with the disclosure of information, in the form of an investor presentation, to be given at meetings with institutional investors, analysts and others. This information may be amended or updated at any time and from time to time through another Current Report on Form 8-K, a later Company filing or other means. A copy of the Company's investor presentation is attached hereto as Exhibits 99.2 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference. The investor presentation is available on the 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 99.2) shall not be deemed to be "filed" for purposes of, or otherwise subject to the liabilities of, Section 18 of the Exchange Act, nor shall it be deemed to be incorporated by reference in any filing under the 33 Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated March 5, 2024 , announcing the Company's reported financial results for the quarter and fiscal year ended December 31, 2023 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q4 Earnings Supplemental Materials dated March 5, 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: March 5, 2024

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Reports Full Year 2023 Financial Results and Provides Business Update

- Reports full year 2023 revenue of $50.6 million and non-GAAP adjusted EBITDA loss of $11.6 million
- Reaffirms expected release of topline pivotal clinical data for Anaphylm™ (epinephrine) Sublingual Film in March 2024
- Reaffirms anticipated FDA decision on Libervant™ (diazepam) Buccal Film application in April 2024
- Provides full year 2024 financial guidance
- Hosts investment community conference call on March 6, 2024

Warren, N.J., March 5, 2024 – Aquestive Therapeutics, Inc. (NASDAQ:AQST), a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a progress update on the key 2024 objectives previously outlined by the Company.

“We ended 2023 on a strong note with double digit base revenue growth, an improved balance sheet, and the start of our pivotal study for Anaphylm. We are now focused on continuing our progress in 2024 and building a strong foundation for the long-term growth of the Company. This includes (1) progressing Anaphylm to a US filing, (2) expanding and growing our revenue base, (3) licensing or launching Libervant (diazepam) Buccal Film, if approved by the FDA with market access, and (4) advancing our next pipeline assets by utilizing our Adrenaverse technology,” stated Daniel Barber, President and Chief Executive Officer of Aquestive. “Anaphylm, as the only orally administered epinephrine product under development for the treatment of severe allergic reactions including anaphylaxis, continues to represent a transformational opportunity for both patients and the Company. We remain excited to see our topline pivotal data and continue to anticipate reporting topline data from our Anaphylm pivotal study this month.”

Anaphylm™
Aquestive is advancing the development of Anaphylm, the first and only orally delivered epinephrine product candidate to demonstrate clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis.

Aquestive received positive feedback in October 2023 from the U.S. Food and Drug Administration (FDA) on the Company's pivotal Phase 3 Pharmacokinetic (PK) clinical protocol for Anaphylm. The FDA indicated that the Company’s proposed endpoints, sample size, and statistical analysis are reasonable. As anticipated, the FDA also reminded the Company that PK sustainability post-dosing (30–60 minutes) is an important factor and recommended using repeat-dose data to support PK sustainability. The Company has incorporated the FDA’s feedback into the design of its clinical protocol for Anaphylm.

Aquestive commenced dosing in December 2023 in the Phase 3 pivotal PK clinical study of Anaphylm. The two-part, single-center, open-label, randomized study is designed to compare the PK and pharmacodynamics (PD) of single and repeat doses of Anaphylm versus single and repeat doses of the epinephrine IM injection and epinephrine autoinjectors in healthy adult subjects. The primary objective of the study is to compare the PK of epinephrine following the single administration of Anaphylm to single administration of epinephrine IM injection in healthy adult subjects. The secondary objectives of the study include evaluating PK sustainability following repeat administration and evaluating the safety and tolerability following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors. Aquestive anticipates reporting topline data from the Anaphylm Pivotal PK study this month and continuing to guide to a filing of the Anaphylm New Drug Application

(NDA) with the FDA before the end of 2024. A comprehensive adult and pediatric Human Factors program, an expected and ongoing part of the Anaphylm clinical development program, will also be included in the Anaphylm NDA to support future labeling and the use of the product by intended patients.

Libervant™
In September 2023, the FDA accepted Aquestive's NDA for Libervant (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients between two and five years of age. Diastat (diazepam) Rectal Gel is the only FDA approved treatment currently available to this patient population for this indication. Based on the latest information available to the Company, the review of the Libervant NDA remains on track and there are currently no outstanding information requests from the FDA. The NDA for Libervant was assigned a PDUFA target action date of April 28, 2024.

The NDA for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) in patients twelve years of age and older was tentatively approved by the FDA in August 2022 and is currently subject to an orphan drug market exclusivity block until January 2027 based on an FDA approved nasal spray product of another company.

The Company continues to engage with the FDA on Libervant's approval for U.S. market access and remains committed to bringing Libervant to patients.

Commercial Collaborations
Aquestive continues to manufacture products for the licensing and supply collaborations that it has established. The Company manufactured approximately 45 million doses in the fourth quarter 2023, compared to approximately 37 million doses in the fourth quarter 2022. The Company continues to see consistent order demand for the manufacture of Indivior's Suboxone® Sublingual Film product and continues to support its other global collaborations including the recent launch of Emilyf (Riluzole) Oral Film product by Zambon in Europe.

Sales of royalty-based products, inclusive of Sympazan® (clobazam) Oral Film for the treatment of seizures associated with Lennox-Gastaut Syndrome in patients two years of age and older, and Azstarys® for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years of age and older continued to improve in the fourth quarter of 2023.

Fourth Quarter 2023 Financials
Total revenues were $13.2 million in the fourth quarter 2023, compared to $10.7 million in the fourth quarter 2022, an increase of 24%. The increase was due to higher manufacture and supply revenues, and license and royalty revenues, offset by the discontinuance of proprietary product sales of Sympazan as a result of the outlicensing agreement with Assertio in October 2022.

Manufacture and supply revenue increased by 23%, or $2.1 million, primarily due to increased manufacturing revenues of $3.2 million for Suboxone partially offset by decreases for Ondif® for Hypera in Brazil and for Sympazan.

In addition, the Company recognized $1.0 million in milestone royalty revenue for Azstarys from Zevra Therapeutics.

Aquestive's net loss for the fourth quarter 2023 was $8.1 million, or $0.12 loss per share. The net loss for the fourth quarter 2022 was $12.4 million, or $0.23 loss per share. The reduction in net loss was primarily driven by increases in revenue described above, decreases in selling, general and administrative expense, including severance costs and lower administrative costs in the commercial organization subsequent to the outlicensing of Sympazan, and a decrease in research and development cost and expenses, partially offset by increases by a one-time loss on extinguishment of debt of $1.0 million and higher interest expense related to the amortization of debt discount related to the 13.5% Notes payable.

Non-GAAP adjusted EBITDA loss was $2.8 million in the fourth quarter 2023, compared to a $9.6 million loss in the fourth quarter 2022. Non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses was $0.1 million in the fourth quarter 2023, compared to a non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $5.6 million in the fourth quarter 2022.

Full Year 2023 Financials

Excluding the impact of prior year proprietary sales of Sympazan, total revenues increased from $40.0 million for the full year 2022 to $50.6 million for the full year 2023, an increase of 26%. The increase was due to higher manufacture and supply revenues and license and royalty revenue offset by the discontinuance of proprietary product sales of Sympazan following the outlicensing of Sympazan.

Total reported revenues were $50.6 million for the full year 2023, compared to $47.7 million for the full year 2022, an increase of 6%.

Manufacture and supply revenue increased 20% due to increased manufacturing revenues of $4.4 million for Suboxone, increased revenues of $2.1 million for Ondif for Hypera subsequent to receiving foreign regulatory approval in February 2022, and increased revenues of $0.6 million for Sympazan.

License and royalty revenue increased 129%, or $3.0 million, for the year ended December 31, 2023 compared to the same period in 2022. This increase was primarily due to $1.5 million in milestone licensing revenues for Azstarys from Zevra Therapeutics and increased licensing and royalty revenue of $1.3 million for Sympazan.

The Company's net loss for the full year 2023 was $7.9 million, or $0.13 loss per share. The net loss for the full year 2022 was $54.4 million, or $1.12 loss per share. The reduction in net loss was primarily driven by $14.5 million of other income which consisted of $6.0 million from an amendment to the Indivior Commercial Exploitation Agreement, and $8.5 million from the patent litigation settlement with BioDelivery Sciences International, increases in revenue described above, decrease in selling, general and administrative expense, including severance costs and significantly lower administrative costs in the commercial organization subsequent to the outlicensing of Sympazan, a decrease in research and development cost and expenses and lower interest expense related to the KYNMOBI® monetization transaction, partially offset by a loss on extinguishment of debt of $1.4 million and higher interest expense related to the amortization of debt discount related to the 13.5% Notes payable.

Non-GAAP adjusted EBITDA loss was $11.6 million in the full year 2023, compared to a loss of $35.3 million in the full year 2022. The year-over-year change in non-GAAP adjusted EBITDA was primarily driven by the items described above. Non-GAAP adjusted EBITDA income excluding adjusted R&D expenses was $1.0 million in the full year 2023, compared to a non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $18.7 million in the full year 2022.

As of December 31, 2023, cash and cash equivalents were $23.9 million. During the fourth quarter 2023, the Company accessed capital net proceeds of $3.7 million under its "At-the-Market" (ATM) facility.

2024 Outlook

Aquestive is providing its full year 2024 financial outlook. The Company expects:

	Guidance
Total revenue (in millions)	$48 to $51
Non-GAAP adjusted EBITDA loss (in millions)	$22 to $26

Revenue guidance does not include any revenue for Libervant. In addition, the guidance for 2024 includes continued focused R&D investments related to the continued development and planned NDA filing of Anaphylm.

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, March 6, 2024.

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: Fourth Quarter 2023 Earnings Call. The webcast will be archived for 30 days.

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 pipeline focused on treating diseases of the central nervous system and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. 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 excluding adjusted R&D expenses, non-GAAP adjusted gross margins, non-GAAP adjusted costs and expenses and other adjusted expense measures, because such measures exclude, as applicable, share-based compensation expense, interest expense, interest expense related to the sale of future revenue, interest income, depreciation, amortization, and income taxes.

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

These measures supplement the Company's financial results prepared in accordance with GAAP. Aquestive management uses these measures to analyze its financial results, and its future manufacture and supply expenses, gross margins, research and development expense and selling, general and administrative expense and to help make managerial decisions. In management's opinion, these non-GAAP measures provide added transparency into the operating performance of Aquestive and added insight into the effectiveness of our operating strategies and actions. The Company may provide one or more revenue measures adjusted for certain discrete items, such as fees collected on certain licensed products, in order to provide investors added insight into our revenue stream and breakdown, along with providing our GAAP revenue. Such measures are intended to supplement, not act as substitutes for, comparable GAAP measures and should not be read as a measure of liquidity for Aquestive. 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 advancement and related timing of our product candidate Anaphylm through clinical development and approval by the FDA, including receipt and release of topline data and the filing of the Anaphylm NDA; regarding the FDA’s approval and related timing of the filing of the NDA for Libervant with the FDA 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 between two and five years of age; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged two years and older; overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for this patient population; regarding the potential benefits Anaphylm and Libervant could bring to patients; regarding the potential growth in market demand for existing licensed products of the Company in the U.S. and abroad and the potential and related timing for expanding the Company’s manufacturing capabilities and supporting the growth of demand for existing and potential future licensed products in the U.S. and other countries; regarding the financial outlook of the Company and its growth and future financial and operating results and financial position; regarding advancing the Company's pipeline assets utilizing the Company's Adrenaverse technology through clinical development and regulatory approval; and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company’s business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm and Libervant and the Company's other pipeline products, pharmaceutical ingredients and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals.

These forward-looking statements are based on the Company’s 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 the Company’s development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm, Libervant and our other product candidates; risk of the Company’s ability to generate sufficient data in its 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 pivotal PK study protocol and other concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm; risks that the FDA will not approve Libervant for U.S. market access by overcoming the seven year orphan drug market exclusivity of an FDA approved nasal spray product of another company in effect until January 2027; risk of delays in or the failure to receive FDA approval of the NDA for Libervant for these epilepsy patients between two and five years of age, including the risk that the FDA may require additional clinical studies for approval of Libervant for this age group, and there can be no assurance that the Company will be successful in obtaining any of the foregoing FDA approvals for Anaphylm and Libervant, including for U.S. market access for Libervant for any age group of patients; risk that a competing pediatric epilepsy product of Libervant will receive FDA approval prior to the Company’s receipt of FDA approval of the Libervant NDA for these epilepsy patients between two and five years of age; risk relating to the unpredictability of the FDA’s decisions regarding orphan drug exclusivity; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product should the FDA approve Libervant for U.S. market access for any age group of this epilepsy patient population; risk in obtaining market access for Libervant for other reasons; risks associated with the Company’s development work, including any delays or changes to the timing, cost and success of the Company’s product development activities; risk of the success of any competing products; risk inherent in

commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates, including Anaphylm and Libervant, and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for Anaphylm, Libervant and our other product candidates; risk of failure to satisfy all financial and other debt covenants and of any default under existing debt financing; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; 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 the size and growth of our product markets; risks 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 the Company's products; risk of unexpected patent developments; uncertainties related to general economic, political (including acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in the Company's 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:
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AQUESTIVE THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 23,872	$ 27,273
Trade and other receivables, net	8,471	4,704
Inventories, net	6,769	5,780
Prepaid expenses and other current assets	1,854	2,131
Total current assets	40,966	39,888
Property and equipment, net	4,179	4,085
Right-of-use assets, net	5,557	5,211
Intangible assets, net	1,278	1,435
Other non-current assets	5,438	6,451
Total assets	$ 57,418	$ 57,070
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 8,926	$ 9,946
Accrued expenses	6,497	7,967
Lease liabilities, current	390	255
Deferred revenue	1,551	1,513
Liability related to the sale of future revenue, current	922	1,147
Loans payable, current	22	18,700
Total current liabilities	18,308	39,528
Loans payable, net	27,508	33,448
Royalty obligations, net	14,761	—
Liability related to the sale of future revenue, net	63,568	64,112
Lease liabilities	5,399	5,085
Deferred revenue, net of current portion	32,345	31,417
Other non-current liabilities	2,016	2,034
Total liabilities	163,905	175,624
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 68,533,085 and 54,827,734 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	69	55
Additional paid-in capital	212,521	192,598
Accumulated deficit	(319,077)	(311,207)
Total stockholders' deficit	(106,487)	(118,554)
Total liabilities and stockholders' deficit	$ 57,418	$ 57,070

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenues	$ 13,206	$ 10,682	$ 50,583	$ 47,680
Costs and expenses:				
Manufacture and supply	4,679	5,305	20,831	19,386
Research and development	2,888	4,278	13,104	17,481
Selling, general and administrative	9,550	11,812	31,750	52,879
Total costs and expenses	17,117	21,395	65,685	89,746
Loss from operations	(3,911)	(10,713)	(15,102)	(42,066)
Other income (expenses):				
Interest expense	(2,273)	(1,650)	(6,337)	(6,552)
Interest expense related to royalty obligations	(905)	—	(905)	—
Interest expense related to the sale of future revenue	(57)	(54)	(220)	(5,891)
Interest income and other income, net	165	65	16,321	99
Loss on the extinguishment of debt	(1,029)	—	(1,382)	—
Net loss before income taxes	(8,010)	(12,352)	(7,625)	(54,410)
Income taxes	(101)	—	(245)	—
Net loss	$ (8,111)	$ (12,352)	$ (7,870)	$ (54,410)
Comprehensive loss	$ (8,111)	$ (12,352)	$ (7,870)	$ (54,410)
Net loss per share – basic and diluted	$ (0.12)	$ (0.23)	$ (0.13)	$ (1.12)
Weighted-average number of common shares outstanding - basic and diluted	67,199,645	54,390,696	61,255,864	48,734,377

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
GAAP net loss	$ (8,111)	$ (12,352)	$ (7,870)	$ (54,410)
Share-based compensation expense	923	712	2,689	4,381
Interest expense	2,273	1,650	6,337	6,552
Interest expense related to the sale of future revenue	57	54	220	5,891
Interest expense related to royalty obligations	905	—	905	—
Interest income and other income (expense), net	(165)	(65)	(16,321)	(99)
Income taxes	(101)	—	(245)	—
Depreciation, amortization, and impairment	433	397	1,345	2,387
Loss on extinguishment of debt	1,029	—	1,382	—
Total non-GAAP adjustments	$ 5,354	$ 2,748	$ (3,688)	$ 19,112
Adjusted EBITDA	$ (2,757)	$ (9,604)	$ (11,558)	$ (35,298)
Excluding adjusted R&D expenses	$ (2,688)	$ (3,975)	$ (12,557)	$ (16,636)
Adjusted EBITDA excluding adjusted R&D expenses	$ (69)	$ (5,629)	$ 999	$ (18,662)

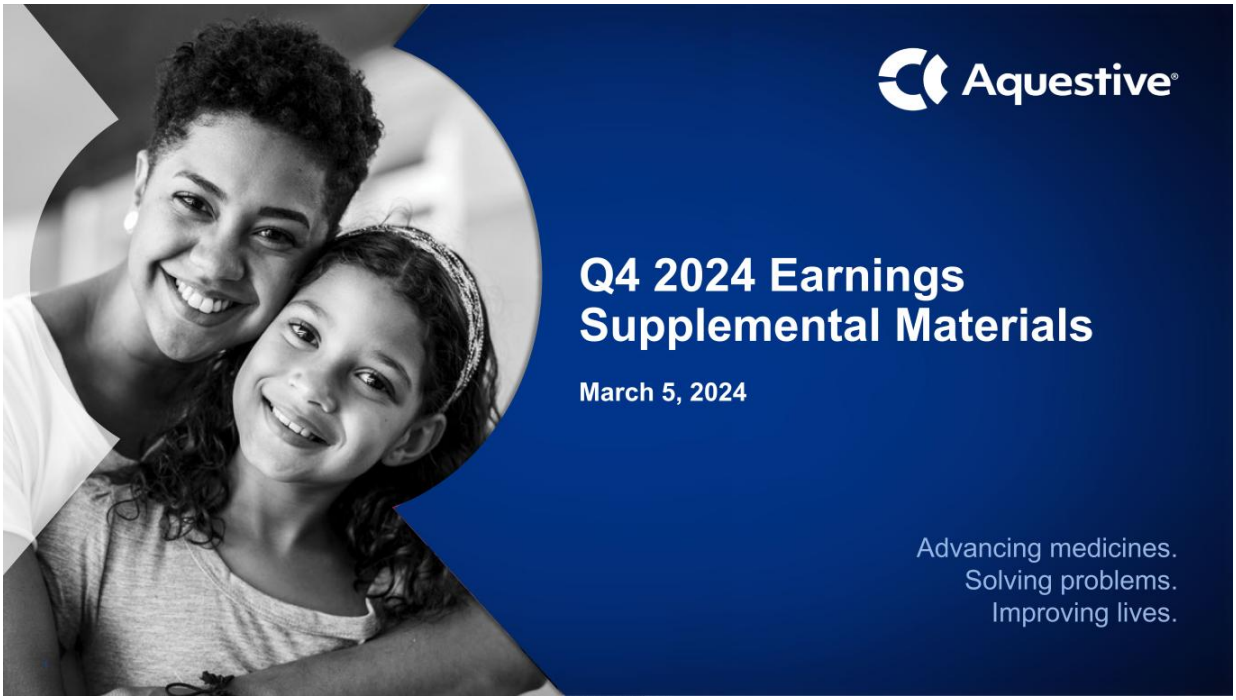
AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - Total Costs and Expenses to Adjusted Costs and Expenses
(In Thousands)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Total costs and expenses	$ 17,117	$ 21,395	$ 65,685	$ 89,746
Non-GAAP adjustments:				
Share-based compensation expense	(923)	(712)	(2,689)	(4,381)
Depreciation, amortization, and impairment	(433)	(397)	(1,345)	(2,387)
Adjusted costs and expenses	$ 15,761	$ 20,286	$ 61,651	$ 82,978

Manufacture and supply expense	$ 4,679	$ 5,305	$ 20,831	$ 19,386
Gross Margin on total revenue	*65 %*	*50 %*	*59 %*	*59 %*
Non-GAAP adjustments:				
Share-based compensation expense	(36)	(44)	(191)	(203)
Depreciation, amortization, and impairment	(395)	(317)	(1,140)	(1,890)
Adjusted manufacture and supply expense	$ 4,248	$ 4,944	$ 19,500	$ 17,293
Non-GAAP Gross Margin on total revenue	*68 %*	*54 %*	*61 %*	*64 %*

Research and development expense	$ 2,888	$ 4,278	$ 13,104	$ 17,481
Non-GAAP adjustments:				
Share-based compensation expense	(179)	(266)	(456)	(672)
Depreciation, amortization, and impairment	(21)	(37)	(91)	(173)
Adjusted research and development expense	$ 2,688	$ 3,975	$ 12,557	$ 16,636

Selling, general and administrative expenses	$ 9,550	$ 11,812	$ 31,750	$ 52,879
Non-GAAP adjustments:				
Share-based compensation expense	(708)	(402)	(2,042)	(3,506)
Depreciation, amortization, and impairment	(17)	(43)	(79)	(324)
Adjusted selling, general and administrative expenses	$ 8,825	$ 11,367	$ 29,629	$ 49,049


Aquestive
Q4 2024 Earnings
Supplemental Materials
March 5, 2024
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Disclaimer

Certain statements in this presentation 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 through clinical development and approval by the U.S. Food and Drug Administration (FDA), including receipt and release of topline data and the filing of the Anaphylm New Drug Application (NDA); regarding the 2024 financial outlook of the Company and its growth and future financial and operating results and financial position; and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company's business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm and Libervant and the Company's other pipeline products, pharmaceutical ingredients and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals. These forward-looking statements are based on the Company's 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 the Company's development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm, Libervant and our other product candidates; risk of the Company's ability to generate sufficient data in its 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 pivotal PK study protocol and other concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm; risks associated with the Company's development work, including any delays or changes to the timing, cost and success of the Company's product development activities; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates, including Anaphylm and Libervant, and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company's short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for Anaphylm, Libervant and our other product candidates; risk of failure to satisfy all financial and other debt covenants and of any default under existing debt financing; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; 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 the size and growth of our product markets; risks 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 the Company's products; risk of unexpected patent developments; uncertainties related to general economic, political (including acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in the Company's 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.

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Q4 2023 Earnings: Key Messages

Financial Performance

- Exceeded our revenue and Non-GAAP Adjusted EBITDA guidance
- $45MM debt refinancing resulted in cash savings of approximately $28MM through June of 2025
- Finished the year with approximately $24MM in cash

Anaphylm™ (epinephrine) sublingual film

- On track for submission of New Drug Application ("NDA") before year end 2024
- Positive top-line data reported from pilot studies in 2023
- Pivotal trial commenced – first patient dosed in December of 2023 - top-line data expected in March of 2024

Libervant™ (diazepam) buccal film

- Submitted NDA for Libervant for patients between the ages of two and five years old
- PDUFA action date is April 28, 2024

Consistent Execution in Q4

October

- Received positive FDA feedback on Anaphylm pivotal study protocol

November

- Completed $45MM debt refinancing
- Presented positive data from Anaphylm pilot studies at America College of Allergy, Asthma, and Immunology Annual Meeting

December

- Anaphylm pivotal study commenced – top-line data expected in March of 2024
- Finished the year with approximately $24MM in cash

Anaphylm Pivotal Study

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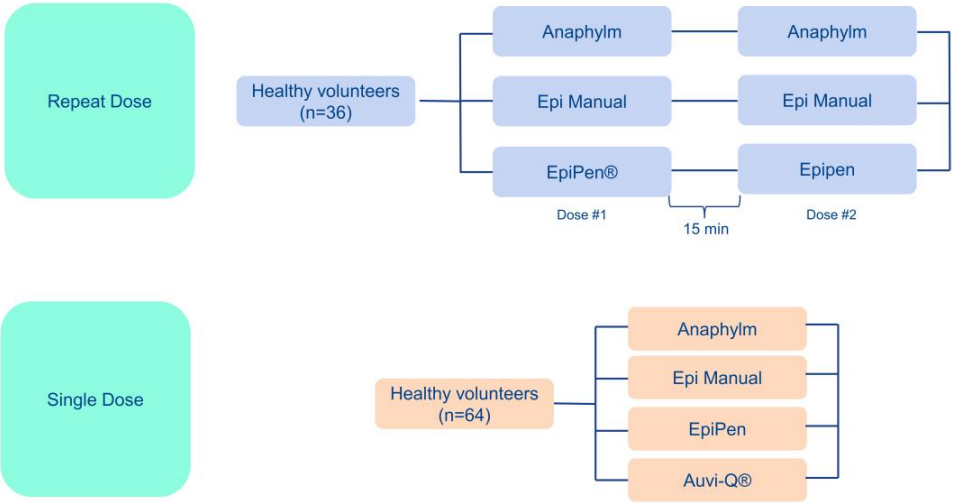
Anaphylm Pivotal Study Design



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Key Endpoints

Pharmacokinetic (PK)	• Maximum plasma concentration (Cmax) • Time to maximum plasma concentration (Tmax) • Partial area under the curve at 10, 20, 30, and 45 minutes
Pharmacodynamic (PD)	• Change in systolic blood pressure • Change in diastolic blood pressure • Change in heart rate

Financial Results

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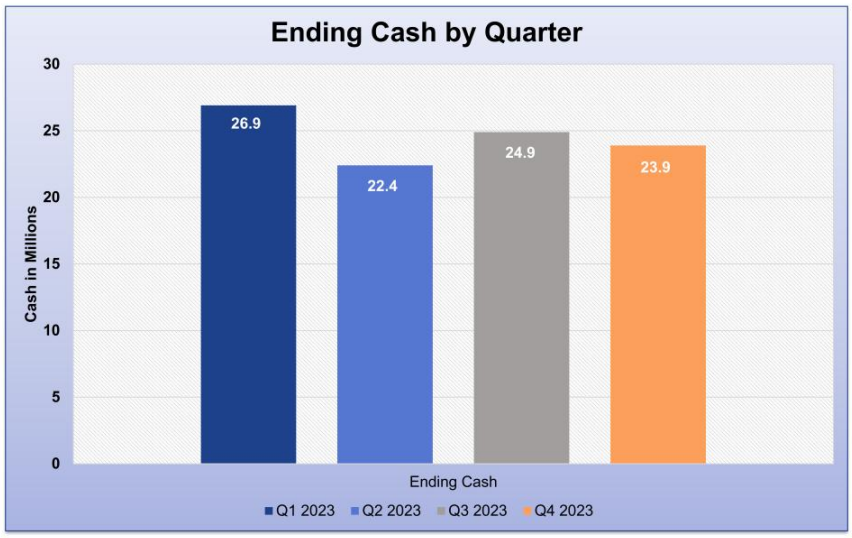
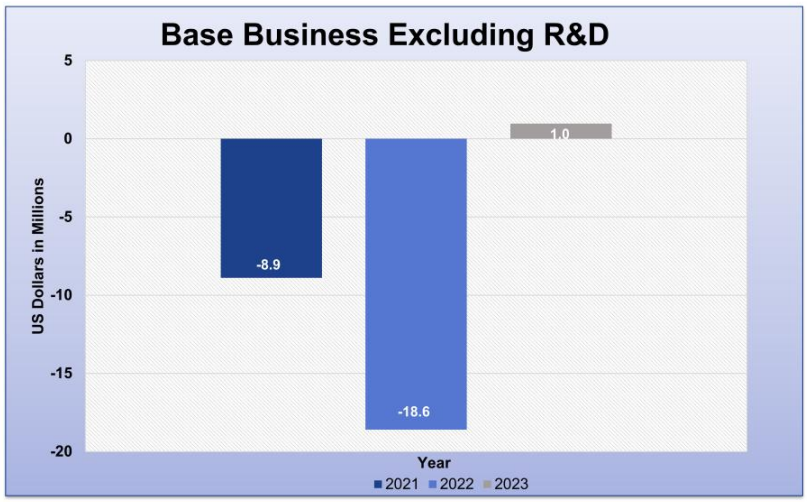
Continuing to Manage Our Cash Position[1]



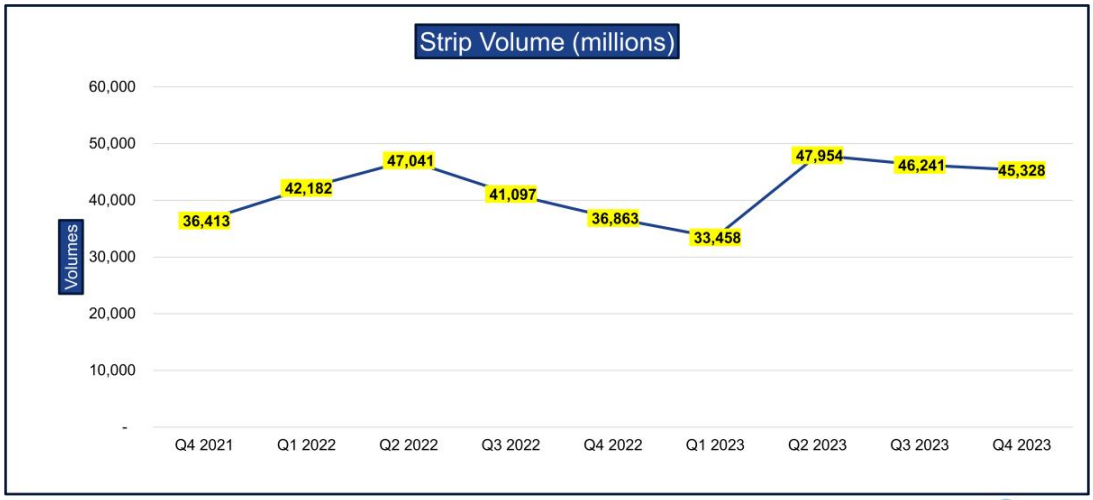
1.Principal and interest debt payments were made on October 2, 2023, when due.

Our Base Business Excluding R&D Expenses[1]



1. Non-GAAP adjusted EBITDA excluding research and development expenses

Manufacturing Volumes Meet Expectations and Generate Cash Flow



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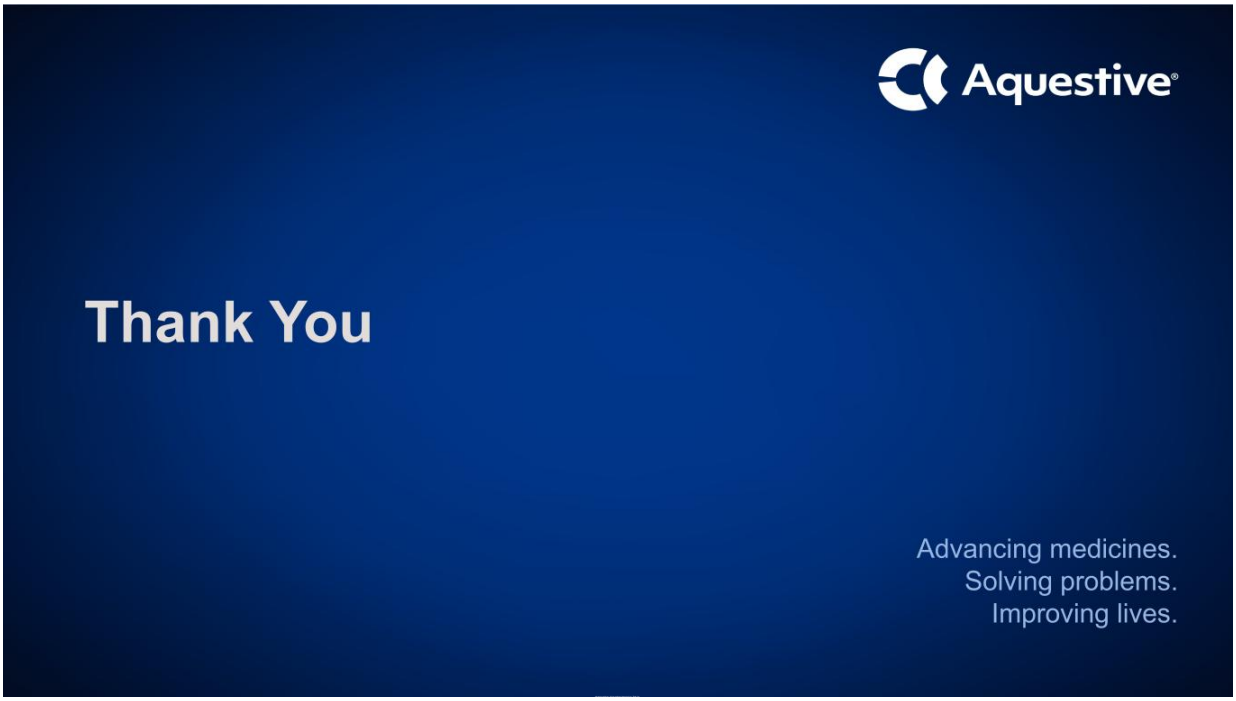
2024 Outlook as of March 5, 2024

2024 Outlook

- Total revenues of approximately $48 to $51 million
- Non-GAAP adjusted EBITDA loss of approximately $22 to $26 million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