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 7, 2023

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 7, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the quarter and fiscal year ended December 31, 2022 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 herein 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 a 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 7, 2023, announcing the Company's reported financial results for the quarter and fiscal year ended December 31, 2022 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q4 Earnings Supplemental Materials dated March 7, 2023.

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 7, 2023

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Reports Fourth Quarter & Full Year 2022 Financial Results and Provides Business Update on Key 2023 Objectives

- Pivotal study for AQST-109 (epinephrine sublingual film) on track to start in third quarter 2023
- Financial turnaround actions on track including 18% reduction of outstanding debt and the receipt of $20 million of non-dilutive capital in the first quarter of 2023
- Continues to engage FDA on next steps for Libervant™ (diazepam) Buccal Film
- Provides full year 2023 financial outlook
- Hosts investment community conference call on March 8, 2023

Warren, N.J., March 7, 2023 – Aquestive Therapeutics, Inc. (NASDAQ:AQST), a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives, today reported financial results for the fourth quarter and full year ended December 31, 2022, and provided a progress update on the key 2023 objectives previously outlined by the Company.

“Our 2022 results and early progress in 2023 continue to drive the Company towards important upcoming inflection points,” said Daniel Barber, Chief Executive Officer of Aquestive. “Our growing portfolio of approved products and collaborations around the world, along with our pipeline products, create the opportunity for significant long-term growth. Our lead pipeline asset, AQST-109, has the potential, if approved by the FDA and other regulatory bodies, to help the millions of patients who need to carry and depend on a rescue medication for allergic reactions. In addition, our continued progress towards the financial turnaround of the Company remains a key focus.”

“We will remain focused on the key initiatives that we outlined at the beginning of 2023: (1) advancing AQST-109 into a pivotal PK study, (2) continuing to work with the FDA to potentially accelerate the U.S. market access for Libervant, (3) exploring new capabilities for our manufacturing business, (4) continuing to expand our base of strategic collaborations with other companies, and (5) strengthening our balance sheet.”

Epinephrine
Aquestive is advancing the development of AQST-109, 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 final minutes in December 2022 from the End-of-Phase 2 (EOP2) meeting with the United Stated Food and Drug Administration (FDA) for AQST-109, which provided clarity as to the FDA’s expectations for information to be included in a New Drug Application (NDA). Specifically, the FDA introduced the concept to Aquestive of utilizing multiple approved injectable products as reference listed drugs (RLDs) in the Company’s proposed pivotal study, which adds broader flexibility to achieve comparability with the RLDs.

Aquestive received further clarification from the FDA in March 2023 indicating that the Company should submit its pivotal study protocol for review once the Company selects its RLDs. The Company is currently conducting an additional clinical study to determine the appropriate RLDs. Aquestive anticipates providing a revised pivotal study protocol to the FDA in the second quarter 2023 and starting the pivotal study in the third quarter 2023. In addition, the Company continues to characterize the administration of AQST-109 under potential conditions of allergic reactions, in a manner consistent with the FDA’s expectations. The Company plans on meeting with the FDA in the second half of 2023 to review the data package related to the characterization of administration.

The Company participated in the American Academy of Allergy, Asthma, and Immunology (AAAAI) annual meeting held in February 2023. The Company’s Scientific Advisory Board members also presented four late breaking posters highlighting the results from the Company’s EPIPHAST I and EPIPHAST II studies for

AQST-109 completed in 2022 at the American College of Allergy Asthma and Immunology (ACAAI) Annual Scientific Meeting held in November 2022. Data from these posters continued to highlight the rapid increase in epinephrine plasma concentration following administration with a median time of 12 minutes to maximum levels. Rapid absorption is believed to be a critical factor in the utilization of epinephrine for treatment of severe allergic reactions, including anaphylaxis.

Commercial Collaborations
The Company completed three significant licensing and supply transactions in 2022 including (1) the worldwide licensing of Sympazan® (clobazam) to Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. ("Assertio"), (2) the licensing of Libervant to Atnahs Pharma UK Limited in Europe and certain other territories, and (3) the licensing of Exservan™ (riluzole) Oral Film to Haisco Pharmaceutical Group Co., Ltd.,in China. On a combined basis, these transactions generated over $25 million in non-dilutive capital in 2022. The Company continues to focus on expanding its collaborations activities and potentially generating additional non-dilutive capital in 2023.

Effective as of March 2, 2023, the Company amended its existing license and supply agreement with Indivior Inc. ("Indivior") for the primary purpose of (i) extending the term of the Agreement until August 16, 2026 and thereafter providing for automatic renewal terms of successive one year periods unless Indivior delivers notice to the Company, at least twelve months prior to the expiration of the then current term, of Indivior's intent not to renew, subject to the earlier termination rights of the parties under the Agreement, and providing that the Agreement will not automatically renew for any renewal term beginning after the expiration of the last to expire of the product patents; and (ii) agreeing to transfer pricing and payment terms for supplied product. In addition, Indivior agreed to pay the Company reimbursable amounts due to the Company under the Agreement in a one-time cash payment of approximately $11.5 million, of which approximately $5.5 million represents: (a) payment of the portion of a 2022 price increase that had not been previously paid and (b) an estimated payment in 2023 for certain price increases.

Libervant™
Libervant was tentatively approved by the FDA in August 2022 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 12 years of age and older. Importantly, the recommended dosage of Libervant considers the impact of food and may be administered without regard to food. This is a critical feature for a product intended for urgent and acute use.

Libervant is subject to an orphan drug market exclusivity block until January 2027 based on a competing product. The Company submitted clinical data to the FDA in September 2022 to address the orphan drug market exclusivity block. The Company is currently awaiting FDA feedback and the FDA has indicated it is actively reviewing the information and making all efforts to respond in a reasonable timeframe.

Patent Litigation Settlement with BioDelivery Sciences International, Inc. ("BDSI")
Aquestive reached a settlement effective March 3, 2023 in the patent infringement lawsuits related to the sale of BDSI's Bunavail and Belbuca drug film products in the United States. Under the terms of the settlement agreement, all pending patent claims have been resolved between BDSI and Aquestive, as well as Indivior Inc., co-plaintiff in the Belbuca lawsuit, in exchange for a one-time, lump-sum payment of $8.5 million to Aquestive. This settlement continues the Company's focus on resolving outstanding litigation matters, where possible and appropriate.

Fourth Quarter 2022 Financials
Total revenues were $10.7 million in the fourth quarter 2022, compared to $11.1 million in the fourth quarter 2021, a decrease of 4%. Comparing the fourth quarter 2022 to the prior year period, the Company saw a 141% increase in
license and royalty revenue, a 17% increase in co-development and research fees revenue, and a 16% increase in manufacture and supply revenue offset by a decrease of 79% in proprietary sales related to the licensing of Sympazan to Assertio.

Aquestive's net loss for the fourth quarter 2022 was $12.4 million, or $0.23 loss per share. The net loss for the fourth quarter 2021 was $28.9 million, or $0.72 loss per share. The change in net loss was primarily driven by a one-time loss on extinguishment of debt of $13.8 million in 2021, lower non-cash interest expense related to the KYNMOBI® monetization transaction of $1.8 million, and a decrease in total operational cost and expenses of $1.4 million primarily due to a reduction in the Company's sales force subsequent to the outlicensing of Sympazan

during the fourth quarter 2022, and lower share based compensation expense, offset by higher raw material and production costs.

Non-GAAP adjusted loss before interest, taxes, depreciation, amortization, share based compensation and other adjustments (adjusted EBITDA loss) was $9.6 million in the fourth quarter 2022, compared to a $9.2 million loss in the fourth quarter 2021.

Full Year 2022 Financials
Total revenues were $47.7 million for the full year 2022, compared to $50.8 million for the full year 2021, a decrease of 6%. Excluding non-recurring revenue of $4.1 million that was recognized in 2021, total revenue increased by 2%. Comparing the year ended 2022 to the prior year period, the Company saw a 3% increase in manufacture and supply revenue and a 10% decrease in proprietary sales due to the outlicensing of Sympazan.

The Company's net loss for the full year 2022 was $54.4 million, or $1.12 loss per share. The net loss for the full year 2021 was $70.5 million, or $1.85 loss per share. The change in net loss was primarily driven by a one-time loss on extinguishment of debt of $13.8 million in 2021, lower non-cash interest expense related to the KYNMOBI® monetization transaction of $6.5 million, and lower interest expense of $3.5 million, offset by higher costs and expenses of $4.2 million, including severance expenses.

Non-GAAP adjusted loss before interest, taxes, depreciation, amortization, share based compensation and other adjustments (adjusted EBITDA loss) was $35.3 million in the full year 2022, compared to $24.9 million in the full year 2021. The year-over-year change in non-GAAP adjusted EBITDA was primarily driven by the items described above.

As of December 31, 2022, cash and cash equivalents were $27.3 million. During the fourth quarter 2022, the Company accessed capital net proceeds of $0.9 million under its "At-the-Market" (ATM) facility.

2023 Outlook
Aquestive is providing its full year 2023 financial outlook.

The Company expects:

	Guidance
Total revenue (in millions)	$37 to $41
Non-GAAP adjusted EBITDA loss (in millions)	$31 to $36

Please note the Company's revenue guidance for 2023 no longer includes proprietary net sales for Sympazan due to the license of Sympazan to Assertio, but it does include manufacturing and supply revenue and royalty fees. In addition, the guidance for 2023 includes continued focused R&D investments related to the development of AQST-109.

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Wednesday, March 8, 2023.

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: Fourth Quarter 2022 Results. The webcast will be archived for 30 days.

About Aquestive Therapeutics
Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. 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 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 2022 and 2021 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 AQST-109 through clinical development and approval by the FDA and other regulatory authorities, including the Company’s ability to provide sufficient data in its new drug application (NDA) submission to address the FDA’s concerns; statements regarding the potential benefits AQST-109 could bring to patients; statements regarding the approval of Libervant by the FDA for U.S. market access and overcoming orphan drug market exclusivity of a competing FDA approved product extending to January 2027; statements regarding the potential and related timing for expanding the Company’s manufacturing capabilities and supporting the growth of demand for other existing and potential future licensed products in the U.S. and other countries; statements regarding potential outlicensing of our product pipeline in the U.S. and abroad and opportunities for long-term growth and generating additional capital; statements regarding entering into commercial transactions with other companies; statements regarding the Company’s ability to strengthen its balance sheet and available cash and cash equivalents; 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 AQST-109; pharmaceutical ingredient 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 the Company’s product development activities and clinical trials for AQST-109 and other product candidates; risk of the Company’s failure to generate sufficient data in its NDA submission for FDA approval of AQST-109; risk of the Company’s failure to address the concerns identified in the FDA End of Phase 2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109, including the risk that the FDA may require additional clinical studies for FDA approval of AQST-109, and there can be no assurance that the Company will be successful in obtaining such approval; 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 competing product in effect until January 2027, and there can be no assurance that the Company will be successful in obtaining such approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of our ability to out-license our proprietary products or enter into other commercial transactions with third parties; 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; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk that we are unable to refinance our current corporate debt on terms and conditions satisfactory to the Company, or not at all; risk of eroding market share for Suboxone® and risk of a sunsetting product, which accounts for the substantial part of our current operating revenue; risk of the rate and degree of market acceptance of our licensed and product candidates; the success of any competing products, including generics; 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, business, industry, regulatory 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 its Annual Report on Form 10-K, in its Quarterly Reports on Form 10-Q, and in its Current Reports on Form 8-K filed with the 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

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

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 27,273	$ 28,024
Trade and other receivables, net	4,704	12,120
Inventories, net	5,780	4,038
Prepaid expenses and other current assets	2,131	3,077
Total current assets	39,888	47,259
Property and equipment, net	4,085	5,055
Right-of-use assets, net	3,816	2,725
Intangible assets, net	1,435	51
Other non-current assets	6,451	6,903
Total assets	$ 55,675	$ 61,993
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 9,946	$ 8,314
Accrued expenses	7,967	8,736
Lease liabilities, current	406	899
Deferred revenue	1,513	765
Liability related to the sale of future revenue, current	1,147	1,225
Loans payable, current	18,700	2,025
Total current liabilities	39,679	21,964
Loans payable, net	33,448	51,551
Liability related to the sale of future revenue, net	64,112	59,059
Lease liabilities	3,539	1,946
Deferred revenue, net of current portion	31,417	7,122
Other non-current liabilities	2,034	2,485
Total liabilities	174,229	144,127
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 54,827,734 and 41,228,736 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	55	41
Additional paid-in capital	192,598	174,621
Accumulated deficit	(311,207)	(256,796)
Total stockholders' deficit	(118,554)	(82,134)
Total liabilities and stockholders' deficit	$ 55,675	$ 61,993

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,	
	2022	2021	2022	2021
Revenues	$ 10,682	$ 11,078	$ 47,680	$ 50,832
Costs and expenses:				
Manufacture and supply	5,305	3,366	19,386	14,989
Research and development	4,278	4,400	17,481	17,047
Selling, general and administrative	11,812	14,981	52,879	53,475
Total costs and expenses	21,395	22,747	89,746	85,511
Loss from operations	(10,713)	(11,669)	(42,066)	(34,679)
Other income (expenses):				
Interest expense	(1,650)	(1,744)	(6,552)	(10,049)
Interest expense related to the sale of future revenue	(54)	(1,845)	(5,891)	(12,412)
Interest income and other income, net	65	135	99	423
Loss on the extinguishment of debt	—	(13,822)	—	(13,822)
Net loss before income taxes	(12,352)	(28,945)	(54,410)	(70,539)
Income taxes	—	—	—	—
Net loss	$ (12,352)	$ (28,945)	$ (54,410)	$ (70,539)
Comprehensive loss	$ (12,352)	$ (28,945)	$ (54,410)	$ (70,539)
Net loss per share – basic and diluted	$ (0.23)	$ (0.72)	$ (1.12)	$ (1.85)
Weighted-average number of common shares outstanding - basic and diluted	54,390,696	40,391,538	48,734,377	38,077,660

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,	
	2022	2021	2022	2021
Net loss	$ (12,352)	$ (28,945)	$ (54,410)	$ (70,539)
Share-based compensation expense	712	1,691	4,381	6,819
Interest expense	1,650	1,744	6,552	10,049
Interest expense related to the sale of future revenue	54	1,845	5,891	12,412
Interest income and other income (expense), net	(65)	(135)	(99)	(423)
Income taxes	—	—	—	—
Depreciation, amortization, and impairment	397	731	2,387	2,964
Loss on extinguishment of debt	—	13,822	—	13,822
Total non-GAAP adjustments	$ 2,748	$ 19,698	$ 19,112	$ 45,643
Adjusted EBITDA	$ (9,604)	$ (9,247)	$ (35,298)	$ (24,896)

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,	
	2022	2021	2022	2021
Total costs and expenses	$ 21,395	$ 22,747	$ 89,746	$ 85,511
Non-GAAP adjustments:				
Share-based compensation expense	(712)	(1,691)	(4,381)	(6,819)
Depreciation, amortization, and impairment	(397)	(731)	(2,387)	(2,964)
Adjusted costs and expenses	$ 20,286	$ 20,325	$ 82,978	$ 75,728

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - Manufacture & Supply Expense to Adjusted Manufacture and Supply Expense
(In Thousands, except percentages)
(Unaudited)

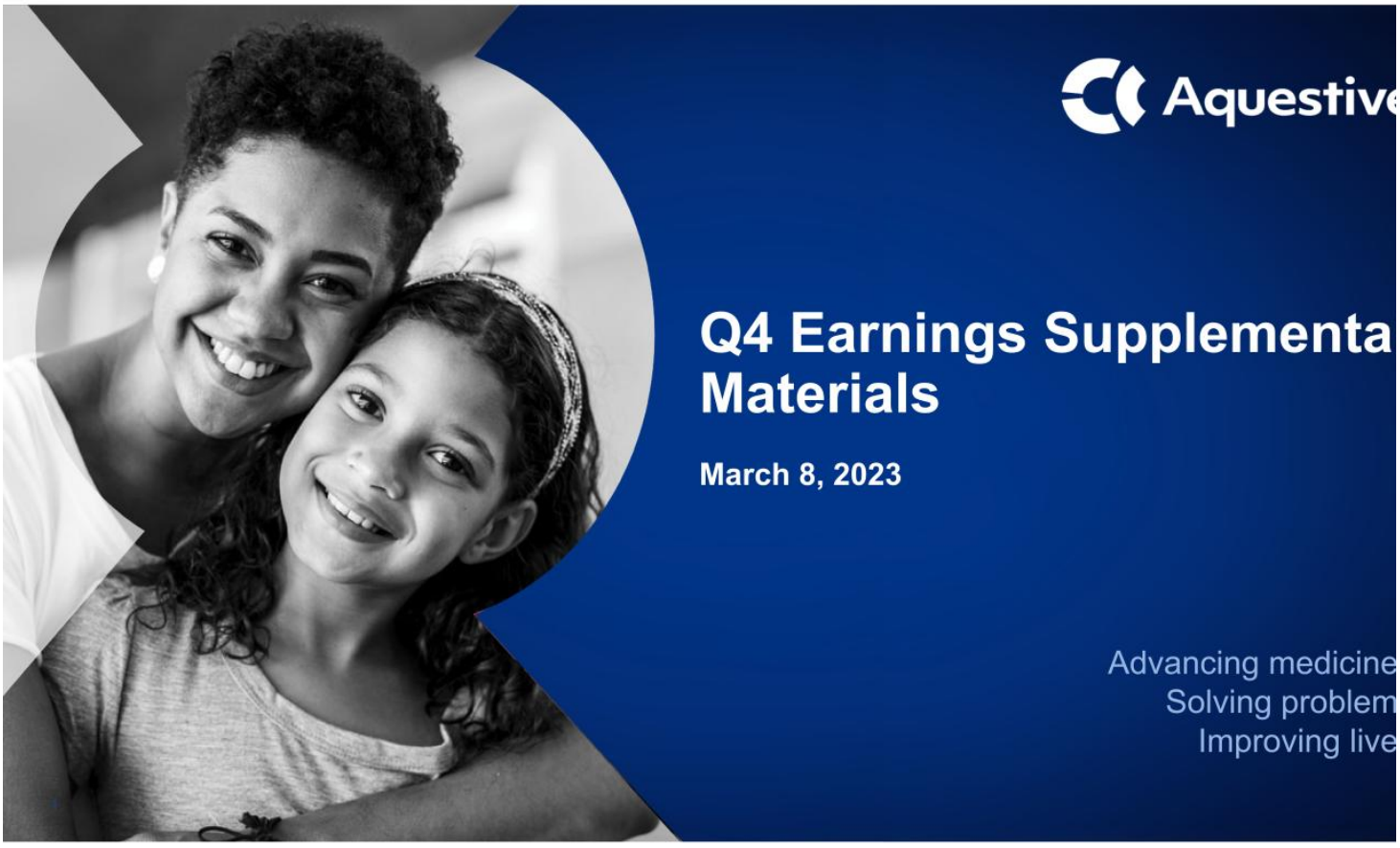
	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Manufacture and supply expense	$ 5,305	$ 3,366	$ 19,386	$ 14,989
Gross Margin on total revenue	*50 %*	*70 %*	*59 %*	*71 %*
Non-GAAP adjustments:				
Share-based compensation expense	(44)	(72)	(203)	(313)
Depreciation, amortization, and impairment	(317)	(580)	(1,890)	(2,324)
Adjusted manufacture and supply expense	$ 4,944	$ 2,714	$ 17,293	$ 12,352
Non-GAAP Gross Margin on total revenue	*54 %*	*76 %*	*64 %*	*76 %*

AQUESTIVE THERAPEUTICS, INC.
Reconciliation of Non-GAAP Adjustments - Research and Development Expense to Adjusted Research and Development Expense
(In Thousands)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Research and development expense	$ 4,278	$ 4,400	$ 17,481	$ 17,047
Non-GAAP adjustments:				
Share-based compensation expense	(266)	(211)	(672)	(881)
Depreciation, amortization, and impairment	(37)	(48)	(173)	(208)
Adjusted research and development expense	$ 3,975	$ 4,141	$ 16,636	$ 15,958

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Selling, general and administrative expenses	$ 11,812	$ 14,981	$ 52,879	$ 53,475
Non-GAAP adjustments:				
Share-based compensation expense	(402)	(1,408)	(3,506)	(5,625)
Depreciation, amortization, and impairment	(43)	(103)	(324)	(432)
Adjusted selling, general and administrative expenses	$ 11,367	$ 13,470	$ 49,049	$ 47,418


Aquestive
Q4 Earnings Supplementa
Materials
March 8, 2023
Advancing medicine
Solving problem
Improving live

Disclaimer

This presentation contains “forward-looking” statements that are based on the beliefs and assumptions and on information currently available to management of Aquestive Therapeutics, Inc. (together with its consolidated subsidiary, the “Company”, “we” or “our”). All statements other than statements of historical fact contained in this presentation are forward-looking statements. Forward-looking statements include information regarding our estimated financial position for the quarter and year ended December 31, 2022 and financial outlook for 2023; the Company’s estimated forecasts to pay down its current debt; the anticipated impact of our End-of-Phase 2 (EOP2) meeting with the United States Food and Drug Administration (FDA); the advancement and related timing of AQST-109 through the regulatory and development pipeline; clinical trial timing and plans for AQST-109, including the ability to address the FDA’s concerns provided in the EOP2 meeting; statements regarding the approval of Libervant™ by the FDA for U.S. market access and overcoming orphan drug market exclusivity of a competing FDA approved product extending to January 2027 and the timing of such review; and business strategies, market opportunities and other statements that are not historical facts. These forward-looking statements are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredients and other raw materials supply chain, manufacture and distribution; sale of and demand for our products; our liquidity and availability of capital resources, customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, we are unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic. 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.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks, uncertainties and other factors 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 AQST-109; risk of the Company’s failure to generate sufficient data in support of its New Drug Application (NDA) submission for FDA approval of AQST-109; risk of the Company’s failure to address the concerns identified in the FDA EOP2 meeting for AQST-109; risk of delays in or the failure to receive FDA approval of AQST-109; 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; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company described under “Risk Factors” in the Company’s annual report on Form 10-K for the year ended December 31, 2021, quarterly reports on Form 10-Q, current reports on Form 8-K and our other filings with the Securities and Exchange Commission. Forward-looking statements represent the Company’s beliefs and assumptions only as of the date of this presentation. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this presentation, or to conform any of the forward-looking statements to actual results or to changes in its expectations.

Financial information contained in this presentation relating to the three and twelve months ended December 31, 2022 are preliminary and unaudited and remain subject to change. As such the Company’s independent auditors have not audited, studied, reviewed or performed any procedures with respect to such preliminary information and, accordingly, they did not express an opinion or provide any other form of assurance with respect thereto for the purpose of this presentation. Our financial closing procedures for the quarter and year ended December 31, 2022 have not been completed, and as such there can be no assurance that such preliminary results are indicative of the future performance of the Company and actual results may differ materially.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

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.

Q4 2022 Earnings: Key Messages

AQST-109 (Epinephrine Sublingual Film)

- Completed End-of-Phase 2 (EoP2) meeting with the FDA in December 2022
- On track to start pivotal pharmacokinetic (PK) study in Q3 2023 with top-line data readout anticipated in late Q4 202
- Continuing to characterize administration of AQST-109 under potential conditions of allergic reaction consistent with FDA's expectations

Solid Financial Performance in 2022

- Ended 2022 with $27.3 million in cash and cash equivalents
- Generated $47.7 million in revenue, compared to guidance range of $46 million to $49 million
- EBITDA loss of $35.3 million, compared to guidance range of $37 million to $43 million

LIBERVANT™ (diazepam) buccal film

- Provided clinical data to FDA addressing orphan drug exclusivity block
- FDA responded that it is actively reviewing the data

Strong Ending to 2022….

OCTOBER

- Positive decision to dismiss Aquestive from Suboxone® States' antitrust case
- Sympazan® licensing deal with Otter Pharmaceuticals, subsidiary of Assertio Holdings

NOVEMBER

- Completion of End-of-Phase 2 meeting with FDA for AQST-109
- Announced the prepayment of outstanding debt

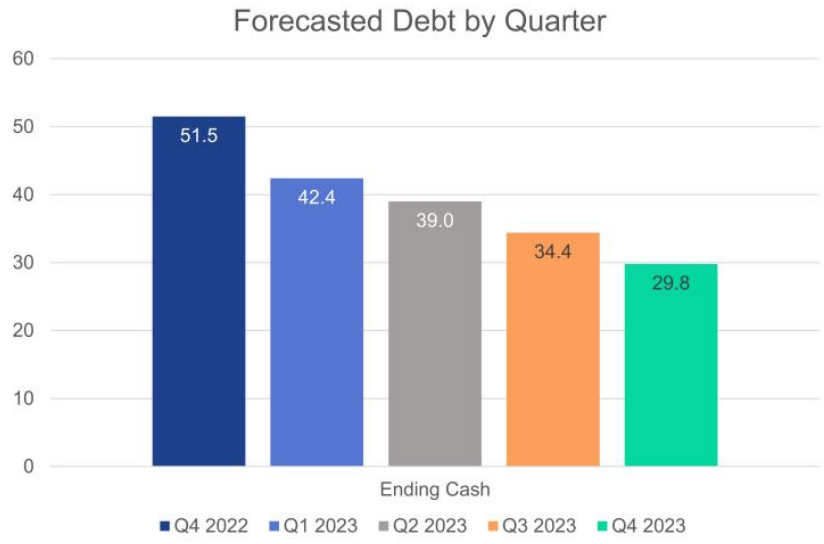
DECEMBER

- Ending cash of $27.3 million
- Met or exceeded revenue and EBITDA guidance

Cash Position Strengthened Each Quarter in 2022

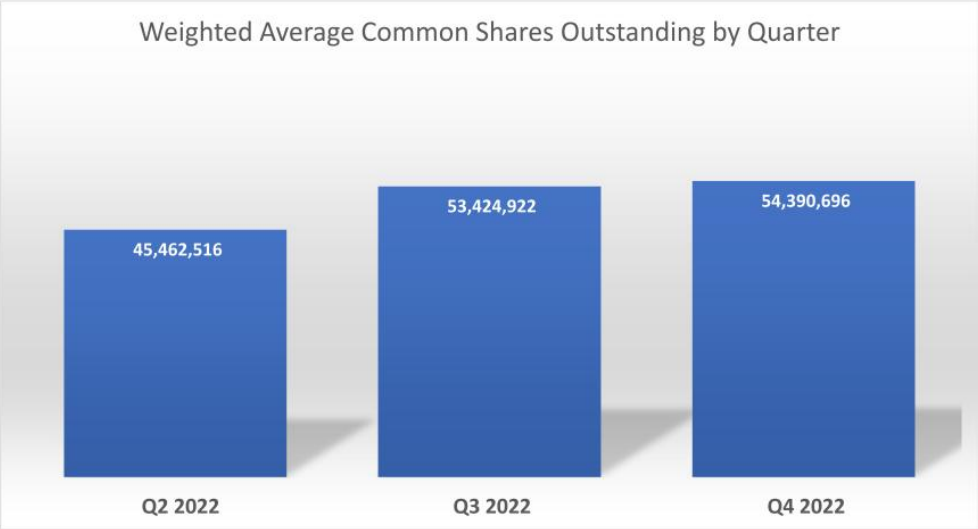
All figures in USD millions

Debt Position Forecasted to Decrease in Q1 and Throughout 2023



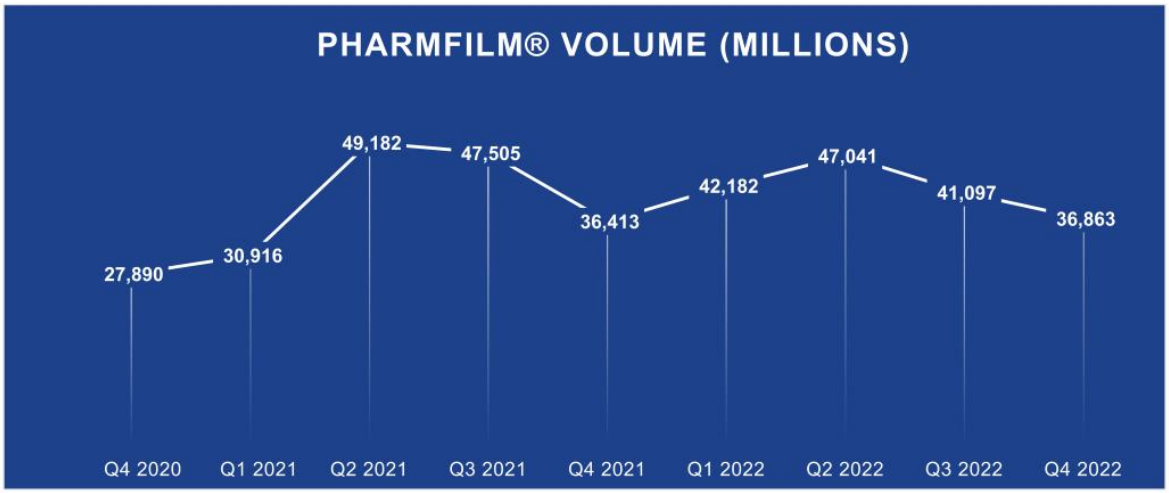
All figures in USD millions

Limited Common Share Issuance Since June 2022 Capital Raise




Aquestive
Manufacturing Operations
Advancing medicine
Solving problem
Improving live
8

Manufacturing Operations Continues to Meet Expectations and Generate Cash Flow



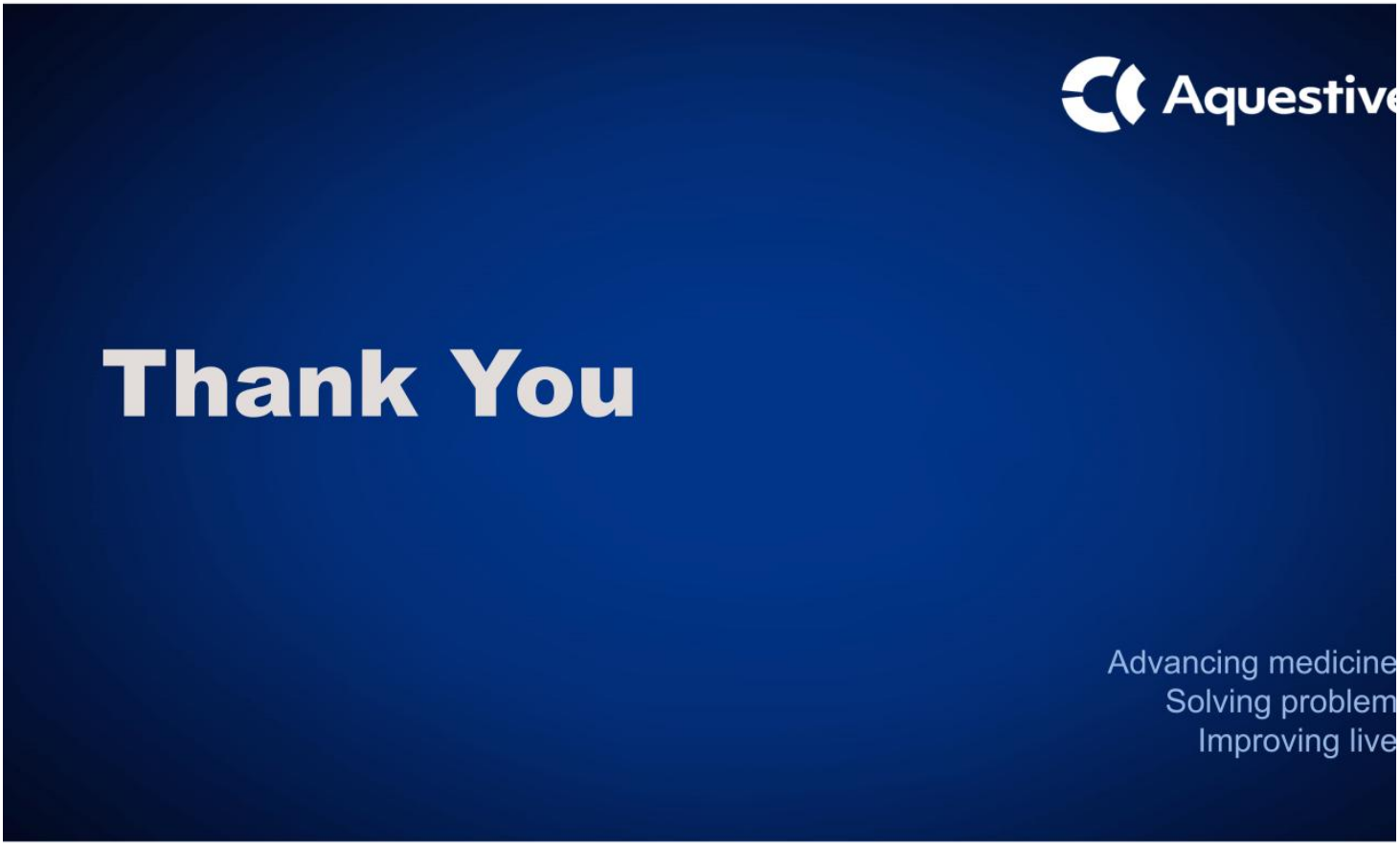
2023 Outlook

Advancing medicine
Solving problem
Improving live

2023 Outlook Update

2023 Outlook

- Total revenues of approximately $37 to $41 million
- Non-GAAP adjusted EBITDA loss of approximately $31 to $36 million


Aquestive
Thank You
Advancing medicine
Solving problem
Improving live