UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): November 6, 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 November 6, 2023, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its reported financial results for the third quarter ended September 30, 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 Current Report On Form 8-K 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 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 November 6, 2023, announcing the Company's reported financial results for the third quarter ended September 30, 2023 and providing an update on recent developments in its business.
99.2	Aquestive Therapeutics Q3 Earnings Supplemental Materials dated November 6, 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: November 6, 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 Third Quarter 2023 Financial Results and Provides Business Update

- Reiterates commencement of pivotal pharmacokinetic (PK) study for Anaphylm™ (epinephrine) Sublingual Film expected in fourth quarter 2023 with topline data targeted for first quarter 2024
- Completes debt refinancing resulting in approximately $28 million of cash savings through June of 2025
- Reported 25% year-over-year growth in year-to-date revenue adjusted for the out-license of Sympazan®
- Raises full year 2023 revenue guidance to $47-$50 million and improves non-GAAP adjusted EBITDA loss guidance
- To host investment community conference call at 8:00 am ET on November 7, 2023

Warren, N.J. November 6, 2023 – 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 third quarter ended September 30, 2023 and provided an update on recent developments in its business.

“We continue to successfully execute on our 2023 key initiatives as demonstrated by our third quarter 2023 results,” said Daniel Barber, Chief Executive Officer of Aquestive. “We are on track to have a strong finish to 2023 and believe 2024 has the potential to be a transformative year for the Company. We remain focused on achieving our upcoming clinical and regulatory milestones, while continuing to grow our base business."

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

The Company received positive feedback in October 2023 from the U.S. Food and Drug Administration (FDA) on the Company's pivotal Phase 3 PK clinical program 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 program that includes two pivotal PK studies and three supportive PK studies.

The Company is on track to commence its initial Phase 3 pivotal PK study for Anaphylm in the fourth quarter 2023. The study design is a two-part open-label, randomized study comparing the pharmacokinetics and pharmacodynamics of single and repeat doses of Anaphylm to that of epinephrine administered as an intramuscular injection to healthy adult subjects. Aquestive anticipates reporting topline data in the first quarter 2024.

Libervant™
In September 2023, Aquestive's New Drug Application (NDA) for approval of 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 was accepted by the FDA. 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 for this 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 46 million doses in the third quarter 2023, compared to 41 million doses in the third quarter 2022. The Company continues to see strong 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) 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 third quarter of 2023.

Debt Refinancing
As previously reported, on November 1, 2023, the Company issued (the "Offering") $45 million aggregate principal amount of its 13.5% Senior Secured Notes (the "13.5% Notes") to a large leading institutional investor and some of its affiliated entities (the "Note Holders"). A portion of the net proceeds from the Offering was used to redeem all of the outstanding 12.5% Senior Secured Notes of the Company and to pay expenses relating to the Offering, with the balance of the proceeds to be used for the Company's general corporate purposes. The 13.5% Notes are senior secured obligations of Aquestive and will mature on November 1, 2028, unless earlier redeemed or repurchased in accordance with their terms. The 13.5% Notes bear interest at a fixed rate of 13.5% per year, payable quarterly commencing on December 30, 2023. Principal on the 13.5% Notes will be repaid starting on June 30, 2026. The 13.5% Notes contain no revenue or cash covenants, and no warrants for purchase of the Company's common stock were issued under the terms of the debt refinancing transaction.

In connection with the Offering, the Company entered into agreements with each of the Note Holders granting the Note Holders a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm for a period of eight years from the first sale of Anaphylm on a global basis. The Note Holders are also entitled to a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant.

Third Quarter 2023 Financials
Excluding the impact of prior year proprietary sales of Sympazan, total revenues increased from $9.2 million in the third quarter 2022 to $13.0 million in the third quarter 2023. This 42% increase in revenue was primarily driven by higher revenue from the Company's five out-licensed products. The year-to-date revenue increased 25% as compared to the prior year when adjusted for the out-license of Sympazan®.

Total reported revenues were $13.0 million in the third quarter 2023, compared to $11.5 million in the third quarter 2022. For the third quarter 2023 compared to the prior year period, the Company saw a 36% increase in manufacture and supply revenue, a 193% increase in license and royalty revenue and a 24% increase in co-development and research fees.

Aquestive's net loss for the third quarter 2023 was $2.0 million, or $0.03 for both basic and diluted loss per share compared to the higher net loss for the third quarter 2022 of $12.5 million, or $0.23 for both basic and diluted loss per share. The decrease in net loss was primarily driven by increases in revenue described above, and decreases in selling, general and administrative expenses and research and development expenses, and non-cash interest expense related to the KYNMOBI® monetization transaction.

Non-GAAP adjusted EBITDA loss was $1.3 million in the third quarter 2023, compared to non-GAAP adjusted EBITDA loss of $7.7 million in the third quarter 2022. Non-GAAP adjusted EBITDA income excluding adjusted R&D expenses was $1.7 million in the third quarter 2023, compared to a non-GAAP adjusted EBITDA loss excluding adjusted R&D expenses of $4.6 million in the third quarter 2022.

Cash and cash equivalents were $24.9 million as of September 30, 2023.

Outlook
Aquestive is updating its full-year 2023 financial guidance based on third quarter 2023 results and updated outlook for the remainder of 2023.

The Company expects:

	Updated Guidance	Prior Guidance
Total revenue (in millions)	$47 to $50	$44 to $48
Non-GAAP adjusted EBITDA loss (in millions)	$14 to $17	$19 to $22

Tomorrow's Conference Call and Webcast Reminder
The Company will host a conference call at 8:00 a.m. ET on Tuesday, November 7, 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: **Third Quarter 2023 Earnings Conference Call**

About Aquestive Therapeutics
Aquestive is 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 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 2023 and 2022 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™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the filing of pivotal PK clinical trials and other supporting clinical studies for Anaphylm; regarding the Company’s ability to provide sufficient data in its NDA submission to address the FDA’s recent comments on the Company’s proposed pivotal PK study protocol and the FDA’s other concerns following the End-of-Phase 2 meeting with the FDA; 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 twelve years and older, and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for this age group of the 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 2023 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, 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 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 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 2022 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,917	$ 27,273
Trade and other receivables, net	8,550	4,704
Inventories, net	7,079	5,780
Prepaid expenses and other current assets	1,911	2,131
Total current assets	42,457	39,888
Property and equipment, net	4,551	4,085
Right-of-use assets, net	5,669	5,211
Intangible assets, net	1,317	1,435
Other non-current assets	5,454	6,451
Total assets	$ 59,448	$ 57,070
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 9,994	$ 9,946
Accrued expenses	5,468	7,967
Lease liabilities, current	367	255
Deferred revenue, current	2,637	1,513
Liability related to the sale of future revenue, current	985	1,147
Loans payable, current	4,606	18,700
Total current liabilities	24,057	39,528
Loans payable, net	34,555	33,448
Liability related to the sale of future revenue, net	63,511	64,112
Lease liabilities	5,509	5,085
Deferred revenue	32,732	31,417
Other non-current liabilities	2,011	2,034
Total liabilities	162,375	175,624
Contingencies		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 66,740,765 and 54,827,734 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	67	55
Additional paid-in capital	207,972	192,598
Accumulated deficit	(310,966)	(311,207)
Total stockholders' deficit	(102,927)	(118,554)
Total liabilities and stockholders' deficit	$ 59,448	$ 57,070

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

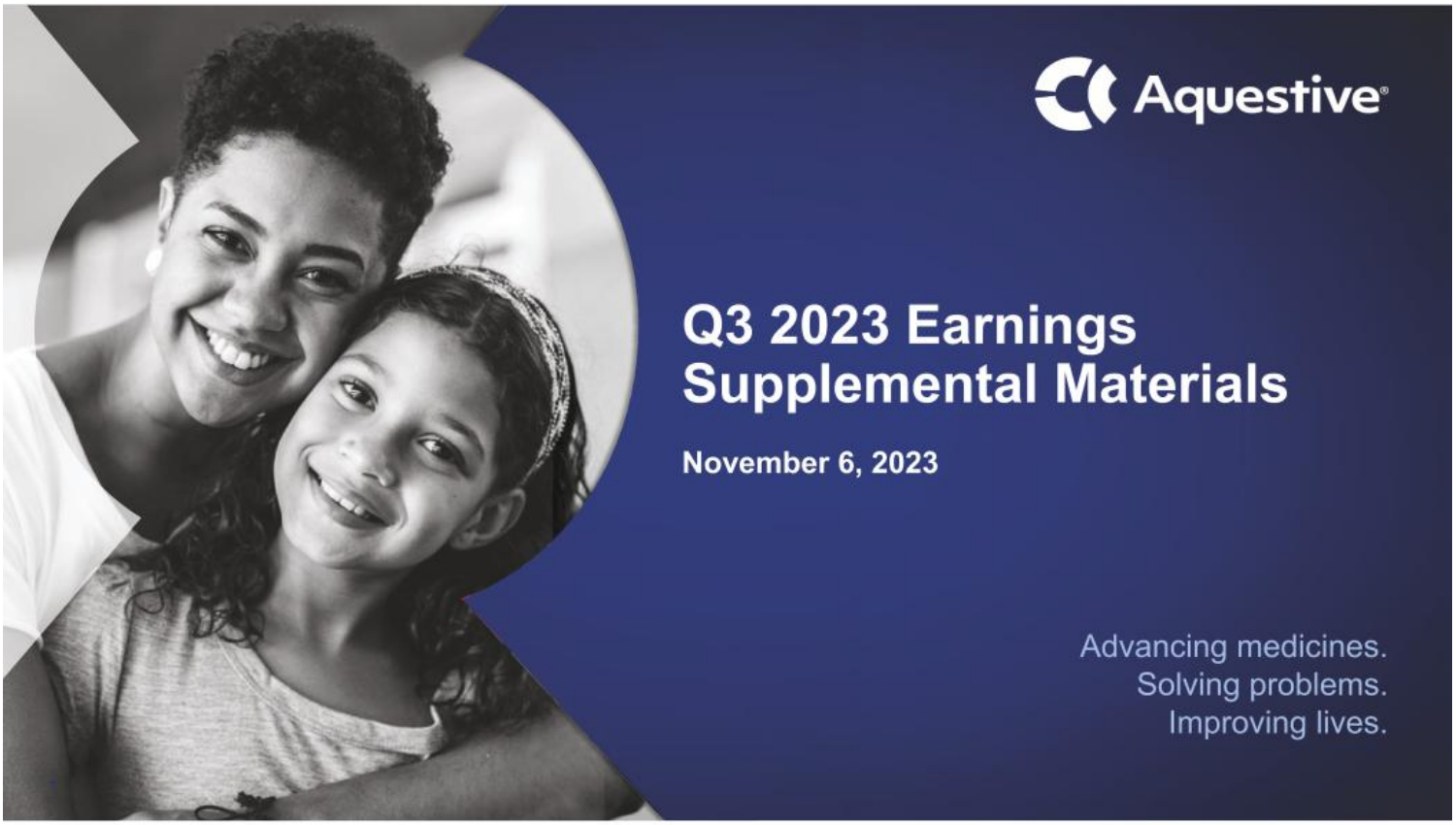
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues	$ 13,002	$ 11,463	$ 37,377	$ 36,998
Costs and expenses:				
Manufacture and supply	4,798	4,625	16,152	14,081
Research and development	3,196	3,232	10,216	13,203
Selling, general and administrative	7,385	12,459	22,200	41,067
Total costs and expenses	15,379	20,316	48,568	68,351
Loss from operations	(2,377)	(8,853)	(11,191)	(31,353)
Other income/ (expenses):				
Interest expense	(1,256)	(1,649)	(4,064)	(4,902)
Interest expense related to the sale of future revenue, net	(56)	(2,039)	(163)	(5,837)
Interest and other income (expense), net	1,514	5	16,156	34
Loss on extinguishment of debt	—	—	(353)	—
Net income (loss) before income taxes	(2,175)	(12,536)	385	(42,058)
Income taxes	(140)	—	144	—
Net income (loss)	$ (2,035)	$ (12,536)	$ 241	$ (42,058)
Comprehensive income (loss)	$ (2,035)	$ (12,536)	$ 241	$ (42,058)
Earnings (loss) per share attributable to common stockholders:				
Basic (in dollars per share)	$ (0.03)	$ (0.23)	$ —	$ (0.90)
Diluted (in dollars per share)	(0.03)	(0.23)	$ —	$ (0.90)
Weighted average common shares outstanding:				
Basic (in shares)	64,678,761	53,424,922	59,252,768	46,828,218
Diluted (in shares)	64,678,761	53,424,922	61,513,736	46,828,218

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss	$ (2,035)	$ (12,536)	$ 241	$ (42,058)
Share-based Compensation Expense	774	535	1,766	3,669
Interest expense	1,256	1,649	4,064	4,902
Interest expense related to the sale of future revenue, net	56	2,039	163	5,837
Interest and other (income) expense, net	(1,514)	(5)	(16,156)	(34)
Loss on extinguishment of debt	—	—	353	—
Income Taxes	(140)	—	144	—
Depreciation and Amortization	264	596	878	1,990
Total non-GAAP adjustments	$ 696	$ 4,814	$ (8,788)	$ 16,364
Adjusted EBITDA	$ (1,339)	$ (7,722)	$ (8,547)	$ (25,694)
Excluding adjusted R&D expenses	(3,069)	(3,114)	(9,869)	(12,661)
Adjusted EBITDA excluding adjusted R&D expenses	$ 1,730	$ (4,608)	$ 1,322	$ (13,033)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Total costs and expenses	$ 15,379	$ 20,316	$ 48,568	$ 68,351
Non-GAAP adjustments:				
Share-based compensation expense	(774)	(535)	(1,766)	(3,669)
Depreciation and amortization	(264)	(596)	(878)	(1,990)
Adjusted costs and expenses	$ 14,341	$ 19,185	$ 45,924	$ 62,692
Manufacture and Supply Expense	$ 4,798	$ 4,625	$ 16,152	$ 14,081
Gross Margin on total revenue	*63 %*	*60 %*	*57 %*	*62 %*
Non-GAAP adjustments:				
Share-based compensation expense	(59)	(66)	(155)	(159)
Depreciation and amortization	(214)	(459)	(746)	(1,573)
Adjusted manufacture and supply expense	$ 4,525	$ 4,100	$ 15,251	$ 12,349
Non-GAAP Gross Margin on total revenue	*65 %*	*64 %*	*59 %*	*67 %*
Research and Development Expense	$ 3,196	$ 3,232	$ 10,216	$ 13,203
Non-GAAP adjustments:				
Share-based compensation expense	(105)	(75)	(277)	(406)
Depreciation and amortization	(22)	(43)	(70)	(136)
Adjusted research and development expense	$ 3,069	$ 3,114	$ 9,869	$ 12,661
Selling, General and Administrative Expenses	$ 7,385	$ 12,459	$ 22,200	$ 41,067
Non-GAAP adjustments:				
Share-based compensation expense	(610)	(394)	(1,334)	(3,104)
Depreciation and amortization	(28)	(94)	(62)	(281)
Adjusted selling, general and administrative expenses	$ 6,747	$ 11,971	$ 20,804	$ 37,682


Aquestive
Q3 2023 Earnings
Supplemental Materials
November 6, 2023
Advancing medicines.
Solving problems.
Improving lives.

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™ (epinephrine) Sublingual Film for the emergency treatment of severe allergic reactions, including anaphylaxis through clinical development and approval by the U.S. Food and Drug Administration (FDA), including the filing of pivotal pharmacokinetic (PK) clinical trials and other supporting clinical studies for Anaphylm; regarding the advancement and relating timing through clinical development and approval by the FDA of the Company's New Drug Application (NDA) for our product candidate Libervant™ (diazepam) Buccal Film 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 with epilepsy between two and five years of age; regarding the approval for U.S. market access of Libervant for these epilepsy patients aged 12 years and older, and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for this age group of the patient population; regarding the potential for licensing Anaphylm to third parties outside of the U.S.; regarding 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 2023 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, 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 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 clinical trials for FDA approval of Anaphylm and Libervant for patients between 2 and 5 years of age; 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; risk that the FDA may require additional clinical studies for approval of Anaphylm and Libervant for patients between 2 and 5 years of age; risk of delays in or the failure to receive FDA approval of Anaphylm and Libervant; 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 in effect until January 2027, 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 2 and 5 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 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 achieving growth in our base business; risk of the success of any competing products; 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 2022 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Financial information contained in this presentation relating to the nine months ended September 30, 2023, 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 nine months ended September 30, 2023 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.

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

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Q3 2023 Earnings: Key Messages

Anaphylm™ (epinephrine) sublingual film

- Received positive FDA feedback on Pivotal Study Protocol
- Pivotal Study will commence in Q4 2023
- Continue to actively pursue ex-US licensing opportunities for Anaphylm

Financial Performance

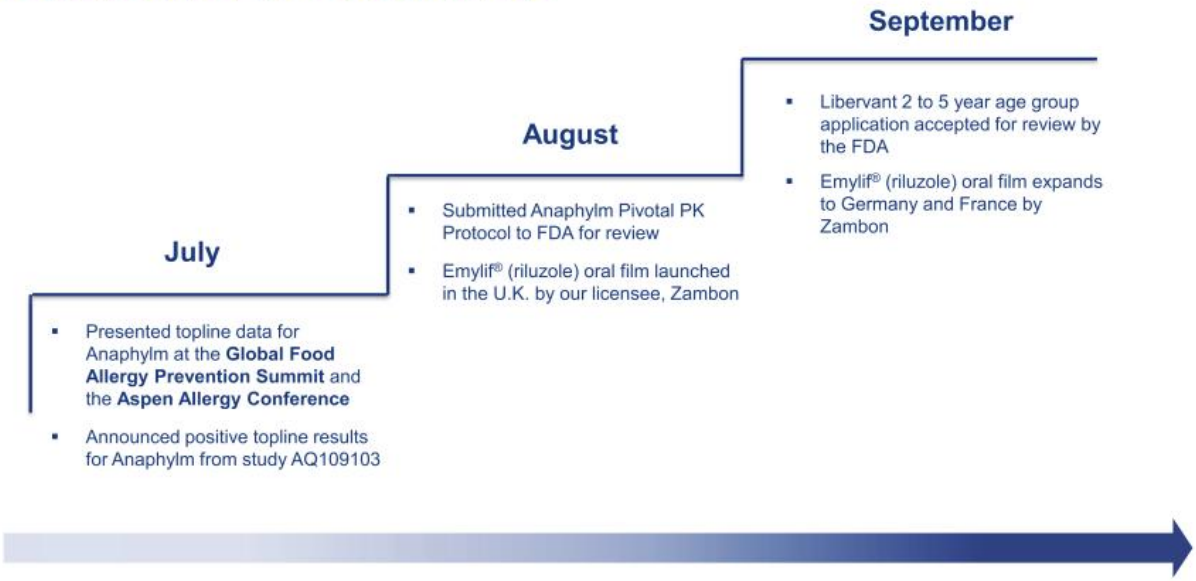
- Completed a debt refinancing in November that will result in a $28 million of cash savings through June of 2025
- FY2023 YTD revenue increased 25% as compared with the same time period in FY2022 (adjusted for the out-license of Sympazan® (clobazam) oral film)
- Non-GAAP adjusted EBITDA excluding adjusted R&D expense was positive for the second quarter in a row
- Ended Q3 2023 with $24.9 million in cash and cash equivalents*

Libervant™ (diazepam) buccal film

- Libervant NDA for the 2 to 5 years age group was accepted by the FDA with an assigned PDUFA target action date of April 28, 2024
- Continue to actively pursue a U.S. licensing opportunity for Libervant

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

Consistent Execution in Q3



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Anaphylm Pivotal Study

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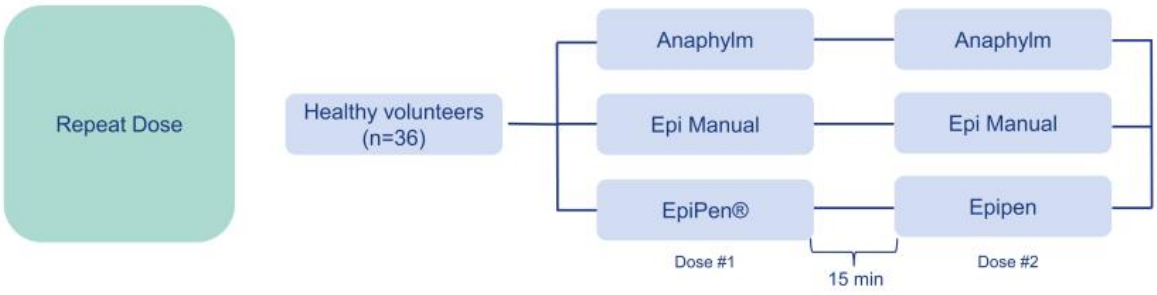
Anaphylm Pivotal Study Design



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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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Debt Refinancing Highlights

Description	New Debt Facility	Previous Debt Facility
Noteholder(s)	Leading Institutional Lender with over $10B under mgmt.	Syndicated
Fixed Interest Rate	13.5%	12.5%
Fixed Interest Rate Net of Fed Funds Rate at Signing	8.0%	10.2%
Warrants	None	2,000,000
Revenue, EBITDA, Cash Covenants	None	None
Interest Only Period	32 months	36 months
Limited Royalty on Pipeline Assets	Yes	No

Continuing to Manage Our Cash Position

All figures in USD millions

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

Base Business Continues to Strengthen

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Manufacturing Volumes Meet Expectations and Generate Cash Flow

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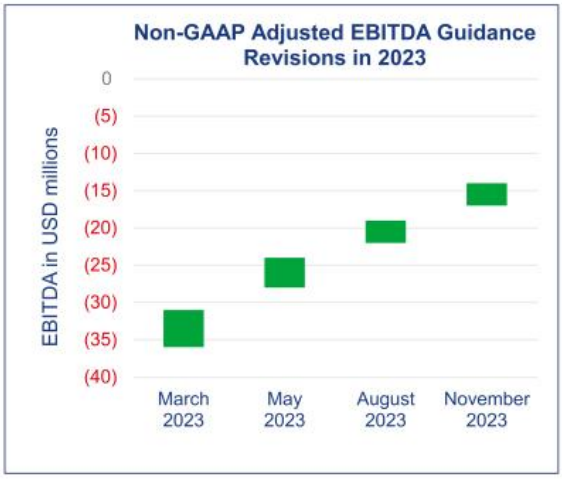
Outlook Update – Revised Guidance

2023 Outlook as of November 2023

- Total revenues of approximately $47 to $50 million
- Non-GAAP adjusted EBITDA loss of approximately $14 to $17 million



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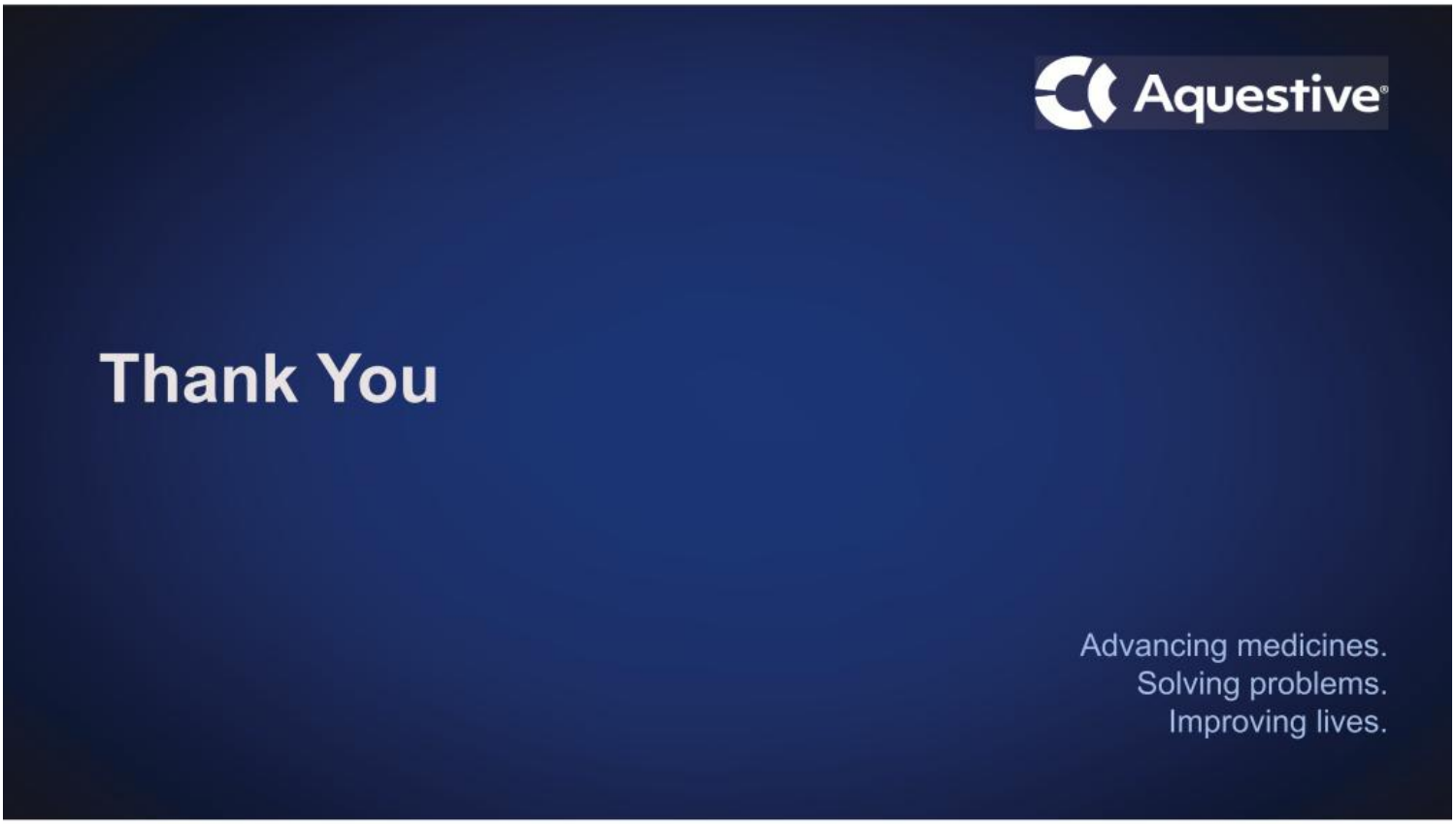
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