

**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 1, 2022

Aquestive Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation or
Organization)

001-38599
(Commission File Number)

82-3827296
(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 1, 2022, Aquestive Therapeutics, Inc. (the “Company”) issued a press release announcing its reported financial results for the third quarter ended September 30, 2022 and provided an update on recent developments in its business. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and incorporated 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, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated November 1, 2022, announcing the Company’s reported financial results for the third quarter ended September 30, 2022 and providing an update on recent developments in its business.

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 1, 2022

Aquestive Therapeutics, Inc.

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



Aquestive Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Update

- Reported positive data from EPIPHAST II trial comparing AQST-109 (epinephrine sublingual film) to EpiPen® 0.3mg (single dose) and AQST-109 to epi 0.3mg IM injection (repeat dose)
- Scheduled End-of-Phase 2 (EoP2) meeting with FDA on AQST-109 for fourth quarter 2022
- Generated over \$25 million in near-term non-dilutive funding through multiple transactions
- Announces strategic decision to explore US out-licensing opportunities for Libervant (diazepam buccal film)
- Confirms full-year revenue and earnings guidance
- Hosts investment community conference call on November 2, 2022

Warren, N.J., November 1, 2022 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company advancing current standards of care to solve patients’ problems through simplifying complex delivery methods, today reported financial results for the third quarter ended September 30, 2022 and provided an update on recent developments in its business.

“We have made significant progress over the last few months in streamlining our business, reducing expenses, and creating a path to an improved financial position, while continuing to rapidly advance our lead asset, AQST-109,” said Daniel Barber, Chief Executive Officer of Aquestive. “We continue to believe in the real-world utility of epinephrine sublingual film and look forward to reviewing the data and pivotal program plan with the FDA in our upcoming EoP2 meeting. At the same time, we continue to engage with the FDA on Libervant and are prioritizing the exploration of out-licensing this important product for North America. In the meantime, our manufacturing business continues to generate strong results, thereby allowing us to focus on reducing and potentially refinancing our corporate debt as we progress into 2023.”

Epinephrine

Aquestive is advancing the development of AQST-109, the first and only orally delivered epinephrine product candidate to have shown clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis.

According to expert data, nearly 1-in-50 Americans are at chronic risk for acute anaphylactic reactions, however only approximately 3 million prescriptions are filled for injectable epinephrine each year. AQST-109 has the potential to offer these at-risk individuals with an option that overcomes needle phobia and portability challenges seen with existing treatment options.

Aquestive reported positive data from its EPIPHAST II trial comparing AQST-109 to epinephrine 0.3mg intramuscular (IM) injection (repeat dose) and AQST-109 to EpiPen 0.3mg (single dose). The EPIPHAST II trial was designed to compare single doses of AQST-109 to EpiPen 0.3mg and epinephrine 0.3mg IM injection, as well as repeat doses of AQST-109 to repeat doses of epinephrine 0.3mg IM injection. Results from the single dose administration showed AQST-109 achieved a significantly faster median time to maximum concentration (T_{max}) T_{max} (12 minutes), compared to both EpiPen 0.3mg (22.5 minutes) and epinephrine 0.3mg IM injection (45 minutes). AQST-109 repeat dosing provided significantly higher drug plasma concentrations, with a T_{max} of 8 minutes after administration. Results comparing additional pharmacokinetic and pharmacodynamic measures from this study were included in the initial Company press release and supplemental materials dated September 27, 2022. These materials remain available on the Investor page of the Aquestive website.

In September 2022, Aquestive established a Scientific Advisory Board, comprised of eight allergy experts. Each individual on Aquestive’s advisory board have made significant contributions and breakthroughs in the Allergy and Immunology space.

In October 2022, Aquestive received positive written feedback from the U.S. Food and Drug Administration (FDA) for the Company's initial End-of-Phase 2 (EoP2) meeting request to discuss Chemistry, Manufacturing, and Controls (CMC) for AQST-109. Stability and shelf life are well-documented topics for acute rescue products containing epinephrine. Epinephrine is known to degrade quickly and, as the EpiPen label currently indicates, "[e]pinephrine solution deteriorates rapidly on exposure to air or light." AQST-109 has been designed to minimize exposure to air and light until opened for use. The FDA's written response indicates that Aquestive's approach to characterizing these and other attributes of AQST-109 "appear reasonable" in the context of a potential future filing.

The EoP2 meeting with the FDA to obtain guidance and concurrence on specific questions relating to the clinical components of a potential AQST-109 filing is scheduled during the fourth quarter 2022. At this meeting, Aquestive anticipates receiving feedback on the EPIPHAST study data, as well as the remainder of the proposed clinical development plan for AQST-109.

Libervant™

Aquestive was granted tentative approval from the FDA for Libervant™ 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. The FDA has concluded that Libervant has met all required quality, safety, and efficacy standards for approval but, due to an existing FDA regulatory grant of orphan drug market exclusivity for Valtoco®, a diazepam nasal spray product, Libervant is not yet eligible for marketing in the United States. As a result of the FDA determination, the Agency cannot give final approval for Libervant until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by a reversal of the FDA's decision and determination that Libervant is "clinically superior" to Valtoco within the meaning of FDA's regulations, including by establishing a major contribution to patient care relative to the approved product.

Engagement between Aquestive and the FDA is ongoing as the Company has provided its proposed protocol for a head to head clinical study, and is awaiting feedback from the FDA. Concurrently, Aquestive has reached the strategic decision to explore out-licensing opportunities for the North American rights to Libervant (diazepam buccal film).

Out-licensing Activities

In September 2022, Aquestive entered a license, and supply agreement for Libervant with Pharmanovia, a global lifecycle management healthcare company (the "Pharmanovia Agreement"), for the treatment of prolonged or acute, convulsive seizures in all ages, across the European Union, United Kingdom, Switzerland, and Norway, as well as countries in the Middle East and North Africa (MENA). Pursuant to the Pharmanovia Agreement, Aquestive will serve as the exclusive sole manufacturer and supplier for the product and Pharmanovia will be responsible for all regulatory and commercialization activities relating to the product in those licensed territories. Under the Pharmanovia Agreement, Aquestive received an upfront payment from Pharmanovia of \$3.5 million and, if Libervant is approved in the licensed territories, will receive additional milestone payments and double-digit royalties on net sales of Libervant in the licensed territories.

In October 2022, the Company entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. ("Assertio"), a specialty pharmaceutical company offering differentiated products to patients, to license Sympazan® (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients aged two years of age or older (the "Assertio License Agreement"). Under the terms of the Assertio License Agreement, the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of the Assertio License Agreement for an upfront payment of \$9.0 million. Under the terms of the Assertio License Agreement, Aquestive will receive a \$6.0 million milestone payment within thirty (30) days after Aquestive's receipt of a notice of allowance from the United States Patent and Trademark Office (PTO) of the Company's patent application U.S. Serial No. 16/561,573, and payment by the Company of the related allowance fee. The Company received the notice of allowance from the PTO and paid the related allowance fee on October 27, 2022. In addition, under the Assertio License Agreement, the Company will receive royalties from Assertio for the sale of the product through the expiration of the Assertio License Agreement. The Company also entered into a long-term supply agreement with

Assertio, pursuant to which the Company is the exclusive sole worldwide manufacturer and supplier of Sympazan and will receive manufacturing fees from Assertio for the product through the expiration of such supply agreement.

In September 2022, Aquestive received a \$7.0 million upfront cash payment from Haisco Pharmaceutical Group for the previously announced licensing and supply agreement for Exservan (riluzole oral film) in China.

Team Expansion

In August 2022, Aquestive appointed Kenneth Truitt, M.D. as Chief Medical Officer. Dr. Truitt has over 25 years of clinical and regulatory experience across biotechnology and large pharmaceutical companies. Concurrently, Aquestive named Timothy E. Morris to the Company's Board of Directors. Mr. Morris brings close to twenty years of pharma industry experience and presently serves as the Chief Financial Officer of Opthea Limited.

Third Quarter 2022 Financials

Total revenues were \$11.5 million in the third quarter 2022, compared to \$13.3 million in the third quarter 2021. For the third quarter 2022 compared to the prior year period, the Company saw a 15% increase in Sympazan net revenue and a 15% increase in license and royalty revenue, offset by reductions in manufacture and supply revenue as well as co-development and research fees.

Aquestive's net loss for the third quarter 2022 was \$12.5 million, or \$0.23 loss per share. The net loss for the third quarter 2021 was \$14.6 million, or \$0.37 loss per share. The change in net loss was primarily driven by a decrease in interest expense, a decrease in non-cash interest expense related to the KYNMOBI® monetization transaction, a decrease in research and development cost and expenses, partially offset by lower revenue.

Adjusted EBITDA loss was \$7.7 million in the third quarter 2022, compared to an adjusted EBITDA loss of \$5.3 million in the third quarter of 2021. The change in adjusted EBITDA loss year-over-year included a decrease in share-based compensation expense, a decrease in interest expense and a decrease in non-cash interest expense related to the KYNMOBI monetization transaction, partially offset by a lower net loss described above.

Cash and cash equivalents were \$18.6 million as of September 30, 2022.

2022 Outlook

Aquestive is confirming its full-year 2022 financial outlook.

The Company expects:

	Guidance
Total revenue (in millions)	\$46 to \$49
Non-GAAP adjusted EBITDA loss (in millions)	\$37 to \$43

Tomorrow's Conference Call and Webcast Reminder

The Company will host a conference call at 8:00 a.m. ET on Wednesday, November 2, 2022.

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 2022 Results. The webcast will be archived for 30 days.

About Aquestive Therapeutics

Aquestive Therapeutics, Inc. (NASDAQ: AQST) is a pharmaceutical company advancing current standards of care to solve patients' problems by simplifying complex delivery methods. Aquestive is developing pharmaceutical products to deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. Aquestive has five licensed commercialized products which are marketed by our licensees in the U.S. and around the world. The Company 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. The Company is advancing an early stage product pipeline for the treatment of severe allergic reactions, including anaphylaxis. The Company has also developed a product pipeline focused on treating diseases of the central nervous system, or CNS. The Company's production facilities are located in Portage, Indiana, and our corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey. 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 are “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, clinical advancement and related timing of AQST-109 through the regulatory and development pipeline; the potential for AQST-109 as the first orally administered epinephrine product candidate for the treatment of anaphylaxis; statements regarding the approval of Libervant by the FDA for U.S. market access and potential out-licensing of Libervant in North America; potential refinancing of the Company's current corporate debt; profitability of the Company's manufacturing operations and the 2022 financial outlook of the Company; and business strategies, market opportunities, 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 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 ingredient 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, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are also based on our current expectations and beliefs and are subject to a due 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 our product development activities and clinical trials and plans for AQST-109, AQST-108 and our other drug candidates; risk of delays in regulatory advancement through the FDA of Libervant, AQST-109, AQST-108, and our other drug candidates or failure to receive approval, including the risk that the FDA may require additional clinical studies for FDA approval of Libervant for U.S. market access; risk of our ability to demonstrate to the FDA the “clinical superiority” of Libervant within the meaning of the FDA regulations relative to FDA-approved Valtoco® (diazepam) spray product of another company, including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved product, as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product in the U.S., and there can be no assurance that the Company will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug product candidates for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk that a competitor will obtain other market exclusivity with respect to our product candidates; risk in obtaining market access for our product candidates for other reasons; 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; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products and other litigation matters in which we are involved; risk of sufficient capital and cash resources, including access to available debt and equity financing, including under the Company's At-The-Market facility and other current equity facility, and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed, or at all; risks and uncertainties concerning the royalty and other revenue stream of the KYNMOBI® monetization transaction, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction; 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 related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk of eroding market share for Suboxone and risk of a sunseting product; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product 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; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory

actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; including anticipated sales of Sympazan®; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, securities, business torts, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities 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 us or any person acting on our 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.

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.

Investor inquiries:

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,649	\$ 28,024
Trade and other receivables, net	10,737	12,120
Inventories, net	6,725	4,038
Prepaid expenses and other current assets	1,976	3,077
Total current assets	38,087	47,259
Property and equipment, net	4,284	5,055
Right-of-use assets, net	2,094	2,725
Intangible assets, net	1,487	51
Other non-current assets	5,893	6,903
Total assets	\$ 51,845	\$ 61,993
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 11,072	\$ 8,314
Accrued expenses	7,733	8,736
Lease liabilities, current	846	899
Deferred revenue, current	774	765
Liability related to the sale of future revenue, current	1,910	1,225
Loans payable, current	14,225	2,025
Total current liabilities	36,560	21,964
Loans payable, net	38,675	51,551
Liability related to the sale of future revenue, net	63,308	59,059
Lease liabilities	1,340	1,946
Deferred revenue	17,622	7,122
Other non-current liabilities	2,159	2,485
Total liabilities	159,664	144,127
Contingencies		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 53,852,126 and 41,228,736 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	54	41
Additional paid-in capital	190,982	174,621
Accumulated deficit	(298,855)	(256,796)
Total stockholders' deficit	(107,819)	(82,134)
Total liabilities and stockholders' deficit	\$ 51,845	\$ 61,993

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues	\$ 11,463	\$ 13,287	\$ 36,998	\$ 39,754
Costs and expenses:				
Manufacture and supply	4,625	4,400	14,081	11,623
Research and development	3,232	4,726	13,203	12,647
Selling, general and administrative	12,459	12,129	41,067	38,494
Total costs and expenses	20,316	21,255	68,351	62,764
Loss from operations	(8,853)	(7,968)	(31,353)	(23,010)
Other income/ (expenses):				
Interest expense	(1,649)	(2,787)	(4,902)	(8,305)
Interest expense related to the sale of future revenue, net	(2,039)	(3,767)	(5,837)	(10,567)
Interest and other income (expense), net	5	(33)	34	288
Net loss before income taxes	(12,536)	(14,555)	(42,058)	(41,594)
Income taxes	—	—	—	—
Net loss	\$ (12,536)	\$ (14,555)	\$ (42,058)	\$ (41,594)
Comprehensive loss	\$ (12,536)	\$ (14,555)	\$ (42,058)	\$ (41,594)
Net loss per share - basic and diluted	\$ (0.23)	\$ (0.37)	\$ (0.90)	\$ (1.12)
Weighted-average number of common shares outstanding - basic and diluted	53,424,922	39,224,863	46,828,218	37,297,892

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net loss	\$ (12,536)	\$ (14,555)	\$ (42,058)	\$ (41,594)
Share-based Compensation Expense	535	1,900	3,669	5,128
Interest expense	1,649	2,787	4,902	8,305
Interest expense related to the sale of future revenue, net	2,039	3,767	5,837	10,567
Interest and other (income) expense, net	(5)	33	(34)	(288)
Income Taxes	—	—	—	—
Depreciation and Amortization	596	736	1,990	2,233
Total non-GAAP adjustments	\$ 4,814	\$ 9,223	\$ 16,364	\$ 25,945
Adjusted EBITDA	\$ (7,722)	\$ (5,332)	\$ (25,694)	\$ (15,649)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total costs and expenses	\$ 20,316	\$ 21,255	\$ 68,351	\$ 62,764
Non-GAAP adjustments:				
Share-based compensation expense	(535)	(1,900)	(3,669)	(5,128)
Depreciation and amortization	(596)	(736)	(1,990)	(2,233)
Adjusted costs and expenses	<u>\$ 19,185</u>	<u>\$ 18,619</u>	<u>\$ 62,692</u>	<u>\$ 55,403</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Manufacture and Supply Expense	\$ 4,625	\$ 4,400	\$ 14,081	\$ 11,623
<i>Gross Margin on total revenue</i>	60 %	67 %	62 %	71 %
Non-GAAP adjustments:				
Share-based compensation expense	(66)	(88)	(159)	(241)
Depreciation and amortization	(459)	(579)	(1,573)	(1,744)
Adjusted manufacture and supply expense	<u>\$ 4,100</u>	<u>\$ 3,733</u>	<u>\$ 12,349</u>	<u>\$ 9,638</u>
<i>Non-GAAP Gross Margin on total revenue</i>	<u>64 %</u>	<u>72 %</u>	<u>67 %</u>	<u>76 %</u>

AQUESTIVE THERAPEUTICS, INC.

**Reconciliation of Non-GAAP Adjustments - GAAP Research and Development Expense to Adjusted Research and Development Expense
(In Thousands)
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and Development Expense	\$ 3,232	\$ 4,726	\$ 13,203	\$ 12,647
Non-GAAP adjustments:				
Share-based compensation expense	(75)	(230)	(406)	(670)
Depreciation and amortization	(43)	(51)	(136)	(160)
Adjusted research and development expense	\$ 3,114	\$ 4,445	\$ 12,661	\$ 11,817

AQUESTIVE THERAPEUTICS, INC.

**Reconciliation of Non-GAAP Adjustments - GAAP Selling, General and Administrative Expenses to Adjusted Selling, General and Administrative Expenses
(In Thousands)
(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Selling, General and Administrative Expenses	\$ 12,459	\$ 12,129	\$ 41,067	\$ 38,494
Non-GAAP adjustments:				
Share-based compensation expense	(394)	(1,582)	(3,104)	(4,217)
Depreciation and amortization	(94)	(106)	(281)	(329)
Adjusted selling, general and administrative expenses	\$ 11,971	\$ 10,441	\$ 37,682	\$ 33,948