

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38599

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

82-3827296

(I.R.S. Employer Identification Number)

30 Technology Drive, Warren, NJ

(Address of Principal Executive Offices)

07059

(Zip Code)

(908) 941-1900

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	AQST	Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

not transferred. See Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue*, and Note 13, *Other-Non-Current Assets* for further detail.

Interest Income and other income, net

Interest income and other income, net consists of earnings derived from an interest-bearing account, investments in money market Treasury mutual funds and other miscellaneous income and expense items. The interest-bearing account and money market Treasury mutual funds have no minimum amounts to be maintained in the accounts nor any fixed length of period for which interest and dividends are earned.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

The following discussion of our results of operations explains the material drivers of these results of operations.

Revenues

The following table sets forth our revenue data for the periods indicated.

	Year Ended December 31,		Change	
	2024	2023	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 39,976	\$ 43,805	\$ (3,829)	(9%)
License and royalty revenue	15,345	5,376	9,969	185%
Co-development and research fees	1,925	1,402	523	37%
Proprietary product revenue, net	315	—	315	N/M
Total revenues	<u>\$ 57,561</u>	<u>\$ 50,583</u>	<u>\$ 6,978</u>	14%

Revenues increased 14% or \$6,978 in 2024 compared to the same period in 2023. The increase was primarily due to certain one-time increases in license and royalty revenue and increases in co-development and research fees, partially offset by decreases in manufacture and supply revenue.

Manufacture and supply revenue decreased 9% or \$3,829 for the year ended December 31, 2024 compared to the same period in 2023. This decrease was primarily due to a \$4,069 decrease in Suboxone revenues mainly due to a decrease in volume and retroactive price increases in the prior period that were not present in 2024, and a \$702 decrease in Sympazan revenue. These decreases were partially offset by a \$586 increase in Emylif revenues from Zambon and a \$368 increase in Ondif revenue which were attributable to an increase in volume. As part of the Indivior Amendment 11 to the Commercial Exploitation Agreement, we received retroactive price increases related to 2022 Suboxone purchases in the amount of \$1,682 which was recognized in Manufacture and supply revenue in the year ended December 31, 2023. There were no retroactive price adjustments included in Manufacture and supply revenue for the year ended December 31, 2024.

License and royalty revenue increased 185% or \$9,969 for the year ended December 31, 2024 compared to the same period in 2023. This increase was primarily due to the one-time recognition of deferred revenues of \$11,544 due to the terminations of licensing and supply agreements. These increases were partially offset by a \$1,500 decrease in milestone licensing revenue for Azstarys from Zevra Therapeutics recognized in the prior year.

Co-development and research fees increased 37% or \$523 for the year ended December 31, 2024 compared to the same period in 2023. The increase was driven by the timing of the achievement of research and development performance obligations which are expected to fluctuate from one reporting period to the next.

Proprietary product revenue, net increased by \$315 for the year ended December 31, 2024 compared to the same period in 2023 due to the launch of Libervant for patients between two to five years of age. This increase was partially offset by an additional accrual for returns allowances related to the period prior to the outlicensing to Assertio of our proprietary product, Sympazan, which is recorded as an addition to accrued distribution expenses and sales return provision.

Expenses, Interest Income and Other Income:

The following table sets forth our expense data for the periods indicated:

	Year Ended December 31,		Change	
	2024	2023	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply	\$ 17,872	\$ 20,831	\$ (2,959)	(14%)
Research and development	20,280	13,104	7,176	55%
Selling, general and administrative	50,180	31,750	18,430	58%
Interest expense	11,122	6,337	4,785	76%
Interest expense related to royalty obligations	5,459	905	4,554	N/M
Interest expense related to the sale of future revenue	236	220	16	7%
Interest income and other income, net	(3,437)	(16,321)	12,884	(79)%
Loss on extinguishment of debt	—	1,382	(1,382)	N/M

Manufacture and supply costs and expenses decreased 14%, or \$2,959, for the year ended December 31, 2024 compared to the same period in 2023. The decrease in manufacture and supply costs was due to lower volume of strips sold, changes in product mix, and lower production costs.

Research and development expenses increased 55%, or \$7,176, for the year ended December 31, 2024 compared to the same period in 2023. The increase in research and development expenses is primarily due to clinical trial costs and product research expenses associated with the continued advancement of the Anaphylm and AQST-108 programs, increases in personnel costs, and an increase in share-based compensation. The tables below provide a breakdown of the major costs included in total Research and development expenses and project costs by type of expense for each of the main clinical development projects in which we are engaged for each period presented:

	Year Ended December 31,		Change	
	2024	2023	\$	%
<i>(In thousands)</i>				
Clinical Trials	\$ 8,837	\$ 3,597	\$ 5,240	146%
Development and Manufacturing	303	664	(361)	(54%)
Product Research Expenses	1,119	678	441	65%
Total Project Costs	10,259	4,939	5,320	108%
Preclinical	987	659	328	50%
R&D personnel costs	6,509	5,775	734	13%
Consulting and Outside Services	331	323	8	2%
Share Based Compensation	1,215	456	759	166%
Depreciation/Amortization	70	91	(21)	(23%)
All Other R&D	909	861	48	6%
Total	\$ 20,280	\$ 13,104	\$ 7,176	55%

	Year Ended December 31,											
	2024	2023		2024	2023		2024	2023		2024	2023	
			%			%			%			%
	Total		inc / dec	Anaphylm		inc / dec	AQST-108		inc / dec	Libervant		inc / dec
Clinical Trials	\$ 8,837	\$ 3,597	146%	\$ 8,231	\$ 4,687	76%	\$ 588	\$ —	N/M	\$ 18	\$ (1,090)	N/M
Development and Manufacturing	303	664	(54%)	310	676	(54%)	10	—	N/M	(17)	(12)	42%
Product Research Expenses	1,119	678	65%	930	463	101%	188	—	N/M	1	215	N/M
Total Project Costs	\$10,259	\$ 4,939	108%	\$ 9,471	\$ 5,826	63%	\$ 786	\$ —	N/M	\$ 2	\$ (887)	N/M

Total project expenses for Anaphylm increased 63%, or \$3,645, for the year ended December 31, 2024 compared to the same period in 2023. Clinical trial expenses and product research expenses for Anaphylm increased \$3,544 and \$467, respectively, offset by decreases in development and manufacturing of \$366 for the year ended December 31, 2024 compared to the same period in 2023. In 2024, Clinical trial expenses for Anaphylm of \$8,231 were primarily due to Clinical trial costs

associated with the continued advancement of the Anaphylm program. In 2023, Clinical trial expenses for Anaphylm of \$4,687 were related to the activities leading up to the Phase 3 PK Study. Total project expenses for AQST-108 increased \$786 for the year ended December 31, 2024 compared to the same period in 2023 and were related to feasibility work for AQST-108. In 2023, Clinical trial expenses for Libervant of \$1,090 were a credit from third party contractors upon the post completion audit of a study. In 2023, product research expenses for Libervant of \$215 were primarily due to data integration and modeling work.

R&D personnel costs increased by 13%, or \$734, for the year ended December 31, 2024 compared to the same period in 2023, due to additional headcount. R&D share-based compensation increased by \$759, or 166%, which was primarily related to awards granted to our Chief Medical Officer upon his commencement of employment and the effect of new grants in 2024 to R&D personnel. All other R&D expenses include rent, utilities, maintenance and other expenses and fees.

Selling, general and administrative expenses increased 58%, or \$18,430, for the year ended December 31, 2024 as compared to the same period in 2023. The increase primarily represents higher commercial spending of approximately \$3,750, higher personnel costs of approximately \$3,000, severance costs of approximately \$2,900, higher share-based compensation expenses of \$2,300, higher regulatory and licensing fees of approximately \$1,400 related to the regulatory fee for Libervant, higher legal fees of \$520, and higher expenses of \$4,600 due to a change in the allocation of manufacture and supply costs compared to the prior period, partially offset by lower insurance expenses of \$1,150.

Interest expense increased 76%, or \$4,785, for the year ended December 31, 2024 compared to the same period in 2023. The increase was mostly driven by the increased amortization of debt issuance costs and discounts and higher interest expense on the 13.5% Notes refinanced in November 2023.

Interest expense related to amortization of the discount on the royalty obligations was \$5,459 and \$905 for the years ended December 31, 2024 and 2023, respectively. These amounts are due to the accounting associated with the royalty obligations as part of the 13.5% Notes issuance in November 2023. The year ended December 31, 2024 reflects 12 months of activity while the year ended December 31, 2023 reflects 2 months of activity.

Interest expense related to the sale of future revenue was \$236 and \$220 for the years ended December 31, 2024 and 2023. These amounts are due to the accounting associated with the sale of future revenue related to KYNMOBI royalties sold to Marathon on November 3, 2020 and do not represent or imply a monetary obligation or cash output at any time during the life of the transaction. These amounts represent amortization of issuance costs. In June 2023, Sunovion announced that it has voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets, therefore, we likely will not receive any of the additional contingent payments under the Monetization agreement. As a result, we discontinued recording interest expense related to the sale of future revenue in the fourth quarter of 2022. See Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue* for details.

Interest income and other income, net was \$3,437 and \$16,321 for the years ended December 31, 2024 and 2023, respectively. The decrease by \$12,884 is due to other income of \$6,000 related to the Amendment 11 to the Indivior Commercial Exploitation Agreement, \$8,500 related to the patent litigation settlement with BioDelivery Sciences International, Inc. and the receipt of the ERTC, which were recognized in the year ended December 31, 2023 and did not recur in 2024. During the year ended December 31, 2024, we recognized a gain of \$1,500 on the termination of a license and supply agreement, which was partially offset by the adjustment of \$1,200 to the remaining balance of the intangible asset due to the termination of the agreement. We also recognized higher interest income of \$2,713 due to higher cash balances invested in interest-bearing and dividend-earning money market accounts.

For the year ended December 31, 2023, we recognized a loss on extinguishment of debt of \$1,382 for prepayment penalties resulting from 12.5% Notes principal payments made in the first quarter of 2023 and fees related to the repayment of the 12.5% Notes in the fourth quarter of 2023. There was no loss on extinguishment of debt in 2024.

Liquidity and Capital Resources

Sources of Liquidity

We had \$71,546 in cash and cash equivalents as of December 31, 2024. While our ability to execute our business objectives and achieve profitability over the longer term cannot be assured, our on-going business, existing cash and cash equivalents, expense management activities, potential asset sales or product outlicensing as well as access to the equity capital markets, including through our ATM facility, provide near term liquidity for us to fund our operating needs for at least the next twelve months as we continue to execute our business strategy.

On October 7, 2021, we entered into a supplemental indenture for the 12.5% Notes, pursuant to which the amortization schedule for the 12.5% Notes was amended to provide for the date of the first principal payment to be extended to March 30, 2023. The indenture did not change the maturity date of the 12.5% Notes or the interest payment obligation due under the 12.5% Notes. In connection with the indenture, we entered into a Consent Fee Letter with the holders of the 12.5% Notes,