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December 12, 2023

VIA FEDERAL EXPRESS AND E-MAIL
United States Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, NE
Washington, D.C. 20549
Attention: Jenn Do and Kevin Vaughn

Re: Aquestive Therapeutics, Inc.
Form 10K for the fiscal year ended December 31, 2022
Filed March 31, 2023
File No. 0001-38599

Ladies and Gentlemen:

We are providing this response to the comments of the staff (the "Staff") of the Securities and Exchange Commission (the "SEC") contained in the Staff's letter dated October 27, 2023 regarding certain disclosure in Management's Discussion and Analysis in Aquestive's Form 10-K for fiscal year ended December 31, 2022, filed by Aquestive with the SEC on March 31, 2023, File No. 001-38599 ("Form 10-K"). Attached are our proposed revisions to our prior disclosures in Form 10-K and in our Form 10-Q for the period ended September 30, 2023, with respect to the Staff's comments.

As we had already filed our Form 10-Q with the SEC for the period ended September 30, 2023 by the time that we received your October letter, we will prepare the next regular report, Aquestive's Form 10-K for the period ending December 31, 2023 (and all future annual and quarterly SEC reports of Aquestive), consistent with the nature and level of the disclosures reflected in the attachment to this letter.

We are available at your convenience should you have any questions or require any additional information. Thank you for your consideration and review of our response.

Very truly yours,
/s/ A. Ernest Toth, Jr.
A. Ernest Toth, Jr.
SVP & Chief Financial Officer

Aquestive®

SEC Comment Letter Response

December 12, 2023

Advancing medicines.
Solving problems.
Improving lives.

SEC Revenue Comments and Recommended Approach

SEC Comments

1. In future filings beginning with your Form 10-Q for the period ended September 30, 2023, revise your discussions of the changes in your various revenue streams to quantify the impact of the factors cited as the reason for the changes, including but not limited to the following:
   - Manufacturing and supply revenue accounted for 76% of consolidated revenues for the year ended December 31, 2022 and increased 3% during 2022. You disclose "This increase was due to increased manufacturing volume of Zuplenz subsequent to receiving foreign regulatory approval in February 2022, increased manufacturing volume of Sympazan subsequent to the outlicensing agreement with Assertio in October 2022, offset by a decline in Suboxone manufacturing volume in 2022." **Revise to quantify the impact of each of these factors.**
   - You disclose that the decrease in your proprietary product sales was due to the execution of the license agreement with Assertio in October 2022, after which Sympazan sales were recognized in manufacture and supply revenue. **Revise to clearly quantify the impact of Sympazan recognized in each revenue stream for the periods presented.**

AQST Response

Aquestive will revise to quantify the impact of each of these factors:
- Update commentary to include the $ impacts
- See following page 3 for revised 10K commentary
- See following page 4 for revised 10Q commentary

Aquestive will revise to clearly quantify the impact of Sympazan recognized in each revenue stream for the periods presented:
- Update commentary to include the $ impacts
- See following page 3 for revised 10Kcommentary
- See following page 4 for revised 10Q commentary

Commentary changes from the original 10K filing

As filed with revisions in red

Manufacture and supply revenue increased approximately 3% or $1,066 for the year ended December 31, 2022 compared to the same period in 2021. This increase was primarily due to increased revenues of $1,255 of Zuplenz subsequent to receiving foreign regulatory approval in February 2022, increased revenues of $935 of Sympazan subsequent to the outlicensing agreement with Assertio in October 2022, offset by a decline in Suboxone revenues of $979 in 2022 as compared to 2021.

License and royalty revenue decreased 56% or $3,029 for the year ended December 31, 2022 compared to the same period in 2021. This decrease was primarily due to the remaining deferred revenue of $2,098 from the terminated license and supply agreement with Fortovia Therapeutics Inc., as well as milestone revenue earned from Zevra of $2,000 that were recognized in 2021 and did not reoccur in 2022. This was partially offset by an increase in royalty and license revenues of $1,069 based on our licensees' sales of products primarily due to $160 in royalty and $126 in license revenues for Sympazan from Assertio, and $443 in royalty and license revenues from Suboxone.

Proprietary product sales, net, which only includes sales of Sympazan, decreased 10% or $847 for the year ended December 31, 2022 compared to the same period in 2021. The decrease was due to the discontinuation of Sympazan proprietary sales revenue in the fourth quarter of 2022. In October 2022, the Company entered into a license agreement with Assertio and granted an exclusive, world-wide license of our intellectual property for Sympazan to Assertio during the term of that license agreement. The Company is the exclusive sole manufacturer and supplier of Sympazan for Assertio and began recognizing Sympazan sales in manufacture and supply revenue of $935, and $160 in royalty and $126 in license revenues for Sympazan from Assertio, instead of proprietary product sales revenue in the fourth quarter of 2022.

Commentary changes from the original 10Q filing

As filed with revisions in red

Manufacture and supply revenue increased approximately 36% or $2,998 for the three months ended September 30, 2023 compared to the same period in the prior year. This increase was due to higher Suboxone and Sympazan manufacturing revenue of $2,795 and $690, respectively, which was offset by lower Zuplenz (marketed as Ondif) revenues of $487.

License and royalty revenue increased 193% or $727 for the three months ended September 30, 2023 compared to the same period in the prior year. This increase was primarily due to higher royalty and license revenues from Suboxone of $223 and $254 in royalty and $176 in license revenues for Sympazan from Assertio.

There were no proprietary product sales, net for the three months ended September 30, 2023 subsequent to the outlicensing agreement with Assertio in October 2022. The Company recognized $2,281 of proprietary product sales for the same period in the prior year.

Manufacture and supply revenue increased approximately 19% or $5,351 for the nine months ended September 30, 2023 compared to the same period in the prior year. This increase was primarily due to increased Zuplenz (marketed as Ondif) and Sympazan manufacturing revenue of $2,463 and $1,421, respectively, as well as higher Suboxone revenues of $1,183.

License and royalty revenue increased 144% or $2,069 for the nine months ended September 30, 2023 compared to the same period in the prior year. This increase was primarily due to a higher milestone license revenue from Zevra of $500 and higher royalty and license revenues of $1,602 from Sympazan and Suboxone which includes $696 in royalty and $528 in license revenues for Sympazan from Assertio, and $379 in royalty and license revenues from Suboxone.

Proprietary product sales, net was not recognized for the nine months ended September 30, 2023 subsequent to the outlicensing agreement for Sympazan with Assertio in October 2022. The Company recognized $7,069 of proprietary product sales for the same period in the prior year.

SEC R&D Comments and Recommended Approach

SEC Comments

2. We note that research and development (R&D) expense increased 3% during 2022, decreased 26% during the three months ended March 31, 2023 and decreased 30% during the six months ended June 30, 2023. However, the explanation for these different changes that R&D is "driven by the timing of clinical trial as well as other product development activities associated with the Company's pipeline" is the same found in each respective results of operations discussion. Please revise your future disclosures, beginning with your Form 10-Q for the period ended September 30, 2023, to address the following:
   - **For the R&D expense that you track by product candidate, revise to separately quantify those amounts by product candidate**. If you do not track any amounts by product candidate, revise to disclose that fact and identify the reasons why you do not track by product candidate.
   - **Revise to provide a reasonably detailed explanation that accounts** for the changes in the underlying components of R&D for the periods presented. Provide quantification where necessary or appropriate.

3. We note that the All Other R&D category of total research and development (R&D) expense in each period presented makes up the largest component of R&D. Please revise your future disclosures, beginning with your Form 10-Q for the period ended September 30, 2023, to **explain the nature of the costs included in this category and to provide a reasonably detailed explanation and quantification of the factors causing the changes therein**. Consider the extent to which this line item can be further disaggregated in your tabular presentation.

AQST Response

Aquestive will revise to separately quantify these amounts by product candidate:

- Clinical Trial, Development and Manufacturing and Product Research expenses tracked by product
- Products defined as:
  - AQST 109 - Anaphylm
  - AQST-108
  - Libervant
- We do not track R&D Labor (Direct and Indirect) and Preclinical expenses by product, but will include in total with note to that effect

Aquestive will revise to provide a reasonably detailed explanation for all other R&D expenses:

- We will expand table to include product research expenses, R&D indirect labor, consulting and outside services, share based compensation, depreciation/amortization and miscellaneous.

- See following page 6 for revised 10K commentary
- See following page 7 for revised 10Q – 3 months commentary
- See following page 8 for revised 10Q – 9 months commentary
- See following page 9 for tabular presentation of R&D expenses

R&D Commentary changes from the original 10K filing

As Filed

Research and development expenses increased 3% or $434 for the year ended December 31, 2022 compared to the same period in 2021. Research and development expenses are driven by the timing of clinical trial as well as other product development activities associated with the Company's pipeline.

Revised

Research and development expenses increased 3% or $434 for the year ended December 31, 2022 compared to the same period in 2021. For **AQST 109,** expenses increased for clinical trials by 30% or $804 due to pilot clinical studies activities, development and manufacturing by 954% or $2,232 related to manufacturing scale–up, and 2,531% or $886 for product research related to PK modelling. For **AQST 108**, expenses decreased for clinical trials by 100% or $375, for development and manufacturing by 91% or $643, and for product research by 77% or $712 as the company shifted priorities to AQST-109 as the lead product candidate in our pipeline. For **Libervant**, expenses decreased for clinical trials by 78% or $97 due to conclusion of the studies, for development and manufacturing by 37% or $175 due to decreased production requirements, and for product research by 74% or $622 primarily due to the completion of modeling work.

R&D Direct Labor expenses decreased by 13% or $631 for the year ended December 31, 2022 compared to the same period in 2021 due to ongoing expense management.

Preclinical expense increased by 74% or $446 for the year ended December 31, 2022 compared to the same period in 2021 related to activities in evaluating product candidates.

All Other R&D decreased by 15% or $1,006 for the year ended December 31, 2022 compared to the same period in 2021. This decrease was primarily driven by decreases in product research expenses by 25% or $448, consulting and outside services by 43% or $448, and share based compensation by 24% or $209.

R&D Commentary changes from the original 10Q filing-3 months

As Filed

Research and development expenses decreased 1% or $36 for the three months ended September 30, 2023 compared to the same period in the prior year. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with our pipeline.

Revised

Research and development expenses decreased 1% or $36 for the three months ended September 30, 2023 compared to the same period in the prior year. For **AQST 109/Anaphylm**, expenses increased for clinical trials by 74% or $347, and development and manufacturing by 134% or $131, offset by a decrease in product research expenses of 72% or $199 related to reduction in PK modelling activities. AQST 108 expenses decreased by 100% or $40 in Development and manufacturing expenses. For **Libervant**, development and manufacturing expenses decreased by 100% or $300, due to completion of these activities.

R&D Direct Labor increased by 22% or $229, for the three months ended September 30, 2023 compared to the same period in the prior year, primarily in support of the company's product portfolio.

Preclinical expense increased by 83% or $94 for the three months ended September 30, 2023 compared to the same period in 2022 related to activities in evaluating product candidates.

All Other R&D expenses decreased by 42% or $496 for the three months ended September 30, 2023 compared to the same period in the prior year. This decrease was primarily related to reduction in product research expense by 72% or $199, and in R&D indirect labor by 42% or $200 related to ongoing expense management.

R&D Commentary changes from the original 10Q filing-9 months

As Filed

Research and development expenses decreased 23% or $2,987 for the nine months ended September 30, 2023 compared to the same period in the prior year. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with our pipeline.

Revised

Research and development expenses decreased 23% or $2,987 for the nine months ended September 30, 2023 compared to the same period in the prior year. For **AQST 109/Anaphylm**, the increase in expenses related to clinical trials of 13% or $380 was offset by decreases in development and manufacturing expenses of 69% or $1,219, and product research expenses of 67% or $585, related to reduction in PK modelling activities. For **AQST 108**, product research expenses decreased 100% or $40, as the company shifted priorities to AQST-109 as the lead product candidate in our pipeline. For **Libervant**, expenses increased by 57% or $6 in Clinical trials and by 14% or $26 in product research expenses offset by a decrease of 100% or $300, for development and manufacturing due to completion of these activities.

R&D Direct Labor increased by 10% or $314, for the nine months ended September 30, 2023 compared to the same period in the prior year primarily in support of the company's product portfolio.

Preclinical expense increased by 36% or $181 for the nine months ended September 30, 2023 compared to the same period in 2022 related to activities in evaluating product candidates.

All Other R&D decreased by 44% or $1,946 for the nine months ended September 30, 2023 compared to the same period in the prior year. This decrease was due to decreases in product research expense by 53% or $559, R&D indirect labor costs by 40% or $600, consulting and outside services of 52% or $299, share based compensation by 32% or $129, depreciation and amortization of 49% or $66, and miscellaneous expense of 38% or $294.

Tabular Presentation of R&D Expenses

Total Expenses (in thousands)	Year Ended December 31,		Change		Three Months Ended September		Change		Nine Months Ended September		Change	
	2022	2021	$ Inc	%	2023	2022	Inc	%	2023	2022	Inc	%
Clinical Trials	**$ 3,521**	**$ 3,189**	**$ 332**	**10%**	**$ 818**	**$ 470**	**$ 347**	**74%**	**$ 3,397**	**$ 3,012**	**$ 385**	**13%**
R&D Direct Labor	**4,284**	**4,915**	**(631)**	**(13%)**	**1,253**	**1,024**	**229**	**22%**	**3,431**	**3,117**	**314**	**10%**
Development and Manufacturing	**2,831**	**1,538**	**1,293**	**84%**	**229**	**438**	**(209)**	**(48%)**	**550**	**2,110**	**(1,560)**	**(74%)**
Preclinical	**1,045**	**599**	**446**	**74%**	**206**	**112**	**94**	**83%**	**327**	**507**	**(181)**	**(36%)**
Product Research Expenses	1,354	1,802	(448)	(25%)	79	277	(199)	(72%)	503	1,061	(559)	(53%)
R&D Indirect Labor	1,984	1,923	61	3%	272	472	(200)	(42%)	902	1,501	(600)	(40%)
Consulting and Outside Services	595	1,043	(448)	(43%)	75	179	(104)	(58%)	278	577	(299)	(52%)
Share Based Compensation	672	881	(209)	(24%)	104	75	29	39%	277	406	(129)	(32%)
Depreciation/Amortization	173	208	(35)	(17%)	22	43	(21)	(49%)	70	136	(66)	(49%)
Miscellaneous	1,022	949	73	8%	139	141	(2)	(2%)	481	775	(294)	(38%)
All Other R&D	**5,800**	**6,806**	**(1,006)**	**(15%)**	**691**	**1,187**	**(496)**	**(42%)**	**2,511**	**4,457**	**(1,946)**	**(44%)**
Total	**$ 17,481**	**$ 17,047**	**$ 434**	**3%**	**$ 3,196**	**$ 3,232**	**$ (36)**	**(1%)**	**$ 10,216**	**$ 13,203**	**$ (2,987)**	**(23%)**

Note: Aquestive does not track R&D Direct Labor and Preclinical expenses by project; as such these expenses are presented in total.

Aquestive