

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

August 6, 2014

Via E-mail
Ronald L. Stotish
Chief Executive Officer
AquaBounty Technologies, Inc.
Two Clock Tower Place, Suite 395
Maynard, MA 01754

Re: AquaBounty Technologies, Inc. Amendment No. 1 to Form 10-12B Filed July 23, 2014 File No. 001-36426

Dear Mr. Stotish:

We have reviewed your responses to the comments in our letter dated May 21, 2014 and have the following additional comments.

General

Item 1. Business, page 3

Overview, page 3

- 1. Refer to the Center for Veterinary Medicine Guidance for Industry #132, The Administrative New Animal Drug Application Process, available on the FDA website. You state here that you "have completed all sections of the New Animal Drug Application, or NADA, process with . . . the FDA, for AquAdvantage® Salmon, but are still waiting for formal approval of the NADA," and you state on page 8 that "[b]y 2010, [you] had completed all of the technical submission requirements for approval under the NADA." It is our understanding that under FDA guidelines, a full NADA is not deemed submitted until all of its technical sections have been completed. Please reconcile this with your disclosure that you submitted a NADA in 1995 and ensure that you present in your revised disclosure a complete summary of the FDA's phased review process and the process for submitting and obtaining approval for an Administrative NADA from the FDA.
- Please disclose and briefly describe each of the technical sections you have submitted or intend to submit to the FDA and for each technical section disclose whether you have received a technical section complete letter. Please also disclose whether you have received any written conclusions of non-acceptance of data submitted for any technical section.

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3. We note your disclosure on page 4 that you entered into a contract research agreement with Tethys Aquaculture Canada, Inc., to provide you with the resources required for your development needs. Please file this agreement as an exhibit, or tell us why you do not believe it is material to your business.

The Aquaculture Industry, page 4

4. We note your response to our prior comment 7 and reissue in part. Please address the risks associated with the piscine reovirus. Additionally, we note your disclosure on page 6 that in 2009 you "incurred an outbreak" of ISA. Please provide additional details regarding this outbreak and the subsequent remediation measures that were taken.

Our Markets, page 8

5. Refer to the second paragraph of this section. Please discuss the basis for your beliefs with respect to cost of production and your expectation that your eggs will "sell at a premium to standard Atlantic salmon eggs." Please ensure that all beliefs in your revised disclosure have a reasonable basis. We note in this regard the stage of development of AquAdvantage® Salmon that you have not received FDA approval for sale of this product, and the lack of historical revenues derived from this product.

Regulatory Approval, page 8

- 6. Refer to the Chairman's Report and transcript of the Veterinary Medicine Advisory Committee Meeting, each available on the FDA website. You state that in September 2010, the Committee concluded that "AquAdvantage® Salmon is indistinguishable from other farmed Atlantic salmon, is safe to eat and does not pose a threat to the environment under the conditions in which it would live and be harvested." Please place this disclosure in context by briefly describing the role and authority of the Committee in the FDA approval process. Please also balance this by disclosing that the panel did not vote or make a recommendation on whether to approve your product for human consumption, and that panel members stated your product would need additional monitoring to determine whether the growing conditions could cause health abnormalities.
- 7. Please tell us whether you anticipate any other regulatory hurdles, such as may be required for importation or distribution of eggs, permits that may be required to establish fish farms, licenses that may be required to sell fish, and any other potentially relevant regulations.

Environmental Regulation, page 9

8. Refer to the Chairman's Report of the VMAC. We note that some committee members recommended Environmental Impact Statements for additional salmon growing facilities. Please address the need for and anticipated costs associated with environmental impact

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statements. To the extent revisions to your risk factors are warranted, please revise accordingly.

9. Please discuss whether you will be required to comply with section 7 of the Endangered Species Act with respect to production of AquAdvantage in the United States.

Intellectual Property, page 9

10. We note your response to our prior comment 10 and reissue in part. Please provide us with a more detailed analysis supporting your conclusion that the license agreement with Genesis and HSC is not required to be filed. Specifically, please address whether your business is substantially dependent on the licensing of this technology. In this regard, we note your disclosure on page 3 that in 2008 you decided to focus your resources on AquAdvantage salmon and "discontinue[d] spending on [y]our other product lines," and on page 10 that despite the expiration of the patent for the licensed technology, "the degree of know-how in the molecular modification process and the regulatory timescales associated with approval of genetically modified fish would present significant barriers to competition."

Research and Development, page 10

11. We note your response to our prior comment 11 and reissue in part. Please explain what you mean by "other technology," and provide further details concerning the "two projects under the ECC" which you have commenced.

Consolidated Financial Statements, page F-1

12. Please note that you should update the financial statements included in the filing pursuant to Rule 8-08 of Regulation S-X if your filing is not effective prior to August 13, 2014.

You may contact Patrick Kuhn at (202) 551-3308 or Doug Jones at (202) 551-3309 if you have questions regarding comments on the financial statements and related matters. Please contact Ryan Adams at (202) 551-3191 or me at (202) 551-3217 with any other questions.

Sincerely,

/s/ J. Nolan McWilliams

J. Nolan McWilliams Attorney-Advisor

cc: <u>Via E-mail</u>
Bradley C. Brasser, Esq.
Jones Day