

August 19, 2014

VIA EDGAR

Division of Corporation Finance
Securities and Exchange Commission
100 F Street N.E.
Washington, D.C. 20549
Attention: Jennifer Thompson

**Re: AquaBounty Technologies, Inc.
Amendment No. 1 to Form 10-12B
Filed April 25, 2014
File No. 001-36426**

Ladies and Gentlemen:

Set forth below are the responses of AquaBounty Technologies, Inc. (the “**Company**”) to the comments of the staff (the “**Staff**”) of the Securities and Exchange Commission (the “**Commission**”) Division of Corporation Finance contained in the Staff’s letter dated August 6, 2014 relating to Amendment No. 1 to the Company’s Registration Statement on Form 10 (“**Amendment No. 1**”). We are also filing simultaneously herewith Amendment No. 2 (“**Amendment No. 2**”) to the Registration Statement on Form 10 (the “**Registration Statement**”). Capitalized terms used but not defined herein have the meanings set forth in the Registration Statement. For reference, the Staff’s comments are provided below in bold immediately prior to the Company’s responses.

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.**

Response:

The Company advises the Staff that it opened an Investigational New Animal Drug (the “*INAD*”) file with the FDA in 1995. The *INAD* was opened because, at that time, there was no defined regulatory framework for the regulation of genetically engineered animals. Thereafter, the Company began working with the FDA’s Center for Veterinary Medicine (the “*CVM*”) on the submission of studies that the Company presumed would be part of the eventual regulatory process. The Company understands that *CVM* further presumed that the eventual regulatory process would be under the authority granted to the FDA in the Federal Food, Drug, and Cosmetic Act of 1938. In January 2009, the FDA published its Final Guidance Document No. 187 in the Federal Register. Final Guidance Document No. 187 clarified the FDA’s view of its authority for regulation of genetically modified animals.

This phased review process, which included a cycle of study conduct, submission, review and acceptance, continued over the period from 1995 to 2010. Under this process, the Company submitted studies to the *CVM* responsive to each technical *NADA* section. These technical sections required submission of studies, information and other materials relating to molecular characterization of the construct, molecular characterization of AquAdvantage Salmon lineage, phenotypic characterization of AquAdvantage Salmon, a genotypic and phenotypic durability plan, support for environmental, food and feed safety and claim validation. Specifically:

- In August 2006, the Company submitted to the *CVM* the last correspondence for the review of the molecular characterization of the AquAdvantage construct. On October 6, 2006, the Company received a letter from the *CVM* stating “the data and information that you have submitted adequately supports the molecular characterization of the opAFP-GHc2 construct.”
- In May 2007, the Company submitted to the *CVM* the last correspondence for the review of the molecular characterization of the AquAdvantage Salmon lineage. On July 2, 2008, the Company received a letter from the *CVM* stating “[w]e have reviewed the data and information you have submitted in support of the molecular characterization of the genetically engineered (GE) salmon referred to as ‘AquAdvantage Salmon’ and find that it is adequate support to conclude the molecular characterization of the inserted rDNA construct and GE animal lineage step of our review.”

- In July 2009, the Company submitted to the CVM the last of the correspondence for the review of the AquAdvantage Salmon claim validation. On March 12, 2010, the Company received a letter from the CVM stating “[w]e have reviewed the data and information that you have submitted in support of the Claim Validation of the genetically engineered (GE) salmon referred to as ‘AquAdvantage Salmon’, and consider this section complete.”
- In December 2009, the Company submitted to the CVM the last of the correspondence for the review of the phenotypic characterization of AquAdvantage Salmon. On June 4, 2010, the Company received a letter from the CVM stating “[w]e have reviewed the data and information that you have submitted in support of the phenotypic characterization of the genetically engineered (GE) salmon referred to as ‘AquAdvantage Salmon’ and find that it is adequate support to conclude the phenotypic characterization step of our review.”
- In March 2010, the Company submitted to the CVM the final correspondence for the review of the data submitted in support of the safety of food from AquAdvantage Salmon. On August 27, 2010, the Company received a letter from the CVM stating “[w]e have reviewed the data and information that you have submitted in support of the food safety assessment of food from the genetically engineered (GE) salmon referred to as ‘AquAdvantage Salmon’ and find that it is adequate to conclude our evaluation of food safety.”
- In April 2010, the Company submitted to the CVM the last of the correspondence for the review of the genotypic and phenotypic durability of AquAdvantage Salmon. On June 11, 2010, the Company received a letter from the CVM stating “[w]e have reviewed the data and information that you have submitted in support of the Genotypic and Phenotypic Durability of the genetically engineered (GE) salmon referred to as ‘AquAdvantage Salmon’ and find that you have adequately supported the Genotypic and Phenotypic Durability step of our review.”

Accordingly, by the Spring of 2010, the Company had submitted to the CVM data for each technical submission requirement for approval under the NADA. By the Fall of 2010, the Company had received from the CVM technical section complete letters for each submission requirement.

Once all of the technical submissions had been received and reviewed by the CVM, the FDA posted its findings on its website and scheduled a meeting of the Veterinary Medicine Advisory Committee (the “**VMAC**”) on September 20, 2010. The VMAC was a group of independent experts charged with providing scientific advice to the FDA on animal drug and food issues. This meeting signaled the conclusion of the review of the technical phases of the application.

The remaining items in the NADA review process include: (i) the environmental assessment for the application, which the FDA published in December 2012, (ii) the Final Label and Package Insert, which was submitted on July 23, 2014; and (iii) a catch-all item called "all other information", under which the Company is required to submit to CVM all other information, not included in any of the other technical sections, that is pertinent to an evaluation of the safety or effectiveness of AquAdvantage Salmon. The Company's latest supplement to the "all other information" portion of the NADA was submitted to the CVM on March 13, 2014.

The NADA is currently subject to administrative review by the FDA. As disclosed in the Registration Statement, the Company is awaiting a final decision from the FDA on the NADA for AquAdvantage Salmon.

The Company has revised its disclosure on page 3 of Amendment No. 2 to reflect that it has completed all technical sections of the NADA and on pages 8 through 10 of Amendment No. 2 to provide a summary of the FDA's phased review process and the process for submitting and obtaining approval for the NADA.

- 2. 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.**

Response:

The Company advises the Staff that it has completed all of the technical sections of the NADA. A brief summary of the submission of each section and the receipt of the section complete letters is included in the response to comment 1. The Company also informs the Staff that it has not received any written conclusions from CVS of non-acceptance of data submitted for any technical section of the NADA or for the environmental assessment.

The Company has revised its disclosure on page 9 of Amendment No. 2 to reflect the submission of each section, the receipt of the section complete letters and the fact that it has not received any written conclusions of non-acceptance of data.

- 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.**

Response:

The Company acknowledges the Staff's comment and respectfully submits that the contract research agreement with Tethys Aquaculture Canada, Inc., which is doing business as the Center for Aquaculture Technologies Canada, has previously been filed as Exhibit 10.15 to Amendment No. 1.

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.**

Response:

Piscine reovirus (“**PRV**”) is a newly described fish reovirus of anadromous and marine fish ubiquitous among fish in Norwegian salmon farms. It is not currently listed as one of the reportable disease agents by the Canadian Food Inspection Agency (“**CFIA**”). Since PRV is only recently described (see Virology Journal 2013, 10:230, Kibenge et. al. (the “**2013 Report**”)), and only putatively associated with salmon disease, it is very difficult to measure its incidence, significance or threat to populations. A report published in the Journal of Fish Diseases (see Marty, Morrison, Bidulka, and Siah, 2014) (the “**2014 Report**”) described the results of a study covering a span of 39 years (from 1974 to 2013) and concluded that PRV is a benign virus that has long been present in fish in the Pacific Northwest. Importantly, the study reports that PRV was not associated with diseases of heart or skeletal muscle. As was the case in previous activist claims regarding infectious salmon anemia virus in Pacific salmon species, the claims of PRV-induced disease appear to be unfounded in light of the study described in the 2014 Report. The study also refutes the inference in the 2013 Report that PRV may be the causative agent for the heart and skeletal diseases. The Company’s hatchery on Prince Edward Island, Canada is a closed facility which is routinely screened by CFIA and the Canadian Department of Fisheries and Oceans (“**DFO**”) for fish diseases or the presence of organisms known to cause reportable disease in fish. To date, the results of testing conducted by the Company, CFIA and DFO has not indicated the presence of PRV in its stocks. In any event, given the conclusions described in the 2014 Report, the Company does not believe that PRV presents a risk to its current or future stocks. Notwithstanding, in response to the Staff’s comment, the Company has revised the disclosure on pages 6 and 7 of Amendment No. 2 to state that there are other diseases or health management issues, in addition to ISA and sea lice, that have impacted and may in the future impact salmon populations in certain farming geographies.

In addition, the Company has revised the disclosure on page 6 of Amendment No. 2 to provide additional detail regarding the ISA outbreak in the Company’s hatchery in 2009. The Company has also supplementally provided a copy of the 2014 Report for the Staff’s review.

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.**

Response:

The Company believes that once it receives FDA approval for its AquAdvantage Salmon eggs, it will be able to sell the eggs to Atlantic salmon farmers for a premium to current market prices. This belief is based on the fact that AquAdvantage Salmon grows faster than conventional Atlantic salmon, which presents a cost benefit to farmers who grow it to harvest size. Since AquAdvantage Salmon grows to harvest size more quickly than conventional Atlantic salmon, over time, a farmer can spread its fixed costs over a greater number of fish. Additionally, less time in the water means less cost for variable inputs, such as manpower and feed. The Company believes that the cost benefits to the farmer associated with AquAdvantage Salmon eggs will outweigh any potential costs associated with market acceptance risk.

The Company has revised the disclosure on page 8 of Amendment No. 2 to describe these factors.

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.**

Response:

The Company advises the Staff that the VMAC, which was a group of outside experts whose purpose was to offer its opinion on animal drug and food issues to the FDA, had no authoritative power regarding the approval of an NADA. Instead, the VMAC was convened to listen to the results of the FDA review process and to provide an outside opinion on the FDA's conclusions. In the case of AquAdvantage Salmon, the FDA convened the VMAC in September 2010 to review the FDA's conclusions regarding the NADA. Specifically, the FDA posed four questions to the VMAC, each of which was addressed in the VMAC Chairman's Report dated October 14, 2010 (the "**Chairman's Report**"). These questions, as well as relevant excerpts of the VMAC's responses, are set forth below:

Question 1: Do the data and information demonstrate that the rDNA construct is safe to AquAdvantage salmon?

Response: The committee found no evidence in the data to conclude that the introduction of the construct was unsafe to the animal.

Question 2: Do the data and information demonstrate that there is a reasonable certainty of no harm from consumption of foods derived from AquAdvantage salmon?

Response: The committee deemed the studies selected to evaluate this question to be overall appropriate and a large number of test results established similarities and equivalence between AquAdvantage Salmon and Atlantic salmon.

Question 3: Do the data indicate that AquAdvantage Salmon grow faster than their conventional counterparts?

Response: The committee found evidence in support of this claim.

Question 4: Are any potential environmental impacts from AquAdvantage Salmon production adequately mitigated by AquaBounty Technologies' proposed conditions of use?

Response: Although the committee recognized that the risk of escape from either facility could never be zero, the multiple barriers to escape at both the PEI and Panama facilities were extensive. Because part of the containment strategy is dependent on management SOP's, the committee felt that rigorous adherence to policy would need to be maintained at both sites to sustain the barriers. Further, it is the committee's understanding that both facilities will be regulated as "drug manufacturing" locations, which carries a high level of FDA scrutiny. Although information was presented to indicate that mitigation for escape risk had been planned, the potential for theft was mentioned as an additional risk.

Furthermore, the conclusions published in the Briefing Packet for the September 20, 2010 meeting contained the following conclusion of the FDA:

ABT salmon meets the standard of identity for Atlantic salmon as established by FDA's Reference Fish Encyclopedia. All other assessments of composition have determined that there are no material differences in food from ABT salmon and other Atlantic salmon.

We conclude that food from the triploid ABT Salmon that is the subject of this application is as safe as food from conventional salmon, and that there is a reasonable certainty of no harm from consumption of food from triploid ABT salmon. No animal feed consumption concerns were identified.

Similarly, the Briefing Packet included the following conclusion regarding environmental safety:

Except for minor issues to be addressed in the final public display version of the EA, the information provided by ABT to evaluate the environmental safety of AquAdvantage Salmon is acceptable and complete. There is substantial, reliable information available in the environmental assessment document to conclude that GE Atlantic salmon in the AquAdvantage lineage that contain the AquAdvantage construct at the α -locus are not expected to have a significant impact on the quality of the human environment (1) in the United States; (2) in foreign nations not involved in the action; or (3) on the global commons VMAC Briefing Packet AquAdvantage Salmon Page 132 – Environmental Analysis when raised and reared under the current conditions of physical, biological, and geographic/geophysical confinement present at hatchery and grow-out facilities in Canada and Panama. Subject to further public and outside expert comment, there appears to be adequate justification at this time for preparation of a finding of no significant impact (FONSI).

While the FDA is not bound by the VMAC's recommendations or opinions, the VMAC did not dispute FDA's conclusions that AquAdvantage® Salmon is safe for human consumption.

In response to the Staff's comment, the Company has revised the disclosure on page 10 of Amendment No. 2.

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.**

Response:

As disclosed in the Registration Statement under the caption "Regulatory Environment", the Company does anticipate additional regulatory hurdles in connection with the grow-out of AquAdvantage Salmon following FDA approval of the NADA. Specifically, each grow-out site located in the United States will require FDA review for compliance with the NADA conditions of use, as well as FDA approval of a Supplemental NADA and a site-specific environmental assessment. Additionally, the Company must comply with normal local permitting requirements for construction of grow-out facilities. The Company does not believe there are other regulatory hurdles that might materially impede its current plans with respect to the grow-out of AquAdvantage Salmon.

The Company has revised the disclosure on pages 10 and 11 of Amendment No. 2 to discuss the local permitting requirements.

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

Response:

As discussed on the Company's responses to comment 6 and disclosed on page 10 of Amendment No. 2, the role of the VMAC is advisory. As reflected in the Chairman's Report, the VMAC agreed with the FDA's conclusion on the environmental impact of AquAdvantage Salmon, though some members of the committee voiced a recommendation for an Environmental Impact Statement. However, it is the FDA's responsibility to decide if an Environmental Impact Statement is warranted. The Company notes that in December 2012 the FDA published an environmental assessment for AquAdvantage Salmon along with a preliminary Finding of No Significant Impact. Accordingly, the Company believes that it is very unlikely that the FDA will conclude that an Environmental Impact Statement is warranted.

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.**

Response:

The Company acknowledges that it will be required to comply with each section of the Endangered Species Act (the "*ESA*") with respect to the production of AquAdvantage Salmon. The Company notes that Section 7 of the ESA relates to cooperation among federal agencies. The Company notes that the FDA has already consulted with the U.S. National Oceanic and Atmospheric Administration and the U.S. Fish and Wildlife Services. Both agencies have supplied the FDA with letters indicating that they concur on the FDA's environmental assessment for AquAdvantage Salmon and the preliminary Finding of No Significant Impact but that they reserve judgment for circumstances outside the scope of the current NADA.

The Company does not believe that its costs and potential risks associated with its compliance with ESA warrant additional disclosure in the Registration Statement.

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.”**

Response:

In response to the Staff’s comment, the Company has filed the license agreement with Genesis and HSC as Exhibit 10.16 to Amendment No. 2.

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.**

Response:

Under the ECC between the Company and Intrexon, the two companies have commenced work on two projects, which are both in their early stages. The first project, which commenced in June 2013, is a research effort to determine the effectiveness of utilizing precise genome engineering technology to produce desirable features in a finfish. The second project, which commenced in September 2013, is a research effort to determine if the use of germ cells to perform gene modification is effective in reducing the time required to develop new traits in finfish. If these technology-enabling projects prove to be successful, they will allow the Company to add additional beneficial traits to AquAdvantage Salmon.

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.**

Response:

In response to the Staff’s comment, the Company has included updated financial statements to comply with Rule 8-08 of Regulation S-X.

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In connection with the Company's response to the Staff's comments, the Company acknowledges that:

- the Company is responsible for the adequacy and accuracy of the disclosure in the filing;
- Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please call Brad Brasser at (312) 269-4252 should you wish to discuss the matters addressed above or other issues relating to the subject Form 10. Thank you for your attention to this matter.

Very truly yours,

/s/ Ronald L. Stotish
Ronald L. Stotish
Chief Executive Officer

cc: Brad Brasser
Jones Day