

AquAdvantage Salmon The Regulatory Journey

4<sup>th</sup> International Workshop – Regulatory Approaches for Agricultural Applications of Animal Biotechnologies

# **Forward-Looking Statements**

#### **Safe Harbor Statement**

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact contained in this presentation are forward-looking statements, including, but not limited to, statements regarding the economic viability of land-based production facilities; the economic and operational benefits of AquAdvantage salmon ("AAS"); projections for revenue, margin, and payback periods; the potential for increases in productivity, EBITDA, and the profitability of AquaBounty Technologies, Inc. ("AquaBounty"); the size and timing of future harvests; projected growth in seafood consumption and market size, expansion of the aquaculture industry, and increasing demand for salmon; continuing supply constraints and their impact on pricing; the impacts of future environmental conditions; market interest in land-based aquaculture; the anticipated benefits of AAS and land-based production to consumers and the environment; non-exposure to pathogens, parasites, or environmental contaminants; the use of antibiotics, chemicals, and medications; continued operational performance against targets; the potential for consumer acceptance of AAS; AquaBounty's farm development and commercial strategy, including demonstration of commercial viability, successful positioning and messaging of AAS, the realization of particular marketing events and campaigns, the establishment and types of sales channels, agreements with distributors and industrial producers, joint-venture relationships, and progress against commercial launch timelines; the potential for the development of additional products, product traits, operational efficiencies and scale, nutritional enhancements, recirculating aquaculture system improvements, and production sites; potential siting and countries for expansion; and the completion of field trials, approval of AAS, and potential relationships with local partners in other markets. Although management believes that the plans, objectives, and expectations reflected in or suggested by these forward-looking statements are reasonable, all forward-looking statements involve risks and uncertainties, and actual future results may be materially different from the plans, objectives, and expectations expressed in this presentation. These risks and uncertainties include, but are not limited to: (i) our limited operating history and track record of operating losses; (ii) our cash position and ability to raise additional capital to finance our activities; (iii) the anticipated benefits and characteristics of AAS; (iv) the ability to secure any necessary regulatory approvals to commercialize any products; (v) our ability to adapt to changes in laws or regulations and policies; (vi) the uncertainty of achieving the business plan, future revenue, and operating results; (vii) the impact of business, political, legal, or economic disruptions or global health concerns, including the impact of the current global health pandemic; (viii) developments concerning our research projects; (ix) our ability to successfully enter new markets or develop additional products; (x) competition from existing technologies and products or new technologies and products that may emerge; (xi) actual or anticipated variations in our operating results; (xii) market conditions in our industry; (xiii) our ability to protect our intellectual property and other proprietary rights and technologies; (xiv) the rate and degree of market acceptance of any products developed through the application of bioengineering, including bioengineered fish; (xv) our ability to retain and recruit key personnel; (xvi) the success of any of our future joint ventures, acquisitions or investments; (xvii) international business risks and exchange rate fluctuations; (xviii) the possible volatility of our stock price; and (xix) our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing. We caution you that the foregoing list may not contain all of the risks to which the forward-looking statements made in this presentation are subject. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see AquaBounty's public filings with the Securities and Exchange Commission ("SEC"), available on the "Investors" section of our website at www.aquabounty.com and on the SEC's website at www.sec.gov. Forward-looking statements are not promises or guarantees of future performance, and we may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments that we may make. All information in this presentation is as of the date of its release, and AquaBounty undertakes no duty to update or revise this information unless required by law.

# AquaBounty: Leaders in Aquaculture and Biotechnology

## **Company Profile**

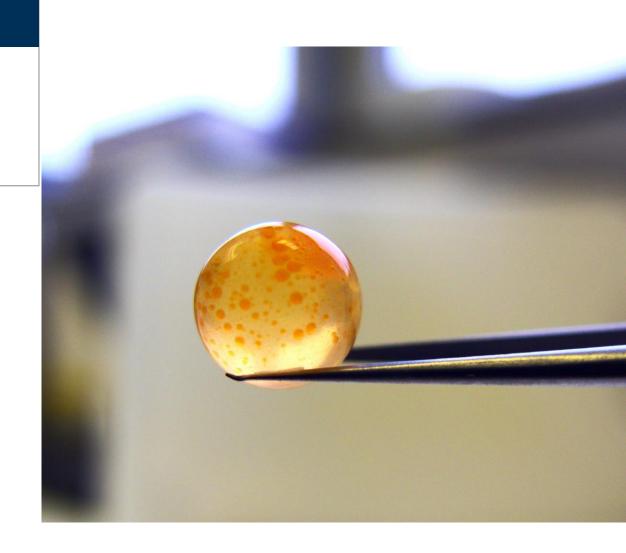
Headquarters: Maynard, MA

Total Employees: 95

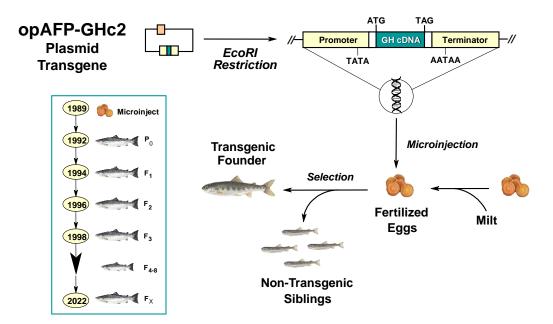
RAS Farms: Albany, Indiana

Prince Edward Island, Canada

- Committed to feeding the world with land-based salmon farmed efficiently, sustainably and profitably
- Blazed the trail for genetically engineered animal protein; overcoming political and perceptual hurdles
- Leveraging 25 years of operational experience with RAS to produce efficiently and ensure success of new farming methods



## The Discovery





Journal of Fish Biology (1995) 47 (Supplement A), 1-19

#### **GENETICS AND BREEDING**

#### **INVITED PAPER**

#### Transgenic salmon: tailoring the genome for food production

C. L. HEW\*, G. L. FLETCHER† AND P. L. DAVIEST

\*Research Institute, Hospital for Sick Children and Departments of Biochemistry and Clinical Biochemistry, University of Toronto, Toronto, Ontario; †Ocean Sciences Centre and Department of Biology, Memorial University of Newfoundland, St John's, Newfoundland and ‡Department of Biochemistry, Queen's University, Kingston, Ontario,

The production of transgenic salmon using gene transfer technology is described. Both antifreeze proteins and growth hormone genes have been successfully transferred. The expression, inheritance and phenotypes are examined using a wide variety of techniques. The development of new transgenics will be beneficial to aquaculture. © 1995 The Fisberies Society of the British Isles

Key words: gene transfer; transgenic salmon; antifreeze proteins; freeze resistance; growth hormone; enhanced growth rate.

#### INTRODUCTION

# **Regulatory Process**

#### All countries want to know: Is it safe? What are the risks?

### Manufacturing

What was the construct? How is it arranged in the fish? Is it stable over multiple generations?

#### Safe for the Animal

Will the health of the fish with the construct as described be negatively impacted?

#### Safe for the Environment

What is the risk of both our facilities and the fish on the environment?



Will the food product produced from the genetically engineered animal be safe for people (and animals) to eat?

- -Composition
- -Allergenicity

## **Efficacy**

What is the claim? Is the claim supported?



# A Long and Winding Road

2008

FDA approves AquaBounty

AquaBounty Technologies

begins construction of a land-based aquaculture

Canada's hatchery

farm in Panama

## 2003

First regulatory study to the FDA for a New Animal Drug •------Application (NADA)

#### 1995

FDA issues INAD # for AAS salmon

#### 1989

First AquAdvantage® (AAS) line was created?

### 2010/11

2009

Submits final

to the FDA

2015

FDA approved AAS for

consumption in USA/

regulatory study

 FDA concludes AAS is indistinguishable from Atlantic salmon; safe to eat; and poses no threat to the environment

2021

- First harvest of AAS in the United States and Canada
- Brazil approves
   AAS for
   consumption

2019

- FDA lifts the Import Alert allowing importation of AAS eggs into US
- Environment and Climate Change Canada (ECCC) approved the Rollo Bay production facility for the commercial production

2016

- FDA Import Alert issued prohibiting importation of AAS into USA until labeling requirements announced by FDA
- Health Canada announces approval of AAS for production, sale and human consumption in Canada

**-2018** 

- Received approval from the FDA to raise AAS Salmon at the Company's Indiana farm
- Completed a second harvest of AAS Salmon in Panama farm and sold in Canada
- Commenced production operations at the Indiana farm with traditional Atlantic salmon eggs

2022

 Ground-breaking for 10,000 MT farm in Ohio

# **Keys to Regulatory Success**



Define your product

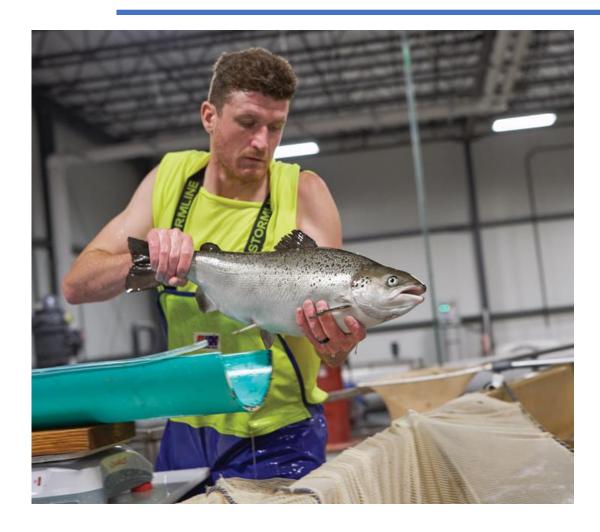
**Pre-submission Consultation** 

**Continued Communication** 

**Quality Data & Documentation** 

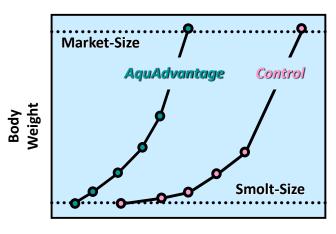
**Recognition of the Economic Opportunity** 

# Today: AquAdvantage Salmon



- Triploid female Atlantic salmon
- Single copy of Chinook salmon GH gene and promoter from Ocean Pout anti-freeze protein gene
- Significantly more AAS grow to 100 g body weight than comparators within 2700°C-day

Achieve smolt- & market-size ~5x & ~2x faster, respectively



**Days Post-Hatch** 



# Thank you!

# Mark Walton, Chris Beattie and the AquaBounty Team



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