Alimentary Health

Changing the way we think about Probiotics: Alimentary Health’s story

SME Regional innovation
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About Alimentary Health: An innovative Irish healthcare company

- A global pioneer in discovery, development and commercialisation of proprietary probiotic and pharmabiotic treatments.

Vision: “To unlock the promise of probiotics”

Mission: “To develop clinically supported probiotic healthcare and nutritional products that health professionals can believe in and feel confident to recommend.”

Structure

PharmaBiotics ↔ R&D IP generator → AH Brands Commercial
Company Overview

- Located in Cork, Ireland.
- Founded in 1999
- Spin-out from University College Cork
  - Pioneering group of early innovators
- 23 years of research
- >100 peer reviewed scientific publications
- Strong patent portfolio in multiple territories
- 21 people in the company – 7 PHD’s in the Sciences
- Large network of external expertise
- Licensed technology to P&G _ OTC probiotic supplement in the US and Canada
- Launched ALFLOREX in IE in Feb 2014……….

Pioneering the science needed to bring the most effective probiotic products to market that healthcare professionals and consumers will believe in.
State support providing the leverage for an SME to engage in real technological innovation
The effect of using University Resources and State funding

Leveraging scarce cash and resources to allow a little company to think Big Science

Helping to move into new areas of competence

With state support you can afford to do a proper job and answer some of the big strategic questions up front - before they trip you up later.
Product value all built on built on Science: Costly infrastructure and resources required

Harvest from Healthy

Selection of strains

Conduct In vitro studies

Conduct Gene array studies

Clinical Trials

Select Candidate culture

Screen in Animal trials

Confidential
AH leveraged State Supports to Innovate: Research

• **SFI funding**
  - Commercial partner in the APC microbiome institute
  - Involved from the start – Foundation partner
    • Iteration 1, 2 and 3
  - Outcomes – Patent applications and mechanism of action data supporting key pipeline strains, new strains, new licensing opportunities, internal expertise generated.

• **EI funding**
  - Innovation Partnership - again allowing us to build the data around our core strains.

• **EU Funding**
  - FP 4,5,6,7 - now looking at Horizon 2020
    • Outcomes – Patent applications and clinical data supporting key pipeline strains
Leveraging infrastructure

• Bio-innovation centre
  – Networking
  – Boardroom
  – Video-conferencing facilities

• Laboratory space
  – Keep cash for data generation and commercial spend rather than capital expenditure on infrastructure

• Equipment available on Campus
  – Access to equipment worth hundred of thousands and the expertise to run it
Research: AH has had active collaborations with multiple APC scientists and clinicians

Gastroenterology, Gut immunology, IBD, IBS
  – *Professor Fergus Shanahan, Professor Eamonn Quigley*

Psychiatry, Food & Mood, Cognition, Stress
  – *Professor Ted Dinan*

Pharmacy, Neuroscience
  – *Professor John Cryan*

Paediatrics, Infant health/nutrition
  – *Professor Tony Ryan, Professor Jonathan Hourihane, Professor Paul Ross, Dr. Catherine Stanton,*

Gerontology, Elderly nutrition
  – *Dr. Aoife Ryan, Dr. Paul O’Toole*

Imaging
  – *Professor Michael Maher*

Cardiology, metabolic diseases
  – *Professor David Kerins*

Microbiology (Food, Gut), Molecular Biology, Bioinformatics
  – *Professor Colin Hill, Professor Paul Ross, Professor Douwe van Sinderen, Professor Mike Prentice*
  – *Professor Gerald Fitzgerald, Dr. Paul O’Toole, Dr. Comac Gahan, Dr. David Clarke*
Expertise networks now extend globally

Los Angeles, US
- HIV
- Gut Health

Hong Kong, China
- Chinese Culture Collection

London Ontario, Canada
- Cognitive function
- Anxiety/ Stress/ Mood

Pittsburgh, US
- Obesity and Metabolic Syndrome

Davos, Switzerland
- Allergy, Immunity

Cork, Ireland
- Gut Health, Immunity and Infection

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Management of the project is key

• The granting process can be time-consuming
  – Learning how to write for success
  – Reporting

• Management of external parties is critical
  – Regular meetings with academic collaborators
  – Relationship management
    • Learning to talk the same language.
    • Understanding academic drivers – very different commercial drivers
  – Having/building an expertise internally or having a commercially minded academic collaborator (or preferably both)
State support must ALWAYS align with the companies strategic goals

- Data driven projects can easily shoot off in interesting but not commercially relevant directions

- A project that is not core will get pushed down the priority list leading to less than satisfying outcomes for the company.

- An internal project champion and minder is required.

- Understand the intellectual property rules associated with the project – they are reasonably rigid.

- Don’t be slow about highlighting issues/changes during the project

  If successful then getting involved has multiple benefits Expertise, IP, Cost effective results and competitive advantage in the national and international marketplace
B. infantis 35624 has shown efficacy for improvement of IBS symptoms. No other probiotic showed significant improvements in IBS symptoms in an appropriately designed study.”

Meta-analysis from Brenner et. al. March 2009
American Journal of Gastroenterology
State support can also provide the leverage for an SME to engage in real marketing innovation and international expansion - if you can do a proper job understanding the market access dynamics; you will save a lot on expensive mistakes you might have had to learn incrementally...
The Human Microbiota is a hot topic

The human microbiome

Me, myself, us

Looking at human beings as ecosystems that contain many collaborating and competing species could change the practice of medicine
AH required new Expertise and Capability

Alimentary Health

Bifidobacteria, Production and Manufacture, Supply chain, Nutrition, Patents, Market analysis, Product concepts, Commercial positioning, Trademarks, Regulatory, Branding, Marketing, Sales

AH Proprietary Strain Bank

Safety
Antibiotic Resistance
Genome Analysis

Pilot Manufacture
Yield
Stability
Formulation

Regulatory
Human study design
FTC
GRAS

Intellectual Property
Publications

Successful Commercial Product

In vitro

Animal Studies

Human studies

Marketing and Branding specialists

Efficacy

Commercial

Strain Isolation, Probiotic Characterisation, Genomics, Gut immunology, Allergy, Nutrition & Metabolism, Gastroenterology, Women's health, Psychiatry, Cognition, Stress, Paediatrics, Infant health/nutrition, Elderly nutrition, Cardiology, Obesity and metabolic diseases etc.
Alimentary Health launches Alflorex with the 35624® culture in Ireland Feb 2014

- Alflorex® food supplement is a proprietary brand containing 35624 Route to market via distributors

- The top selling supplement in the probiotic category in Ireland in 2015 (IMS data)

- ALFLOREX won best Irish Pharmacy product at the Irish Pharmacy News (IPN) awards 2015

Just won Best GI Product and Best Natural Product in the 2016 IPN awards

“I used to have to plan my journeys so carefully, so as not to get caught out – Alflorex has given me my freedom back.”

Testimonial
Flexibility in Company staff important

- an R&D company became a Marketing company - how does that work !!!!

  - All of a sudden SFI grant writers have to become experts in writing websites and marketing literature
    - Carmel, our clinical manager who now also runs our careline and logistics
    - Maeve a dietician in charge of packaging and answering regulatory questions
    - Eileen, a scientist managing brand vision
    - Myself, a scientist setting up an e-commerce capability

All of this required external expertise and upskilling
State support can help you get the right expert and lower the financial risk

- **EI funding**
  - Presently running a Market Access grant
    - Outcomes – key resource (consultancy) and market data being generated in new markets outside of Ireland.
    - AH money concentrated on building up the brand and sales capability to leverage this info.
  - Now looking at grants focussed on improving our digital presence

- **Intertrade Ireland (linked to EI)**
  - Acumen grant to look at cross-border market opportunities via a NI consultancy
    - Outcome: Excellent report on the market opportunity in the North, saving the company significant time and resource
The company ecosystem involved is also valuable

- Networking to find like-minded collaborators
  - EI lists of possible expertise to use
  - Asking those who have done it before..
  - Don’t be afraid to suggest your own experts
  - Other networks e.g.
    - IIBN – Irish International Business Network
      - UK
      - US

And others............
Key learnings from 15 years of accessing state supports
Key learnings from 15 years of accessing state supports

Write it as it says on the tin

- The granting guidelines are accurate
- Tick all the boxes
- Use your Academic collaborators/EI supports to help craft the proposal
- If you are not getting the help you need at this stage – you are with the wrong collaborator.

Internal Champion

- Time flies !!!
- Projects easily de-rail if communication stalls
- Critical commercial expertise must be brought to the table at the right time

Alignment with company goals

- Even cheap money is expensive if it is being spent on the wrong thing.
- If not core by the time the project starts there will be a better use for the money and the project will not get the support it needs
- The projects will/should use internal personell resources

Careful management

- Talk to companies that have worked with Universities to understand the dynamics and drivers
- Never expect that a university collaborator will know what a company needs from the data – you are the experts in the commercial requirement and need to articulate what you need – again & again

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The effect of successfully accessing State funding, University Resources and Expert networks

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