

BIO-GENE TECHNOLOGY LIMITED (ASX : BGT)

ENABLING THE NEXT GENERATION OF NOVEL INSECTICIDES

30 November 2022

Strategy for bringing a new active substance to market in different regions under different regulations, including the BPR

PRESENTED BY

Sarah Driessens

Global Head of Regulatory



TABLE OF CONTENT

- Introduction to Bio-Gene's Technology
 - Bio-Gene key regulatory challenges
 - Roadmap towards registration
 - Opportunities for new technologies
 - Questions
-

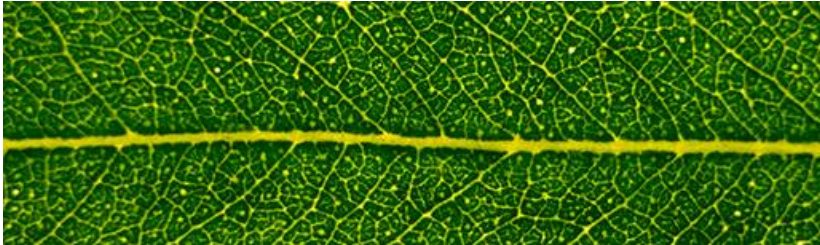
BIO-GENE TECHNOLOGY LIMITED COMPANY OVERVIEW

- Australian Agtech company, ASX listed in 2017
 - Small Team with extensive network of collaborators
 - Developing two naturally derived active ingredients
 - Focussed strategies:
 - ✓ Intellectual Property
 - ✓ Regulatory
 - ✓ Manufacturing
 - ✓ Commercial partnerships
 - ✓ External expert collaborations
 - Targeting key market segments worldwide
-

Examples of some our research collaborators



BIO-GENE'S TECHNOLOGY PLATFORM



Qcide™

Natural Compound

Qcide oil is obtained through oil extraction of a specific cultivar of eucalypt, the Gypmie Messmate, farmed in Queensland, Australia

The natural oil contains high levels of a di-ketone Tasmanone that has insecticidal activity



Flavocide™

Nature Identical Compound

Flavesone a β -triketone is present in plants at low concentrations and has insecticidal activity.

BGT has developed a proprietary chemical process with CSIRO to make this nature identical compound at commercial scale

'Studies have demonstrated Flavocide™ has a unique mode of action, that differs from other available insecticides.'

'A unique mode of action creates the potential to address the ongoing issue of insecticide resistance and control a variety of pest species resistant to currently available chemical entities'

Professor David Spanswick, Neurosolutions (University of Warwick, UK) and Pacific Discovery Services (Monash University, Australia)

ADDRESSING SIGNIFICANT GLOBAL CHALLENGES

The effectiveness of current insecticides is diminishing due to resistance & concerns relating to safety profiles

Our strategy is to secure our Active ingredient registrations and work with strong commercial partners on product development, marketing and distribution.

Food Security & Public Health

Growing Population

Current global population is 7.7 billion, growing at 70 million p.a. It is anticipated that global population will reach nearly 10 billion by 2050¹.

Challenges Of Climate Change

Climbing average temperatures and other weather events impact food production per hectare, increase the habitable environment for mosquitoes

Financial Impact

Production

Currently 20-40% of food produced globally is lost to pests, valued at around US\$2000 billion p.a.^{2,3}.

Cost/Benefit

Direct costs due to Malaria infections valued at US\$12 billion p.a., with economic impact many times that ⁴

Social Impact

Vector Borne Disease

More than half the world is at risk⁵; account for 25% of infectious diseases and exacerbate poverty & economic hardship. Potential to grow beyond 50% under climate change scenarios⁶

Less Arable Land

Increased population puts pressure on available land and resources to produce food for today and tomorrow

1. United Nations, "World Population Prospects 2019"
2. Oerke EC, Crop Losses to pest J. Agri Sci 144: 31-43 (2005)
3. Pimentel D Pesticides and Pest controls. In: Peshin R, Dhawan AK. (eds). Integrated pest management: innovation-development process, 1:83-87. Springer Science (2009)
4. CDC: Malaria's impact worldwide
5. WHO report, 2020
6. IPCC6th assessment report: Climate Change 2022: Impacts, Adaptation and Vulnerability, February 2022

KEY REGULATORY CHALLENGES FOR BIO-GENE

NO HARMONISATION ACROSS THE WORLD

Multiple geographies requires multiple submissions

- Categorisation of the compound
- Different focus e.g EU has a high focus on Endocrine Disruptors
- OECD guidelines versus OPPTS guidelines for testing
- Different formats/risk assessments in the dossier
- Different data protection rules
- Regulatory systems and rules change over time

COMPLEX AND SLOW SYSTEMS

Different end-uses fall under different legislation & regulatory authorities

- EU:** different legislation for Pesticides and biocides (ECHA-EFSA-eMS) with Political influence.
- Australia:** all uses evaluated by APVMA, relatively smooth and quick process.
- USA:** all uses evaluated by EPA, active ingredient and end use product evaluated at the same time. Short track process and fewer requirements for biopesticides
- South America:** no harmonization across the different countries. Evaluations have to pass several ministries in sequence resulting in a slow process
- Asia:** complex, the definition of a biopesticide varies from country to country which makes it even more challenging.

HIGH INVESTMENT COST BEFORE ANY REVENUE INCOME GENERATED

Regulatory costs in Europe are highest relative to market potential

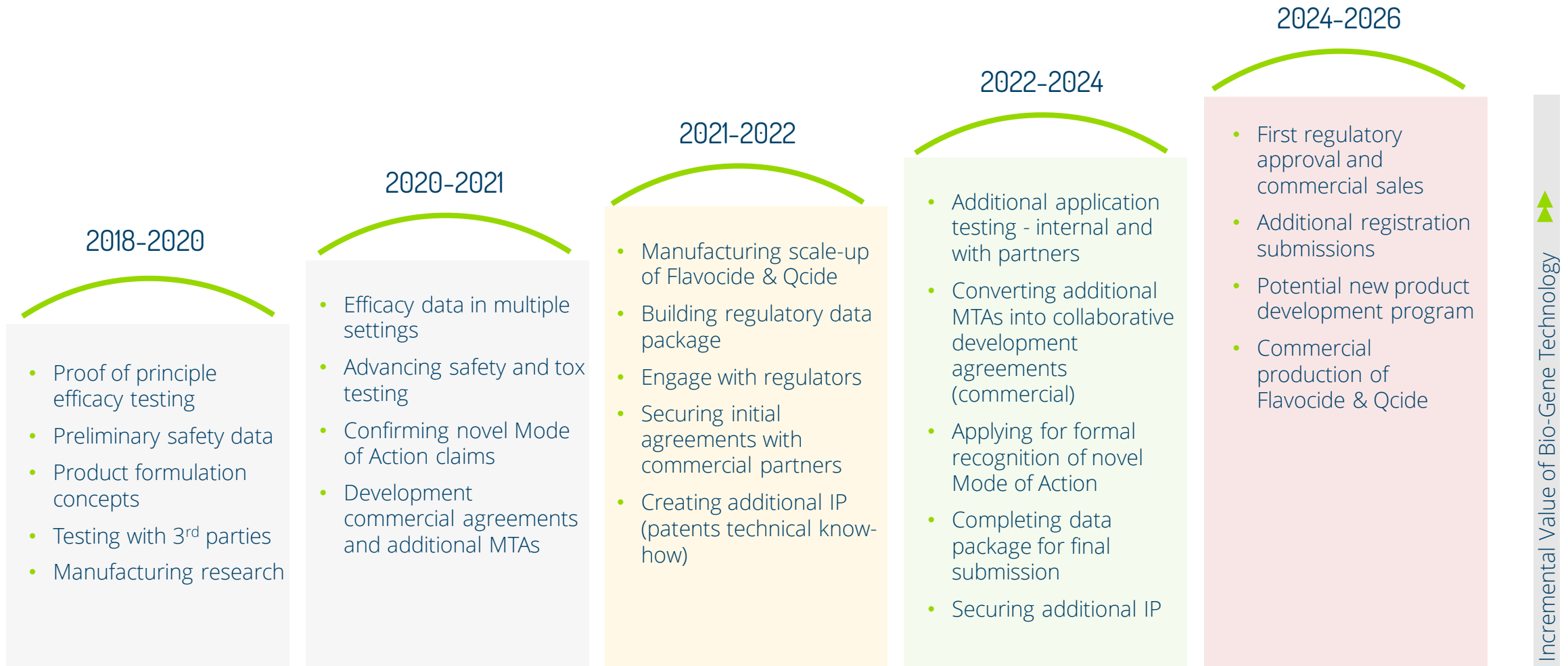
- Study requirements and costs are increasing
- Submission fees are increasing
- Expert and consultancy fees become more and more demanding
- Time it takes before a product can be brought to the market



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



A CLEAR ROAD MAP TOWARDS REGISTRATION



Working for a small Biotech company requires agility and flexibility. There is a need for close and regular consultation, continued reprioritization, careful spending ,transparency and finding the right expert advisers and partners.

OPPORTUNITIES FOR NEW TECHNOLOGIES

Qcide will be considered as a botanical oil. Flavocide is a nature-identical substance. Naturals are currently in high demand as standalone active ingredients or in combination with existing chemicals offering a hybrid solution to farmers.



Examples of evaluation timelines by regulatory authorities for biological products worldwide, 2021, Source [Home Page IBMA-GLOBAL International Biocontrol Manufacturers](#)

*The desire to move towards greener and more sustainable products and regulatory authorities creating programs to **fast track biopesticide registrations**, will help accelerate opportunities for Bio-Gene's 'natural' technologies.*

IN SUMMARY

- Bio-Gene is a small company developing novel insecticide products
 - The cost, complexity and time associated with regulatory approvals is a significant challenge and requires close planning and management
 - The 'natural' qualities of our products provide potential regulatory advantages in some regions but certainly not all
 - We need to be agile and 'creative' to comply with the current regulatory systems in place
 - Consultation is key – with our expert advisers; with the regulators; and with our commercial and product development partners
 - We are making positive progress, first contact with regulators across the world is made
-

BIO-GENE TECHNOLOGY LIMITED (ASX : BGT)

ENABLING THE NEXT GENERATION OF NOVEL INSECTICIDES

Questions?

Sarahd@bio-gene.com.au

Qcide and Flavicide are a registered trade mark of Bio-gene Technology limited

