

## BIO-GENE TO PRESENT AT CHEMICAL WATCH'S ANNUAL BIOCIDES SYMPOSIUM

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- **Bio-Gene's Global Head of Regulatory invited to speak at EU Biocide symposium**
- **Event provides the latest information on the EU Biocidal Products Regulation (BPR)**

Bio-Gene Technology Limited (ASX: BGT, 'Bio-Gene' or 'the 'Company'), an agtech development company enabling the next generation of novel insecticides, is pleased to announce that Sarah Driessens, Global Head of Regulatory will be overseeing the Company's strategy to bring new innovative active substances to the market in different regions under different regulations, including the EU Biocidal Products Regulation (BPR). A copy of Sarah's presentation can be found [here](#).

The highly anticipated two-day "Biocides Europe 2022 Symposium" will provide the latest information on the EU BPR, ongoing challenges and how to increase sustainable use and innovation of Biocides in Europe. The 2-day conference (30 Nov-1 Dec 2022), being held in Vienna, Austria, brings together leading figures from industry, member state competent and regulatory authorities, as well as the European Commission and the European Chemicals Agency.

Sarah Driessens said: "The regulatory system is challenging and the fact it is not harmonised across the world makes it even more complex. It is therefore crucial to collaborate with commercial partners and experts internationally to outline a clear regulatory strategy that can be implemented and adapted where needed. Bio-Gene has recently engaged with regulatory authorities in USA to clarify data requirements as this is crucial to further align our testing programs.

"Both our natural and nature-identical compound Qcide™ and Flavocide™ offer great potential for different market segments, particularly to address insect resistance through a new mode of action. Bio-Gene's strategy is to secure the Active Ingredient product registrations and work with strong commercial partners on product development, marketing and distribution.

"New Modes of Action are quite rare. The last new class to come to market was in 2008, and it has already taken up a substantial proportion of the global market for insecticides."

The World Health Organisation (WHO) reports that currently more than half of the world's population is at risk from vector borne diseases, while globally there are more than 200 million cases of malaria and over 400,000 people die from the disease every year, most of them children under the age of five. Zika virus has been declared a global health emergency, and death due to Dengue Fever has increased 30-fold in the last 50 years<sup>1</sup>.

In 2017 the WHO reported that collectively mosquito-borne diseases such as Malaria, Dengue, Zika claim over 700,000 deaths every year. In addition, these diseases are known to exacerbate poverty and prevent economic development<sup>2</sup>. Unfortunately, the effectiveness of currently used insecticides is diminishing due to resistance.

Further information about Biocides Europe 2022 can be found [here](#)

Approved for release by the Chairman of the Board of Directors.

- ENDS -

**For further information, please contact:***Bio-Gene Technology Limited:*

Richard Jagger

Chief Executive Officer

P: 03 9068 1062

E: [bgt.info@bio-gene.com.au](mailto:bgt.info@bio-gene.com.au)

Roger McPherson

CFO &amp; Company Secretary

P: 03 9068 1062

E: [bgt.info@bio-gene.com.au](mailto:bgt.info@bio-gene.com.au)*IR/Media*

Rudi Michelson

Monsoon Communications

P: 03 9620 3333

E: [rudim@monsoon.com.au](mailto:rudim@monsoon.com.au)**About Bio-Gene Technology Ltd**

Bio-Gene is an Australian agtech company enabling the next generation of novel insecticides. Bio-Gene's novel platform technology is based on a naturally occurring class of chemicals known as beta-triketones.

Beta-triketone compounds have demonstrated insecticidal activity (e.g. kill or knock down insects) via a novel mode of action in testing performed to date. This platform may provide multiple potential new solutions for insecticide manufacturers in applications across crop protection and storage, public health, animal health and consumer applications. The Company's aim is to develop and commercialise a broad portfolio of targeted insect control and management solutions.

**Flavocide™** and **Qcide™** are trademarks of Bio-Gene Technology Limited.

1. Global Mosquito Control Market, Research Report 2020, Forecast to 2026
2. <https://mosquitoreviews.com/learn/disease-death-statistics>

# 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



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- Introduction to Bio-Gene's Technology
  - Bio-Gene key regulatory challenges
  - Roadmap towards registration
  - Opportunities for new technologies
  - Questions
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# 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
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Examples of some our research collaborators



# BIO-GENE'S TECHNOLOGY PLATFORM



## Qcide™

### Natural Compound

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

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



## Flavocide™

### Nature Identical Compound

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Flavesone a  $\beta$ -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'*

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*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 2050<sup>1</sup>.

### Challenges Of Climate Change

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

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## Financial Impact

### Production

Currently 20-40% of food produced globally is lost to pests, valued at around US\$2000 billion p.a.<sup>2,3</sup>.

### Cost/Benefit

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

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## Social Impact

### Vector Borne Disease

More than half the world is at risk<sup>5</sup>; account for 25% of infectious diseases and exacerbate poverty & economic hardship. Potential to grow beyond 50% under climate change scenarios<sup>6</sup>

### Less Arable Land

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

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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.

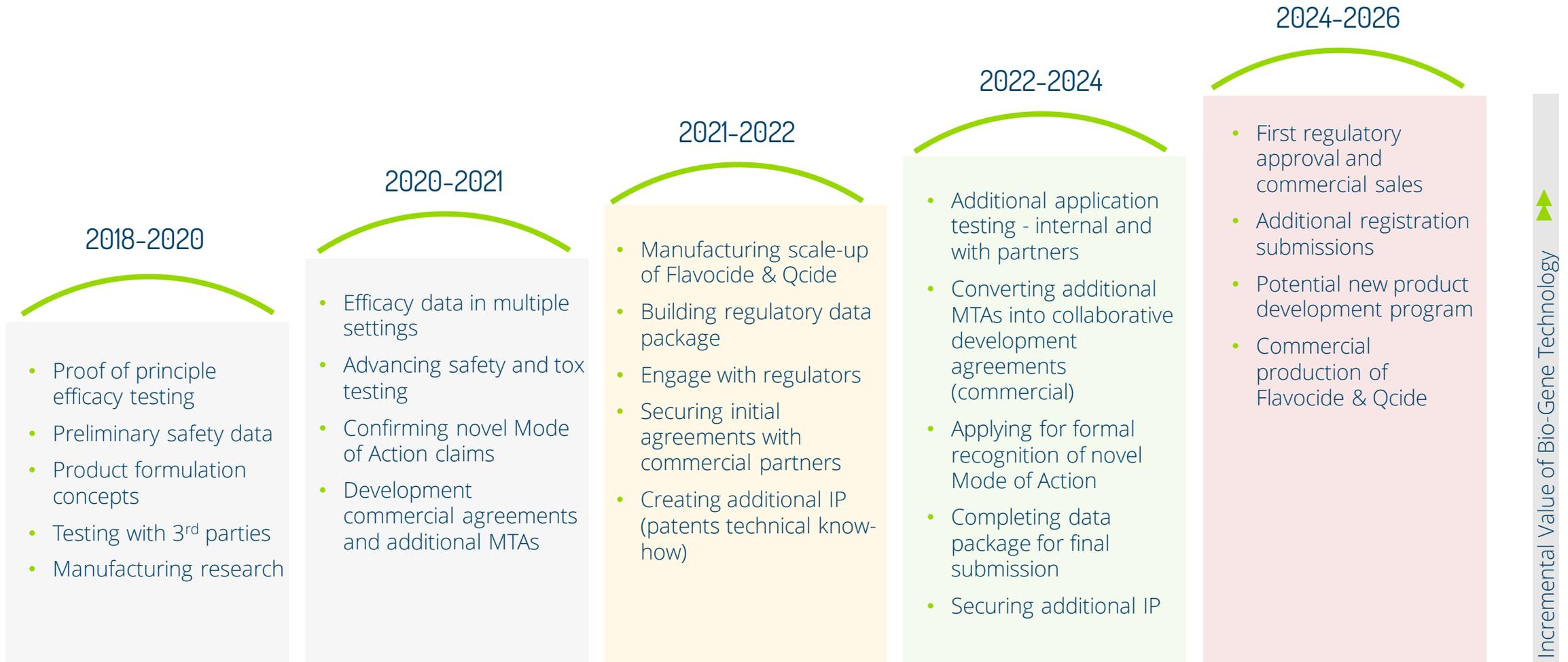
## HIGH INVESTMENT COST BEFORE ANY REVENUE INCOME GENERATED

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



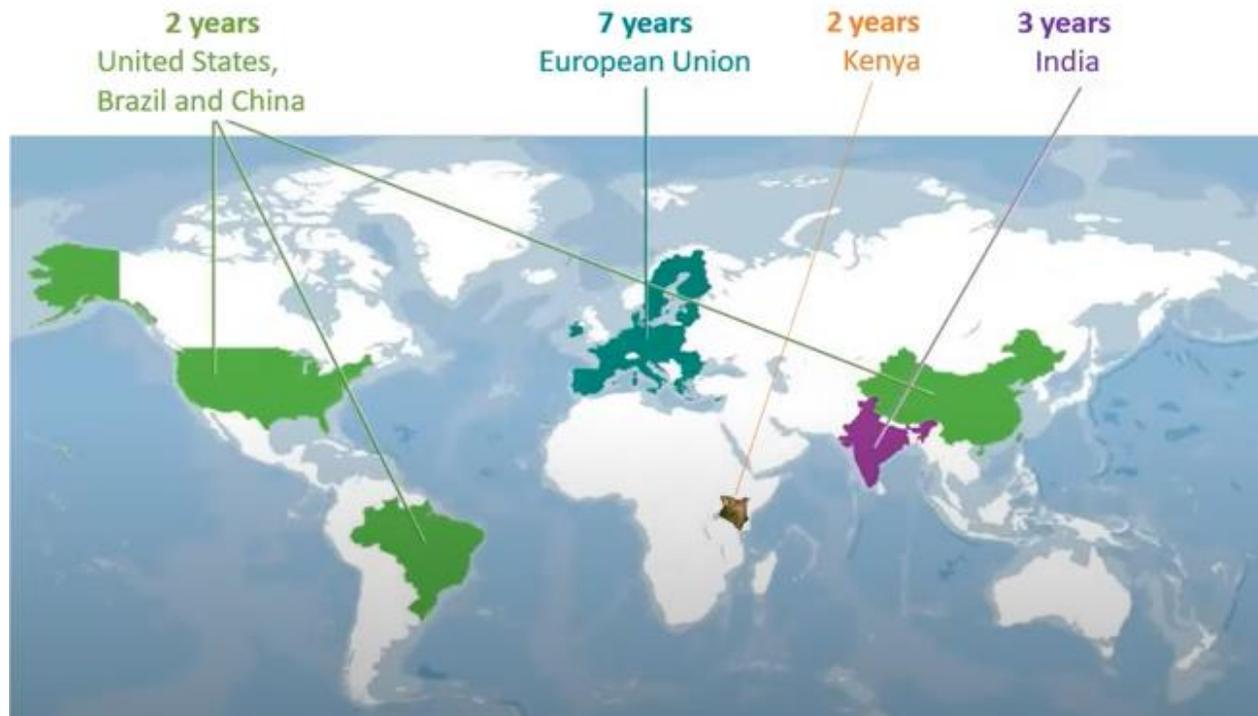
# A CLEAR ROAD MAP TOWARDS REGISTRATION



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.*



*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.*

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

# 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
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# BIO-GENE TECHNOLOGY LIMITED (ASX : BGT)

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Questions?

[Sarahd@bio-gene.com.au](mailto:Sarahd@bio-gene.com.au)

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