### ENABLING THE NEXT GENERATION OF NOVEL INSECTICIDES

# BIO-GENE TECHNOLOGY LIMITED

MAY 2021 Corporate Presentation

PRESENTED BY **Richard Jagger** Chief executive Officer & Managing Director



# KEY INVESTMENT HIGHLIGHTS

Proprietary insecticide technology Naturally derived chemistry, with novel mode of action



Expanding efficacy, toxicity and manufacturing data to support international regulatory submissions – Excellent safety profile



Large addressable markets where insecticide resistance is a growing problem



Commercial partnership strategy provides multiple opportunities to demonstrate and generate near-term value, with several partnerships already in place



Experienced and motivated board & management team



# ADDRESSING SIGNIFICANT GLOBAL CHALLENGES

# Insecticides allow control of agricultural pests and disease vectors and are vital for global food security and health

### Pests are increasingly developing resistance to current insecticides

Food security issues – increased damage

Need for higher rates and / or harsher chemistry to control pests that are vectors for serious diseases. Public concerns relating to the 'toxic' impact of incumbent products on bees & the environment

Pressure to use "softer" chemistry and safer solutions

Regulators banning existing chemistry due to health or off-target impact concerns Very limited new insecticide technologies have been commercialised in recent years

Last significant insecticide, with

a novel Mode of Action, was commercialised in 2008 - now generating in excess of US\$2.3 billion in product sales

The discovery new compounds capable of being used as insecticides is effectively a 1 in +140,000 chance *'At present, there are more than 16,000 documented cases of insecticide resistance involving more than 600 insect and mite species that have developed resistance to at least one insecticide.* 

Most of the primary pest species impacting the major crops and human health have developed resistance to many of the available insecticides since the introduction of synthetic organic insecticides some 75 years ago."

Insecticides, biologics and nematicides: Updates to IRAC's mode of action classification - a tool for resistance management. Thomas C Sparks, et al. Journal of Pesticide Biochemistry and Physiology. June 2020.

# THE VALUE OF **INSECTICIDES**

The world today relies heavily on pesticides... and will into the future as part of Integrated Pest Management programs

"Without Crop Protection, crop losses would double each year"

### CropLife



"No new public health insecticides have been developed for mainstream vector control for 30 years"

CDC<sup>4</sup>

### **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			
Financial Impact				
Production	Currently 20-40% of food produced globally is lost to pests, valued at around US\$2000 billion pa <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 $^4$			
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. Mosquito borne diseases account for over 700,000 deaths every year and there are over 200 million cases of Malaria globally			
Less Arable Land	Increased population puts pressure on available land and resources to produce food			

United Nations, "World Population Prospects 2019" 1. 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)
- CDC: Malaria's impact worldwide 4.
- WHO report, 2015 5.

# OUR TECHNOLOGY ADDRESSES THESE CHALLENGES AND TARGETS GROWING GLOBAL MARKETS



Bio-Gene's insecticide platform has potential application in large, global market segments estimated to represent a total addressable market valued at over US\$31.1 billion



US EPA 2017, WHO 2017, Zoetis & Provue Market Research, Markets & Markets

# OUR TECHNOLOGY PLATFORM

# We are developing two products that allow entry into five key market segments



### Qcide™

### Natural Compound

An extract of a specific cultivar of eucalypt, the Gypmie Messmate

Trees are farmed in concentration by sub-contractors in QLD

The leaves contain oil expressing high levels of Tasmanone, a natural compound that has shown evidence of insecticide efficacy



### Flavocide™

### Nature Identical Compound

BGT has developed a proprietary chemical process with CSIRO to deliver another Beta-Triketone; a nature identical compound that is able to be produced at commercial scale



Both of our products have potential application in all five of our target market segments

# OUR PROPRIETARY CHEMISTRY REPRESENTS A STEP-CHANGE FOR RESISTANT PEST CONTROL



### Naturally Derived Chemistry

Qcide<sup>™</sup> is a natural compound and Flavocide<sup>™</sup> is a 'nature identical mimic' of a natural compound that can be mass produced



### Scalability

Production processes are refined, scale-up in progress

Safe	Chem	istry

Excellent safety profile based on data generated to date. Low toxicity to bees & beneficial insects (5000 times less toxic to bees than neonicotinoids)



insecticides

**Synergies & Combinations** 

Proven synergy in combinations

with synthetic pyrethroids – the

most commonly used mosquito



### Efficacy

Testing to date confirms potential for controlling resistant pests across multiple markets



### **Control of Multiple Generations**

Potential to impact pest populations by controlling adults and offspring



### Novel Mode of Action

Operates via a novel Mode of Action, potentially addressing resistance to other classes of chemistry

# OUR STRATEGIC OBJECTIVE



Generate multiple revenue streams from technology licensing fees, milestone payments and royalties by



Securing & owning active ingredient product registrations



Working with strong commercial partners on product development; marketing and distribution



Developing proprietary manufacturing and production know-how



Potential partnership agreements across multiple geographies and different end-use markets, with collaboration programs now underway in two of our target segments

## **CREATING MULTIPLE PRODUCT DEVELOPMENT OPPORTUNITIES**

Bio-Gene can generate income and incremental company value as agreements are signed with commercial partners

Multiple Material Transfer Agreements provide the opportunity for agreements to be developed across various market segments with numerous commercial partners



# CURRENT DEVELOPMENTS ACROSS OUR KEY MARKETS

		CROP PROTECTION	STORED GRAIN	PUBLIC HEALTH	CONSUMER	ANIMAL HEALTH
TOXICOLOGY & SAFETY	Advances in studies towards registration MoA studies completed	0	0	0		
MANUFACTURING	Scale up towards commercial levels			0		
EFFICACY	Establishing efficacy and demonstrating additional opportunities	Additional results Q3 & Q4 CY21	Additional results <u>Q2</u> & Q4 CY21	Additional results Q2 & Q3 CY21	Additional results Q3 CY21	Additional results Q3 CY21
PARTNERSHIPS		Further work under MTA Anticipated Q4 CY21	Agreement with Commercial partner Anticipated Q4 CY21	Agreement with Commercial partner Anticipated Q3 CY21	Evaluation Agreement Anticipated Q3 CY21	Further work under MTA Anticipated Q4 CY21
TOTAL GLOBAL MARKET		US \$14.9B	US \$1.0B	US \$4.1B	US \$5.1B	US \$6.0B

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# STORED GRAIN PEST EVALUATION PROGRAM

### AUSTRALIA

Substantial market opportunity, with estimated losses of up to **70%** of grain in storage attributed to pests across global markets. Global grain protectant market currently valued at approx. A\$1 billion p.a. and growing\*



Stage 1 identified optimum product combination for control of the major pest, the Lesser grain borer

OUR

PARTNERS



Stage 2 testing demonstrated that Flavocide in combination with other products effectively controls 5 major pest species impacting grain storage

GRDC

Australia's national grains

Research, Development &

extension investment body





Stage 3 (field) testing has commenced to assess residual efficacy & minimum application rates. Interim results announced May (agreement to proceed) with final results anticipated in Q4 CY21



Recognised global experts in the field of stored grain pests

\* https://www.researchandmarkets.com/reports/4744816/grain-protectants-global-market-outlook2017

We create chemistry

company

The world's leading chemical

# MOSQUITO EVALUATION PROGRAM THE AMERICAS



Agreement entered into in April 2020, evaluating Flavocide and Qcide for use in public health mosquito control in North, South and Central America



Testing commenced in September 2020 to assess various solvents as base carriers (results late Q2)



Expect to then test lead formulations on target species in field environments



population is at risk of vector-borne diseases. The effectiveness of currently used insecticides is diminishing due to resistance

The US market for chemical control of mosquitos is currently valued at approximately US\$200 million\*







\* Global Mosquito Control Market, Research Report, 2021



# BIO-GENE USES A MULTI FACETED APPROACH TO CREATE BARRIERS TO ENTRY AROUND OUR PROPRIETARY TECHNOLOGY





Bio-Gene uses a platform of intellectual property to add value to our technology and future customers



New patent applications will succeed existing patents approaching expiry



Significant manufacturing knowhow for both products has been developed. Germplasm development for Qcide trees



Substantial body of detailed technical data based on years of trials relating to efficacy, physical / chemical attributes, safety, interaction with other molecules etc.

# REGISTRATION OF BIO-GENE PRODUCTS

Bio-Gene is making positive progress as it builds a data package to support regulatory approval...

![](_page_13_Picture_3.jpeg)

As we continue to generate data, we are reducing our regulatory risk, adding value to our technology package

### Advanced

Chemistry & Manufacture	Physical/chemical properties determined; manufacture/production processes defined			
Efficacy & Safety	Efficacy for specific use patterns demonstrated; product formulations developed			
Occupational Safety	Phys/chem & toxicology data available to evaluate safety in proposed use patterns			
Advancing				
Toxicology	Acute toxicity testing & de-risking studies completed; definitive testing imminent			
Environment	Ecotoxicity testing initiated to define safety profile; environmental fate studies pending			
Residues	Preliminary studies to establish residues in grain storage; other food crops pending			

...and will meet with the APVMA within next 12 months to review the testing program and determine additional data needs

# MANUFACTURING

![](_page_14_Picture_2.jpeg)

### Qcide

Key molecule found in rare cultivar of Eucalyptus sp.

Unusually high levels of key ingredient found in oil of leaf

Development of extraction techniques with assistance of James Cook University

Development of cloning techniques to replicate target trees with James Cook University

Pilot tree growing and oil extraction site in Far North Queensland

Opportunity for scale up as required

Developing I.P. around specific tree lines and oil extraction protocols

![](_page_14_Picture_11.jpeg)

### Flavocide

Nature Identical molecule found in Australian Flora, but not in commercial quantities

Synthesis process developed with assistance of CSIRO

Scale up of synthesis process underway with Boron Molecular and BGT manufacturing consultant

Development of 5 batch process underway, providing manufacturing capability as well as registration enabling data

I.P. developed around manufacturing process

Opportunity for scale up at multiple global sites as required

# **FUNDING POSITION**

![](_page_15_Picture_2.jpeg)

### Shares on issue 153,633,357

Market capitalisation \$27.7 million\*

As at December 31, 2020, Cash on hand

### A\$5.0 million

Provides working capital needs on budgeted activities for greater than 12 months

\*@18 cents per share

### Sources of future funding:

Development

and commercial partnerships

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Industry organisations Government grants

(\$)

Capital markets

![](_page_15_Picture_17.jpeg)

Philanthropic organisations focused on public health solutions

# **BOARD MEMBERS & MANAGEMENT**

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### **Robert Klupacs**

**Interim Chairman** 

![](_page_16_Picture_4.jpeg)

- 30+ years corporate experience in international tech development
- Previously MD & CEO of ASX-listed Circadian Technologies Ltd
- Previously MD & CEO of ES Cell International Pte Ltd
- Registered Australian patent attorney

![](_page_16_Picture_9.jpeg)

### **Richard Jagger CEO & Managing Director**

- 25+ years working in agriculture globally
- Most recently employed as Managing Director of Sinochem Australia
- Previously spent 15+ years at Monsanto in various management roles

![](_page_16_Picture_14.jpeg)

### **Non-Executive Director**

Peter Beetham

- 30+ years experience in bio-agriculture community
- CEO of Cibus Global
- Previously Scientific Officer at Plant Research Institute, Victorian Dept Ag

![](_page_16_Picture_19.jpeg)

### **James Joughin**

**Non-Executive Director** 

- Highly experienced ASX listed and private company Director.
- Currently the Non-Exec Chair at Spirit Technology Solutions Ltd (ASX:ST1) and a NED at Mydeal.com.au Ltd (ASX:MYD)
- Former partner in Big 4 firm with expertise in capital markets etc.

![](_page_16_Picture_25.jpeg)

### Andrew Guthrie

**Non-Executive Director** 

- 32 years experience in agriculture globally
- Management roles in multiple geographies
- Was part of Syngenta's leadership team responsible for business strategy that leveraged R&D capability to invent, gain regulatory approval and launch new products.

![](_page_16_Picture_31.jpeg)

 20+ years experience in crop protection market with companies Orica & Crop Care Australasia (now Nufarm)

Peter May

- Founded Xavca, consulted to companies such as Syngenta & Sorex (BASF)
- Former CEO & Chairman of BioProspect (now Medibio, ASX:MEB)

![](_page_16_Picture_35.jpeg)

### **Roger McPherson**

### CFO & Co. Sec.

- 15+ years experience as CFO & Company Secretary across both listed & unlisted companies
- Experience in the pharma manufacturing, biotech & biopharma industries
- Previously CFO & Co-Sec of TPI Enterprises (ASX:TPE)

![](_page_16_Picture_41.jpeg)

### James Wade

**Program Manager** 

- PhD with 10+ years experience in research in a broad range of agricultural verticals
- Previously Science and Technology Program Manger for Avigen Ltd

Board and management expertise complemented with expert scientific, technical and advisory support from individuals and partner organisations including CSIRO, Purdue University, James Cook University and Boron Molecular

## A CLEAR ROAD MAP FOR ADDING VALUE SHORT TERM

![](_page_17_Figure_2.jpeg)

A number of key milestones and valueadding activities continue to improve the overall value of BGT technology

![](_page_17_Figure_4.jpeg)

![](_page_17_Figure_5.jpeg)

- BASF / GRDC phase 3 field work completed with lab studies to be developed
- Conversion of MTAs into additional formal evaluation trials
- Agreements with commercial partners
- Additional efficacy data

![](_page_17_Picture_10.jpeg)

CY2104

- Confirmation of yield improvements via extraction process at Qcide harvest
- BASF / GRDC stage 3 results
- Qcide Tree planting scale up
- Anticipate acceptance of additional patents

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# A CLEAR ROAD MAP FOR GENERATING VALUE

### CRITICAL VALUE ADDING & DE-RISKING STEPS

#### 2022-2024 2021-2022 • First regulatory approval and 2020-2021 commercial sales Additional Additional application testing -2018-2020 • Manufacturing scaleinternal and with registration submissions partners up • Efficacy data in • Building regulatory Applying for formal Potential new multiple settings recognition of novel product data package development Mode of Action • Advancing safety • Proof of principle Securing initial program and tox testing efficacy testing Completing data agreements with package for final • Confirming novel commercial partners • Preliminary safety data Mode of Action submission Converting Product formulation claims additional MTAs into concepts • Development collaborative • Testing with 3<sup>rd</sup> parties development agreements and additional MTAs agreements

### 2024-2026

![](_page_18_Picture_5.jpeg)

POTENTIAL UPFRONT AND MILESTONE PAYMENTS, LICENSING FEES

![](_page_18_Picture_8.jpeg)

# SUMMARY

![](_page_19_Picture_2.jpeg)

Bio-Gene is successfully advancing a naturally derived, novel and proprietary class of insecticide chemistry with a new Mode of Action

![](_page_19_Picture_4.jpeg)

Bio-Gene's technology addresses significant environmental, food safety and public health challenges and the growing problem of insecticide resistance

![](_page_19_Picture_6.jpeg)

The global market for insecticides is ~ US\$31 billion and growing

![](_page_19_Figure_8.jpeg)

Excellent safety/tox profile indicated by testing to date – and strong efficacy data

![](_page_19_Picture_10.jpeg)

Existing development agreements with Tier 1 commercial partners

![](_page_19_Picture_12.jpeg)

Clear focus on meeting milestones that build value over time

#### ENABLING THE NEXT GENERATION OF NOVEL INSECTICIDES

# BIO-GENE TECHNOLOGY LIMITED

### CONTACT

![](_page_20_Picture_3.jpeg)

### RICHARD JAGGER CHIEF EXECUTIVE OFFICER

richardj@bio-gene.com.au

![](_page_20_Picture_6.jpeg)

![](_page_21_Picture_1.jpeg)

![](_page_21_Picture_2.jpeg)

# ABOUT BIO-GENE...

![](_page_22_Picture_2.jpeg)

![](_page_22_Picture_3.jpeg)

Bio-Gene is developing the next generation of novel insecticides addressing the global problems of insecticide resistance and toxicity. Our novel platform technology has a unique mode of action and is based on naturally occurring beta-triketones, a type of chemistry showing evidence of effective insect management control in crop protection (including grain storage), public health, consumer applications and animal health. We are progressing towards product registrations and, in parallel, identifying commercial collaboration opportunities that lower our risk and investment and generate value in the near term.

# ESTABLISHING A NOVEL MODE OF ACTION IS A MAJOR MILESTONE

The Mode of Action (MoA) defines the process of how an insecticide works on an insect at the molecular level

Each MoA class identified by IRAC (Insecticide Resistance Action Committee), attacks pests in different ways (Novel Modes of Action). IRAC is a specialist technical group of the global industry association CropLife.

The knowledge gained around Beta-Triketone MoA has the potential to assist in the future development of 2nd generation chemistry based on these molecules.

Effective insecticide resistance management (IRM) is essential if the utility of current and future insecticides is to be preserved. Bio-Gene has successfully completed studies – announced February 2021 – which confirm the definitive target site (the MOA) of Flavocide in insects. These results provide critical information that will be important in creating validation data in support of Bio-Gene's application for a "new class of chemistry" with IRAC

Being allocated to a new MoA class means Bio-Gene products would automatically be considered for a number of IRM plans involving rotation of combination of Active Ingredient strategies.

The confirmation of a definitive new MoA represents a key milestone in the value proposition for potential commercial partners who have a need for new MoA to complement their exiting portfolios

The IRAC MoA classification scheme covers more than 25 different modes of action and at least 55 different chemical classes, however we rely generally on only 5 MoAs for most of our insecticide applications. Diversity is critical to effective resistance management by chemical means and thus it provides an approach to IRM providing a straightforward means to identify potential rotation/alternation options.

A pest that has resistance to one chemical, will have resistance to all other chemistry within the same MoA class (cross resistance), but is unlikely to have developed resistance for chemistry in other MoA classes

# CAPITALISING ON PLATFORM TECHNOLOGY

Bio-Gene has the potential to replicate the success of Nihon's platform technology developed for the Diamide insecticide class (last significant new Mode of Action)

Nihon Nohyaku development program commenced in the 1990s (based on herbicide molecules that indicated weak insecticidal activity) First products were developed with Bayer Crop Sciences and brought to market in 2008 as a way to address resistance to other classes of chemistry

### **DIAMIDE INSECTICIDES**

Most recently launched class of insecticides with a truly novel Mode of Action (2008)

Licensing agreements with Nihon see the class of chemistry being developed by multiple companies across the world Royalties and license fees flow back to Nihon, in a model that Bio-Gene plans to replicate across a number of market segments, with multiple commercial partners

### Global sales achieved US\$1.4 billion in 2013

Current global sales estimated at US\$2.3 billion

(ref.) Sparks T. et al: Insecticides, biologics and nematicides: Updates to IRAC's mode of action classification – a tool for resistance management: Pesticide Biochemistry and Physiology Vol 167

Diamides is a platform technology, with many applications across multiple market segments

# SIGNIFICANCE OF PESTS IN STORED GRAIN

![](_page_25_Figure_2.jpeg)

# ADDITIONAL INTEREST IN OUR TECHNOLOGY

Multiple Material Transfer Agreements (MTAs) in place with companies that cover a range of geographic markets and span our five key end-use markets

![](_page_26_Picture_3.jpeg)

![](_page_26_Picture_4.jpeg)

These agreements cover preliminary assessment of the technology. Discussions now underway with some parties re the potential to transition into additional formal evaluation agreements and commercial partnerships

# **REGISTRATION OF BIO-GENE PRODUCTS**

In Australia, Bio-Gene must satisfy the Australian Pesticides & Veterinary Medicines Authority (APVMA) process for Ag-Chem Products . Both Active Ingredient and specific formulations and use patterns need to be registered. These can be done concurrently.

# Preliminary results can be used to confirm likely future data requirements with the APVMA, with the aim to streamline time and cost of process

The relevant authority reviews application prior to making a decision

![](_page_27_Figure_5.jpeg)

The process is "harmonised" globally, however additional data may be required in some countries to support local registration.

Timeframes for assessment and granting of registration varies by geography.

![](_page_27_Figure_8.jpeg)

# **KEY PRIORITIES FOR THE CURRENT 12 MONTHS**

Generate additional toxicology data – supports our active ingredient registration program

> Progress data package to support IRAC submission on novel class of chemistry (Mode of Action)

Undertake 5-batch analysis testing on scaled up manufacturing process (Flavocide) and achieve further extraction and yield improvements in Qcide production

> Convert existing MTAs into more formal collaboration agreements and secure new MTAs with additional companies

Successfully complete stage 3 trial work as part of Australian stored grain evaluation program and commence discussions with BASF on potential commercial licensing arrangements

> Progress trial work with Clarke on mosquito control and progress potential codevelopment/commercial discussions

Clarification of the data package requirements that will enable us to secure regulatory approval

![](_page_28_Picture_9.jpeg)

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