

## 2020 AGM – CEO'S ADDRESS

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The past year has seen positive progress across our technical, regulatory, manufacturing, intellectual property, and partnership programs.

It is fundamental to the future value of our Company to be able to develop our technology with key industry players. To create these development partnerships, we need to continue to generate data that demonstrate the safety, efficacy of our products and the capability to have them manufactured and produced.

To that end, we have made key advancements in establishing the effectiveness of Flavocide against stored grain pests, including data which shows Flavocide retains that efficacy over extended periods of time.

We have also demonstrated, in our very significant trial work with Purdue University, the efficacy of the product against three species of mosquito which are responsible for the transmission of malaria, Zika and dengue fever.

And further studies have been completed that help articulate the novel mode of action of our products which will be key to supporting our application to have Bio-Gene's technology independently confirmed as a novel class of chemistry.

A critical component of our regulatory package will involve environmental toxicology screening. In the past year, we completed the first two rounds of screening – looking at both aquatic and bird species – and we are underway with further important testing in this area.

The scale-up of our Flavocide manufacturing process from lab-bench to pilot industrial is a significant milestone as it demonstrates the ability to move to larger scale production. And advancements have also been made on the processes that will deliver improved yields and efficiencies in the production of our natural Qcide product.

These outcomes are contributing significantly to the strength and value of our intellectual property, some of which will be captured in various patents that are being progressed across multiple jurisdictions.

A number of additional MTAs were signed over the past year with companies that have an interest in evaluating our technology. While these MTAs represent the very initial stages of that assessment, it is reassuring that we continue to attract interest from companies that cover both a range of geographic markets and span our four key end-use markets - public health, crop protection, grain storage, and consumer products. I would like to focus in a little more detail on the two partnership evaluation programs we now have in place.

In September of last year, the Company announced an exclusive partnership with the world's leading chemical company BASF, to evaluate Flavocide for use in stored grain pest control in Australia. It was subsequently confirmed that the evaluation program would include a collaboration involving GRDC – Australia's leading grains research, development and extension body – and the Queensland Department of Agriculture and Fisheries, which brings recognised expertise in the field of grain pests to the program.

The research program commenced in January and we have now successfully completed the first two stages of that evaluation. Stage 2, which was completed in September, has demonstrated that that we can create product combinations that effectively control the five major pest species impacting grain in storage in Australia and international markets.

The product combinations were tested using two different concentrations, to help determine how low we can go with field rates and still achieve commercial control. This is important, as one of the major goals of insecticide users globally is to minimise environmental impact by reducing application rates whilst still achieving the desired levels of control. This is becoming increasingly difficult with existing commercial products, as populations of pests resistant to those chemistries continue to grow.

The third and final stage of testing, which commenced this month, takes our preferred product combinations to the field for residual efficacy evaluation. The testing will be undertaken over a 9-month period. We have a strong basis for being optimistic about the outcome for Stage 3 testing, given earlier results (announced on March 26 this year) that indicated Flavocide was able to control a key stored grain pest, the Lesser Grain Borer, for over 13 months based on both field and laboratory work.

It is important to note that this evaluation agreement with BASF is focused on the Australian market for stored grain pest control only. The problem of grain storage pests is world-wide, and Bio-Gene may seek to extend the geographic area of any future agreements, or work with multiple partners where that makes sense. It is also important to note that other potential partners currently under MTAs have an interest in this field.

At present, there is no single chemistry that controls all major pests that impact stored grain. The incidence of pest resistance is rising in Australia, and around the world. In some cases, losses of up to 70% of grain in storage have been attributed to pests. This creates a substantial opportunity for Bio-Gene as there are few solutions currently available that can address the resistant pests.

I look forward to continuing to update you on progress on this front and to reporting on the results of the stage 3 testing when it is expected to be complete in about September of next year.

Our second formal evaluation program – executed in April - is with US based Clarke, a global leader in environmentally responsible mosquito control solutions. Clarke is evaluating its interest in partnering with Bio-Gene on the development of both Flavocide and Qcide for use in public health mosquito control in North, South and Central America.

Clarke began its evaluation work in September, which is a little behind schedule due to some COVID-related changes that needed to be implemented in their laboratories. The current testing being undertaken by Clarke involves the evaluation of a large number of solvents as the base carrier for Flavocide and Qcide. This is very important, as the carrier can impact how well the active ingredient can cross the insect exoskeleton.

Clarke's commitment to and investment in this work is extremely encouraging to us. Clarke brings proven levels of expert formulation chemistry to this project, which will be invaluable to the ultimate success of Bio-Gene's products.

The current testing program is scheduled to take around 4-5 months, meaning we should be able to provide some updates on this work towards the end of the first quarter of calendar year 21.

Our expectation is that the next phase of testing under the Clarke arrangement will involve evaluating lead formulations identified in the current work on target mosquito species.

Our objective with both of these evaluation agreements is to progress to a point where we can negotiate a product development and commercial partnership with the companies involved. While we recognise the importance of

achieving that as quickly as possible, we are also mindful that the completeness and strength of our data is fundamental to negotiating better financial and commercial terms in any such agreement.

As I noted earlier, the three key areas of data generation that are fundamental to our regulatory objectives; our partnership aspirations and the overall value of our technology are:

- Safety
- Efficacy; and
- Manufacturing/production

We will maintain a relentless focus on these areas of activity.

The current 12 months represents another very important period for Bio-Gene and we have identified a number of objectives and milestones which will be key to building the value of the Company during the year.

- Additional toxicology studies are underway and the first results will be available next month. We will utilise the results of those studies – together with the work already completed – to further refine our testing priorities over the course of the year so that it helps support an efficient registration program. We are also speaking with the regulatory teams of Clarke, BASF, and others about the best way to work through the various regulatory processes in our target geographies around the world.
- Our aim is to have a completed initial registration package ready for submission here in Australia in mid-2022 and -based on an estimated 18 month review period by the regulator – a first active ingredient approval by around the end of 2023.
- Over coming months we will finalise a program of studies to support our case to have the Insecticide Resistance Action Committee or IRAC acknowledge that our technology represents a novel class of chemistry. IRAC is recognised by the Food and Agriculture Organisation and the World Health Organisation of the United Nations as an advisory body on matters pertaining to insecticide resistance and a successful application helps drive adoption of our technology via Integrated Pest Management Programs. Submission to IRAC will occur just prior to our first active ingredient registration submission.
- On the manufacturing and production front, we will be undertaking further work including a 5-batch pilot plant production which is needed to demonstrate the repeatability of our current methods and provides additional samples for testing with our collaboration partners. This work should reach some reportable outcomes in the first quarter of the new calendar year.
- We have also just completed another trial harvest for our Qcide product in Queensland. The trial was aimed at testing refinements to processing equipment designed to further improve Qcide yield from the harvested bio-mass. Observations on site were promising, and we are now waiting on the formal review of the collected data.
- During this current 12 months, we will be conducting a number of Bio-Gene funded projects relating to specific attributes of our technology - such as sub lethal effects and combination studies - to support further applications for our technologies in markets that would be of potential interest to companies currently engaged under MTAs and to attract the interest of additional companies willing to enter into similar agreements.

- While we can continue to exert pressure on these companies to move as quickly as possible, it is important to note that this work assumes different levels of priority within those organisations. Our ultimate goal, of course, is to convert this level of interest into a formal evaluation agreement and then product development and marketing partnerships. The MTAs cover a range of different geographies and market segments.
- With our BASF agreement covering stored grain pests in Australia, we will undertake and complete the stage 3 trial work which provides a strong platform for entering into discussions with BASF around further product development and commercialisation.
- And we expect to complete the next phase of trials with Clarke on mosquito control which, if successful, also places us in a position to progress partnership discussions with that company.

I would also like to take the opportunity to thank our small but talented team at Bio-Gene for their work over the past 12 months and their continued commitment to helping us achieve our objectives. In some cases, we have seen delays in the commencement or continuation of certain studies or activities, as we and the organisations we work with, have had to adjust policies and work environments to keep people safe during the COVID pandemic. But despite those challenges, our progress has been strong and the interest from our research collaborators and potential commercial partners remains high.

Bio-Gene has the opportunity to develop and commercialise unique insecticide technology which addresses multiple end-use markets of significant value, while addressing global environmental, public health and food production challenges. It's an exciting prospect...and one we are dedicated to realising.

Approved for release by the Board of Directors.

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**About Bio-Gene Technology Ltd**

Bio-Gene is an Australian agtech company enabling the next generation of novel insecticides to address the global problems of insecticide resistance and toxicity. 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, consumer applications and animal health. 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.

**Bio-Gene Technology Limited**

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