# Bio-Gene makes strong progress against strategic priorities

## Quarterly Activities Report and Appendix 4C

### Q3 FY24 Highlights

- The scale-up synthesis and planned regulatory-enabling studies with Flavocide® remain on track, with the current key milestone of filing the registration dossier with the APVMA planned to take place in Q4 CY25
- Pilot scale production of Flavocide has commenced following the appointment of a large contract manufacturing company located in India
- Additional opportunities to reduce the estimated commercial cost of manufacture of Flavocide as scale-up takes place, have been identified
- Pre-application advice submission made to the Australian regulator (APVMA) to confirm that the existing and planned registration data package will satisfy the requirements for Flavocide active ingredient registration
- An experienced European regulatory consulting firm has been appointed to undertake study concept management and monitoring for the Flavocide registration enabling testing program
- Strong progress has been made in the formulation development activities aligned with the specific use patterns of the company's product pipeline in crop protection, public health and consumer applications
- Qcide® production optimisation remains focused on tree improvement and processing efficiency to support programs to scale-up tree production area and oil extraction
- Qcide product testing and registration-related activities remain on-track in collaboration with STK Bio-Ag Technologies (STK)
- Engagement with commercial partners Clarke and Evergreen, and a pipeline of potential other commercial partners, continues to create demand for Bio-Gene's products, including stand-alone and combination products
- Patents granted in Japan and Australia for use of Flavocide against insects and arachnid pests when used in combination with another pesticide
- As part of Bio-Gene's activities to raise its profile and awareness with parties relevant to its target markets for Flavocide and Qcide, articles have been published in major Agricultural publications
- Professor Catherine Hill, Head of the Department of Entomology at Purdue University in the United States, presented an update on Bio-Gene's development of Flavocide and Qcide to a seminar arranged by the Bill & Melinda Gates Foundation
- Bio-Gene has been accepted as the only Australian company member of The International Biocontrol Manufacturers Association (IBMA)
- R&D tax incentive of $504,000 received
- Mr Edmond Tern has been appointed as Bio-Gene's Chief Financial Officer and Company Secretary



**Bio-Gene Technology Limited**
ABN: 32 071 735 950
Level 6, 400 Collins Street, Melbourne, VIC 3000

Bio-Gene Technology Limited (Bio-Gene or the Company), an agtech company developing and commercialising the next generation of novel insecticides derived from nature, provides this update on activities for the quarter ended 31 March 2024 (Q3 FY2024) and to date, alongside the Company's Appendix 4C.

**Summary Comments by Tim Grogan, Bio-Gene's Managing Director & CEO:**

*"I am very pleased with the strong progress made during Q3 in accordance with our four strategic priorities. These are the timely filing of our Flavocide regulatory dossier with the Australian regulator, focussed development of our product pipeline, further commercial validation to support the development and launch of products containing Flavocide and Qcide, and the efficient use of our shareholder capital.*

*The scale-up synthesis of Flavocide AI and the required safety studies to include in our application to obtain regulatory approval for use of Flavocide AI initially in Australia are on track. Subject of course to external factors that may impact our timeline, the key milestone of filing our dossier with the Australian regulator is currently planned to take place in Q4 CY25.*

*Bio-Gene's critical success factors are (1) the generation of products supported by a strong data package, (2) building a unique IP portfolio, (3) creating multiple strong commercial partnerships for market access, (4) our ability to manufacture Flavocide and Qcide cost-effectively and at scale, and (5) access to capital required to achieve our development milestones ahead of post-launch royalties from our partners.*

*We continue to see evidence of the increasing relevance and commercial interest in Bio-Gene's products – derived from nature. This is rapidly increasing due to consumer and regulatory changes in the external environment and the commercial pressures being placed on developers and marketers of insecticidal products internationally to move to products that have a more 'balanced' efficacy and safety profile.*

*The diverse range of applications and target markets for Flavocide and Qcide are important factors supporting the large commercial opportunities we are targeting internationally with both products.*

*I recently had the privilege of meeting Prof. Robert Spooner-Hart who in the early 2000's, along with his colleague Dr Albert Basta at the University of Western Sydney (now Western Sydney University) undertook a systematic evaluation of the insecticidal properties of a range of natural essential oils. This work was undertaken with the assistance of a range of collaborators and the foresight involved in this early scientific investigation has ultimately led onto the development of Flavocide and Qcide by Bio-Gene today. It is important to reflect on this journey to date and how far we have come since that early work."*



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**Progress - Flavocide Active Ingredient (AI):**

Bio-Gene's priority programs include the focussed development of the scale-up manufacture and generation of safety data for Flavocide to support our regulatory dossier. This is initially due to be filed with the Australian Pesticides and Veterinary Medicines Authority (APVMA) in December next year.

As insecticides are regulated products, the filing of this dossier in Q4 CY25 and the estimated completion of the APVMA's review during Q1 CY27 (average review period of 15 months) will be transformative for Flavocide AI and for Bio-Gene.

**Manufacture Scale-up of Flavocide**

Bio-Gene is pleased to report that the Flavocide manufacturing project being undertaken by a large contract manufacturing company (CMO) based in India has successfully progressed from lab-scale to pilot-scale batch processing. This will fully validate the synthesis process for Flavocide at scale.

Pilot-scale batches are required to satisfy regulatory requirements to demonstrate the consistency of the process to produce quality product and to provide product to be used in the next phase of the planned GLP (Good Laboratory Practices) testing. This includes mammalian toxicity, ecotoxicity and environmental fate studies.

Development of a synthesis route, and the associated IP, to manufacture Flavocide at large scale with consistency and on a cost-effective basis is a key foundation for the future commercial supply of Flavocide AI by Bio-Gene to our commercial partners.

During Q3 FY24 additional opportunities to reduce the estimated commercial cost of manufacture of Flavocide have been identified at lab-scale. Flavocide scale-up will implement these improvements at scale including the potential to use key ingredients that are obtained from the most environmentally friendly and sustainable sources available.

**Flavocide - Regulatory Planning & Development**

*Flavocide Pre-Application Assistance submission to APVMA*: As planned, Bio-Gene submitted a Pre-Application Assistance (PAA) request with the APVMA in February. This process enables early interaction with the regulator to ensure that the data requirements for Flavocide registration as an active ingredient in Australia are clear. This step ensures early alignment between the regulator and Bio-Gene's regulatory planning on the data package required to support the registration of Flavocide as a new active constituent. The process of dialogue with the Australian regulator will continue into Q4 FY24.

*Appointment of European consultants to undertake study concept management and monitoring:* Bio-Gene has appointed a highly experienced European-based firm of scientific and regulatory consultants to provide oversight, guidance and monitoring of the various analytical, safety and environmental fate studies required to support the application for approval of Flavocide AI. Importantly, this expertise will assist to ensure that all planned studies are conducted to a standard required to support Flavocide registration in all regulatory jurisdictions.



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**Formulation Development & Product Pipeline**

Bio-Gene has made strong progress in a series of focused formulation development activities that are aligned with specific target markets and use patterns listed in the company's product pipeline.

Following a detailed strategic review of Bio-Gene's database of product and market related information, and patent portfolio, eight initial product opportunities across crop protection, public health and consumer applications were selected as high priority to bring Bio-Gene products to market. These are:

- Crop protection: grain protectant for control of grain storage pests
- Public health: indoor and outdoor space sprays, indoor and outdoor barrier sprays
- Consumer applications: indoor and outdoor space sprays, outdoor garden spray

Bio-Gene is working with several formulation development groups both in Australia and overseas, to optimise the performance of both Flavocide and Qcide through enhancing efficacy, safety and overall effectiveness and considering the different uses in Bio-Gene's pipeline.

**Progress: Qcide Active Ingredient**

Bio-Gene has previously announced that it has entered into a Development and License Agreement with STK for it to fund all costs associated with securing Qcide AI registration.

**Qcide production**

The agreement with STK, and arrangements with other Bio-Gene's commercial partners, provide a strong commercial basis to plan for the expansion of Qcide area and production, and the introduction of various efficiency initiatives.

During Q3 FY24 Bio-Gene has continued with its planned programs directed at the ongoing objective to improve the quality (including yield) of trees for use in Qcide production. Tree improvement programs are focused on the use of seed and tissue culture plant production to support the most efficient method of crop expansion to meet future demand for Qcide oil. This involves collaborations with farmers, tissue culture operators and commercial nurseries.

Bio-Gene continues to utilise expertise at James Cook University to support our research and field operations relating to processing and distillation of oil from biomass.

The next Qcide harvest is planned for May 2024 and will involve on-site experimentation at scale as well as further validation of the extraction process that has now been established and is supporting the GLP 5-batch analysis project being undertaken as an important step in the regulatory process to register Qcide oil as a natural active ingredient.

During Q3 FY24 additional opportunities have been identified to reduce the estimated commercial cost of manufacture of Qcide as scale-up continues.

### Qcide Regulatory Planning & Development

Bio-Gene continues to work closely with STK's regulatory experts on the registration pathway for Qcide. Product testing and registration-related activities are on-track. STK is undertaking an extensive testing program to develop a comprehensive data package to support registration of Qcide as an active ingredient in Australia, USA and other countries targeted for commercialisation for pest control in both crop and non-crop applications.

### Flavocide & Qcide Commercial partnership update

Overall, Bio-Gene's commercial partnering strategy is directed at both the engagement of new commercial partners and the expansion of our existing partnerships across Agriculture, Public Health, and Consumer opportunities internationally. The Company is currently very active in this area and, following the synergy data announced in April 2023 these engagements relate to both Flavocide and Qcide as stand-alone and as potential combination products.

In addition to Bio-Gene's ongoing partnerships with Clarke Mosquito Control & Evergreen Garden Care, during Q3 FY24 Bio-Gene has continued its engagement with potential commercial partners with interest in the protection of stored grain from insects. This opportunity continues to grow as a result of increasing levels of resistance to current products by the common problem insects, such as the Lesser Grain Borer and the Flat Grain Beetle.

Bio-Gene is also engaged in discussions with Asian government efforts to manage mosquito populations to minimise the risk of the spread of vector-borne diseases. These efforts also include the capacity to assess the efficacy of new insecticidal solutions within their territories.

Finally, the lab-testing of our products under the US Center for Disease Control (CDC) funded vector control program focussed on activity against ticks as vectors of Lyme disease has been largely completed by Purdue University and preparation is in hand for expansion of this program into the field following the northern hemisphere winter.

### Evaluation of new opportunities

In addition to managing the development of Flavocide AI, and Qcide AI in conjunction with STK, during the period Bio-Gene continued to evaluate several new product opportunities generated from both internal and external sources. The company frequently reviews new product and commercial growth opportunities that may provide commercial and technical synergy with Bio-Gene's current business.



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**Patent update**

During the quarter the following patents relating to the use of Flavocide were granted, strengthening Bio-Gene's IP platform:

- JP 2020-522757 – Japan: Flavocide use against insects and arachnid pests when used in combination with another pesticide
- AU 2021-232738 – Australia: Flavocide use in combination

A number of patents are subject to examination proceedings in a range of countries, including in Canada, USA, and Europe.

Bio-Gene is continuing to prosecute patents and plant breeder's rights (for superior tree lines to support Qcide production) as part of our strategy to build an extensive portfolio of intellectual property knowhow relating to the use, manufacture, registration, and formulation of Flavocide and Qcide.

This strategy will support future income from commercialisation of our technology by commercial partners under license, as well as ensure ongoing competitiveness and positioning in the market.

**Relevance of Bio-Gene's New Products & and Increasing Awareness**

*Agriculture sector publications*: Bio-Gene regularly prepares articles and other background material to assist to raise the company's profile with key stakeholders and interested parties relevant to its target markets for Flavocide and Qcide. As part of these efforts, articles have been published during Q3 FY24 in The Australasian Farmer and Dealer's Journal, Cropping News, Australian Grain magazine and in Stock & Land.

*Presentation to The Bill & Melinda Gates Foundation by Prof. Catherine Hill:* During Q3 FY24 Professor Catherine Hill, Head of the Department of Entomology at Purdue University in the United States, presented an update on Bio-Gene's development of Flavocide and Qcide to a seminar arranged by the Bill & Melinda Gates Foundation to consider novel approaches to deal with the increasing challenge of mosquito resistance to current insecticides.

*Bio-Gene is now a member of the IBMA*: During the period Bio-Gene was accepted as the only Australian company member of The International Biocontrol Manufacturers Association (IBMA), based in Brussels. The IBMA is a worldwide association of the biocontrol industry and Bio-Gene's membership will ensure that the company has access to up-to-date information about the development path for biochemical products in different countries. Bio-Gene's membership of the IBMA will also assist to raise the Company's profile with potential commercial partners and their awareness of the development and potential of Flavocide and Qcide.

**Shareholder & Investor Engagement**

In addition to calls and meetings with shareholders, recent initiatives during the quarter to increase shareholder and potential investor engagement have included publication of an analyst Initiation Report on Bio-Gene by Pitt Street Research, and an interview with Tim Grogan available on MarketOpen Podcast.



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**Financial update**

As of 31 March 2024, Bio-Gene held $2.8m in cash, a $392k decrease over the quarter (31 December 2023 cash balance of $3.2m). The cash position this quarter was supported by the receipt of the R&D Tax Incentive of $504k which was received in the current quarter.

Cash outflows from operating activities was $924k with funds being used on:

- R&D ($450k);
- Commercialisation expenses ($73k);
- Intellectual property expenses ($84k); and
- Administration and corporate costs ($211k), mainly insurance premiums.

**Management update**

In April, Mr Edmond Tern was appointed Chief Financial Officer and Company Secretary, who will be replacing Mr Roger McPherson following a period of handover.

**Outlook**

Bio-Gene is now well placed to execute on its Flavocide regulatory strategy, including scale-up and the regulatory enabling studies, to support the filing of the dossier of data required to apply for regulatory approval to use Flavocide AI in Australia and other key jurisdictions such as the USA.

Securing additional and expanded commercial partnerships, along with further external validation and funding from partnerships, remains a core focus for the company.

Approved for release by the Board of Directors

**- ENDS -**

**For further information, please contact:**

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**About Bio-Gene Technology Ltd**

Bio-Gene is an Australian agtech development company enabling the next generation of novel insecticides to address the global problems of insecticide resistance and toxicity. Its unique technology is based on a naturally occurring class of chemicals proven to overcome resistance to control pests with minimal impact on human health and the environment.

Bio-Gene's technology provides multiple potential new solutions for insecticide manufacturers in applications across crop protection, grain storage, public health, and consumer products. Bio-Gene's is developing and commercialising a broad portfolio of targeted insect control and pest management solutions.

# Appendix 4C

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

| **Name of entity** | |
|---|---|
| Bio-Gene Technology Limited | |
| **ABN** | **Quarter ended ("current quarter")** |
| **32 071 735 950** | **31 March 2024** |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | 22 |
| 1.2 | Payments for | | |
| | (a) research and development | (450) | (1,324) |
| | (b) commercialisation expenses | (73) | (279) |
| | (c) management administration expenses | (35) | (170) |
| | (d) directors' expenses | (48) | (159) |
| | (e) professional services | (23) | (103) |
| | (f) intellectual property | (84) | (276) |
| | (g) administration and corporate costs (see note 6) | (211) | (425) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 28 | 73 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 504 | 504 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(392)** | **(2,137)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | - | - |
| | (a) entities | | |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | (2) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | - |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | 4 |
| 2.3 | Cash flows from loans to other entities | - | - |
| 2.4 | Dividends received (see note 3) | - | - |
| 2.5 | Other (provide details if material) | - | - |
| **2.6** | **Net cash from / (used in) investing activities** | **-** | **2** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | 2,034 |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | (55) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | - |
| 3.7 | Transaction costs related to loans and borrowings | - | - |
| 3.8 | Dividends paid | - | - |
| 3.9 | Other (share proceeds received in advance) | - | - |
| **3.10** | **Net cash from / (used in) financing activities** | **-** | **1,979** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | 3,227 | 2,991 |
| 4.1 | Cash and cash equivalents at beginning of period | | |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (392) | (2,137) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | 2 |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | - | 1,979 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **2,835** | **2,835** |

| **5.** | **Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | **Current quarter $A'000** | **Previous quarter $A'000** |
|---|---|---|---|
| .1 | Bank balances | 35 | 26 |
| 5.2 | Call deposits | 1,300 | 1,701 |
| 5.3 | Bank overdrafts | 0 | 0 |
| 5.4 | Other (Term Deposits) | 1,500 | 1,500 |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **2,835** | **3,227** |

| **6.** | **Payments to related parties of the entity and their associates** | **Current quarter $A'000** |
|---|---|---|
| 6.1 | Aggregate number of payments to related parties and their associates included in item 1 | 228 |
| 6.2 | Aggregate number of payments to related parties and their associates included in item 2 | N/A |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

Note 6.1: Director's fees paid to Directors or their related entities which includes FY23 incentives for Executive Directors.

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | N/A | N/A |
| 7.2 | Credit standby arrangements | N/A | N/A |
| 7.3 | Other (please specify) | N/A | N/A |
| 7.4 | **Total financing facilities** | **N/A** | **N/A** |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | **N/A** |
| 7.6 | Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well. | |

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (392) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 2,835 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | **2,835** |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 7.2 |

*Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.*

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

## Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 April 2024

Authorised by: The Board of Directors
(Name of body or officer authorising release – see note 4)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – e.g. Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

6. Net movements in GST are included in this item.

7. Prior Quarter Corrections. Immaterial minor errors and reallocations of expenses from previous quarter reports are corrected on a year-to-date basis. Movements disclosed for the current quarter have been correctly calculated.