

Game-changing insecticide solutions are coming soon

Share Price: A\$0.045

Bio-Gene Technology Ltd (ASX:BGT) is an ASX-listed AgTech company developing two natural compounds (Flavocide™ and Qcide™) to be used as insecticides.

ASX: BGT

Sector: Materials

9 September 2024

The market needs new insecticide solutions

Flavocide™ and Qcide™ are not just another couple of insect sprays (think your typical Mortein) that will sit on the shelves of supermarkets with little to differentiate each of them from competing products other than branding. Flavocide™ and Qcide™ are in a unique type of chemical or insecticide class (specifically beta-triketones) that possess a unique Mode of Action (MoA) (in other words, mechanisms to attack insects), not present in any other insecticides on the market today.

BGT is targeting 5 major markets, comprising Consumer Applications, Public Health, Grain Storage, Crop Protection, and Animal Health. All these markets need Flavocide™ and Qcide™ because of the demand for new solutions to prevent the damage insects can cause, including in public health through spreading vector borne diseases.

On track

While BGT is still at the development stage, it is engaged in several collaborations (including, programs with Envu (ex-Bayer Environmental Science) and Clarke Mosquito Control) that have developed into commercial agreements and are providing further evidence of the superiority of the company's products. Earlier in September 2024, the company achieved pilot-scale production of Flavocide™ in conjunction with Rallis India, a major Agri-sciences company and subsidiary of Tata Chemicals – showing Flavocide™ can be produced at a consistent quality and yield at precommercial scale. BGT aims to file its application for its first regulatory approval for Flavocide™ Active Ingredient with the Australian regulator (APVMA) at the end of CY25, with a regulatory approval target for mid-CY27.

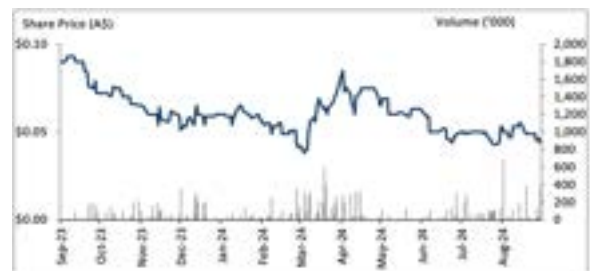
Previous valuation range reiterated

We reiterate our valuation of BGT as outlined in our initiation report - at \$31.8m in a base case scenario and at \$42.8m per share in an optimistic (or bull) case scenario, equating to 16.9c per share and 22.3c per share respectively. Please see p.10 for the key risks that may impact our investment thesis.

Market cap. (A\$ m)	9.1
# shares outstanding (m)	201.4
# shares fully diluted (m)	210.2
Market cap ful. dil. (A\$ m)	9.5
Free float	100%
52-week high/low (A\$)	0.093 / 0.038
Avg. 12M daily volume ('1000)	61.0
Website	Bio-gene.com.au

Source: Company, Pitt Street Research

Share price (A\$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

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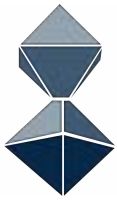
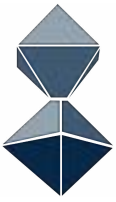


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Re-cap to Bio-Gene Technology (ASX:BGT)

To refresh investors' minds about Bio-Gene (ASX:BGT), we will recap the company, its products and the opportunity before it. Investors interested in further scope beyond this report are encouraged to view our initiation report, published in February 2024.

Bio-Gene (ASX:BGT) is an AgTech company focused on developing Flavocide™ and Qcide™ as natural insecticides.

Bio-Gene (ASX:BGT) is an AgTech company focused on developing Flavocide™ and Qcide™ as natural insecticides. The company believes it has an addressable market opportunity of US\$31bn spanning Consumer Applications, Public Health, Grain Storage, Crop Protection, and Animal Health. There is an urgent need for new insecticide solutions given the damage insects and the diseases they carry can do to public health and to crops – just to name a couple.

What are Flavocide™ and Qcide™ and what is so special about them compared to other solutions on the market?

Flavocide™ and Qcide™ are based on naturally occurring beta-triketone plant compounds. Flavocide™ contains flavesone, a nature-identical compound that can be synthetically produced via a proprietary process that allows production in large volumes for global demand. Qcide™ is a natural oil product containing tasmanone as the major active component, extracted from the biomass of a rare cultivar of an Australian eucalypt, the Gympie Messmate, by utilizing a steam distillation process. Trees are currently being grown in a plantation farming system by sub-contractors in Far Northern Queensland.

Flavocide™ specifically has been proven to have a MoA (Mode of Action) different from any other insecticide on the market today

Both assets have been confirmed by testing to be effective against a range of insects. Flavocide™ specifically has been proven to have a MoA (Mode of Action) different from any other insecticide on the market today. Over time, insects develop resistance to insecticides, meaning insecticides with new MoAs are needed – to replace or complement existing solutions. The need is also compounded by increasing awareness of the dangers of some of the current insecticide classes, with Neonicotinoids being a notorious example because of their harm to bee populations.

Discovery of insecticides with new MoAs is not common, the last major new MoA to be commercialised as an insecticide for use in agriculture was for the Diamide class in 2008. The case study of Diamides shows there is huge potential for value creation, given sales hit US\$1.5bn within 5 years. And Diamides are just the most recent in a very long line of blockbuster chemical discoveries (Figure 1).

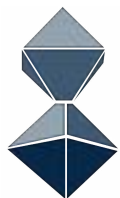
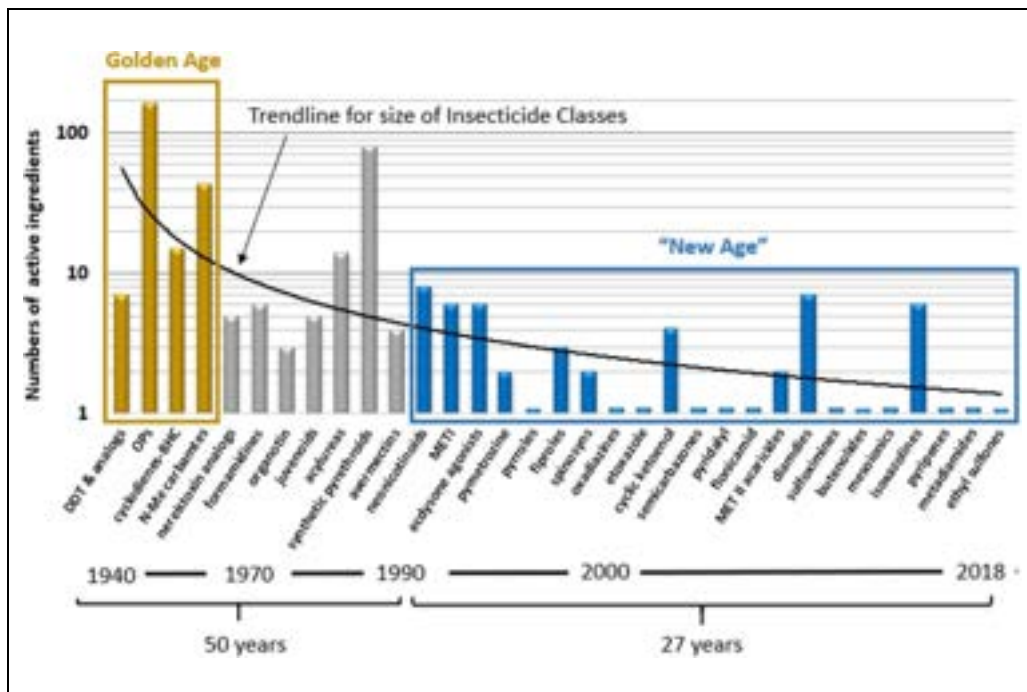


Figure 1: Timeline for the major classes of insecticides highlighting the numbers of different active ingredients (AIs) in each class.



Source: Company¹

If Flavocide™ and Qcide™ were bought to market, they would be the first ever beta-triketone insecticides and have the potential to be the first major new insecticide class bought to market since 2008.

If Flavocide™ and Qcide™ were bought to market, they would be the first ever beta-triketone insecticides to be commercialised and offer the potential to be a major new insecticide class globally. The specific way in which Flavocide™ and Qcide™ work has not been disclosed publicly, although research has not only shown they are effective, but that they can be produced in a commercially viable way, with a high yield from the chemical synthesis process, and that the compounds are up to 5,000 times less toxic to bees upon ingestion compared to some existing insecticides.

The key market opportunities for BGT

There are five markets that BGT has identified for Flavocide™ and Qcide™: Crop Protection, Grain Storage, Public Health, Consumer Applications and Animal Health.

There are five markets that BGT has identified for Flavocide™ and Qcide™: Crop Protection, Grain Storage, Public Health, Consumer Applications and Animal Health (Figure 2). Collectively, these represent an addressable market worth US\$31.1bn. The largest of these is Crop Protection, with Grain Storage also significant, given the importance of crops and grain in feeding the world's population and the impact that insects can have on crops before and after harvest. It is estimated that US\$20.8bn damage per annum occurs worldwide, a figure that has increased 30% in the past decade. The impact of vector-borne diseases also means that Public Health and Consumer Applications will be opportunities for Flavocide™ and Qcide™.

¹ The new age of insecticide discovery-the crop protection industry and the impact of natural products, Thomas C. Sparks et al, Pesticide Biochemistry and Physiology, Vol 161, November 2019, Pg 12-22

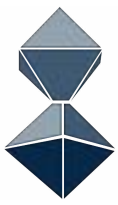


Figure 2: BGT's key target markets



Source: Company

BGT is planning on filing an active constituent dossier submission for Flavocide™ in December 2025.

BGT's commercialisation plan

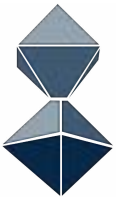
BGT plans to commercialise globally both Flavocide™ and Qcide™. To do this, the company will need to obtain regulatory approvals from the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Environmental Protection Agency (EPA) in the USA. BGT is planning on filing an active constituent dossier submission for Flavocide™ in Australia in December 2025. The average time to APVMA approval is 15 months, providing for a potential green light in the June quarter of 2027.

In the meantime, BGT has been working with several commercial partners including Clarke Mosquito Control, Evergreen Garden Care, STK Bio-Ag and Australia's Grain Research & Development Corporation (GRDC). The partnerships with Clarke Mosquito Control and GRDC are the most important for Flavocide™ - the GRDC partnership for Australia and the Clarke Mosquito Control arrangement for the USA.

The GRDC collaboration started as a four-way partnership including the Queensland Government and BASF which involved testing Flavocide™ against several insect pest types in grain storage, and this testing was a success, showing Flavocide™ could prevent infestation of stored grain for up to 13 months

BGT's collaboration with Clarke Mosquito Control progressed to an initial Commercial Development Agreement that was updated 12 months later. The deal provided for BGT to supply Clarke Mosquito Control with the Active Ingredient Flavocide™ and to focus on data generation and preparation and submission of the Active Ingredient in the USA. Clarke Mosquito Control, meanwhile, would have the responsibility of developing and registering the formulated end use product containing Flavocide. The deal provided BGT with an immediate milestone payment, technical transfer fees and other milestone payments over time - the specific figures were undisclosed. The deal covered the United States and the Cayman Islands.

BGT's partnership with Evergreen Garden Care is a commercial development agreement to develop new insecticide solutions for the home and garden consumer market. It provided for Evergreen Garden Care to have access to



BGT's proprietary technology and data so that Evergreen Garden Care could evaluate and develop green product solutions targeting insects in the UK, Europe, Australia, and New Zealand. The deal provided for license and milestone payments to be made during development and for an undisclosed royalty on all commercial sales on any products commercialised using BGT's technology.

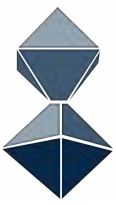
Finally, BGT's collaboration with STK Bio-Ag could be pivotal for the ultimate commercialisation of Qcide™. In early 2023, STK and BGT signed a term sheet (which was made into a binding agreement in July 2023) which granted STK a non-exclusive license to develop Qcide™ for crop protection, aquaculture, professional turf and ornamental markets. Under the deal, STK is responsible for all costs associated with securing registration of the active ingredient Qcide™ while BGT would retain exclusive rights to the public health, animal health and consumer markets for Qcide™ as well as full access to the registration data package to support other commercial opportunities (including crop protection).

Bio-Gene's recent progress

Advancing a regulatory submission for Flavocide™

Bio-Gene's key goal is to submit the regulatory dossier for Flavocide™ in Q4 of CY25. The company remains on track for this goal and made progress towards Flavocide™ commercialisation in recent months. Among them:

- The company is undertaking a manufacturing project with a large-scale contract manufacturing company based in India to validate the synthesis process for Flavocide™ at scale. This project has successfully progressed from lab-scale to pilot-scale batch processing. The pilot-scale batches are intended to satisfy regulatory requirements to demonstrate that the product can be produced with consistent quality when produced on a larger scale. These batches will also provide the product to be used in GLP (Good Laboratory Practices) testing for mammalian toxicity, ecotoxicity and environmental fate studies required for registration of the Active Ingredient. As the scale-up process continues, BGT is also exploring ways to minimise the cost of manufacturing of Flavocide™ to optimise market competitiveness.
- BGT submitted a Pre-Application Assistance (PAA) request with the APVMA (Australian Pesticides and Veterinary Medicines Authority) in February 2024, enabling BGT to consult with the regulator to confirm and validate data requirements for registration. Feedback was received in August 2024, and while the company has kept the specific recommendations confidential, it has told investors that it received feedback on areas that will be useful prior to making a formal submission. These include assessment of the chemistry and manufacturing data, and on the data requirements for safety studies to be included in the information dossier.
- A highly experienced European-based firm of scientific and regulatory consultants were appointed to provide oversight, guidance and monitoring of the various analytical, safety and environmental fate studies required to support the application for approval of Flavocide™.



Eyeing off more commercial partnerships and advancing existing ones

BGT's most fruitful partnership in the past 12 months has been its agreement with STK. BGT has continued to work closely with STK's regulatory experts on determining a registration pathway for Qcide™. STK is undertaking an extensive testing program to develop a comprehensive data package to support an application for approval for Qcide™ as an active ingredient.

BGT has also completed another Qcide oil harvest in Far North Queensland in 4Q24, the 12th completed to date. Each harvest is an opportunity to implement ongoing modifications to achieve improvements in oil yield. This has been achieved through the assistance of James Cook University through process engineering, and specialist nurseries for improving tree quality and tree and seed production systems to support future Qcide oil demand. STK representatives visited Australia during 4Q24 and the company hosted them at its facilities.

BGT is continuing to pursue potential commercial partners as well, both private companies and government authorities.

BGT is continuing to engage with other potential commercial partners, both private companies and government authorities. In particular, BGT has told investors it is in discussions with Asian government agencies to manage mosquito populations to minimise the risk of the spread of vector-borne diseases. These efforts also include assessment of the efficacy of BGT products within their territories. BGT has undertaken other efforts to increase awareness. Among them:

- Articles have been prepared by BGT which have appeared in multiple publications during CY24 including the Australasian Farmer and Dealer's Journal, Cropping News, Australian Grain and Stock & Land; and
- BGT joined the International Biocontrol Manufacturers Association (IBMA). The IBMA is a worldwide association of the biocontrol industry and Bio-Gene's membership will ensure the company has access to up-to-date information about the development path for biochemical products in different countries. Membership will also raise BGT's profile (and that of its products) with potential commercial partners.

One of BGT's newest partnerships, announced in August 2024, is with North Carolina-based environmental science company Envu. Envu was previously Bayer's Environmental Sciences business unit and was spun out in 2022. It supplies products to control pests, diseases and weeds in non-agricultural sectors and is active in over 100 countries. It is the world leader in the development and supply of mosquito control products. The companies are undertaking a collaboration, to evaluate Flavocide™ for mosquito management across a range of professional applications.

A key production milestone has been achieved

Another major milestone was achieved in September 2024. BGT has been working with Rallis India, a company that is one of India's leading Agri-sciences companies and is a subsidiary of Tata Chemicals. It has over 75 years' experience in agrochemicals. Rallis was appointed to undertake the process development and pilot-scale synthesis of Flavocide™ following a detailed evaluation of potential partners. This was undertaken at its plant in Dahej, India (Figure 3), which lies between Mumbai and Ahmedabad, on the East side of the Gulf of Khambhat.

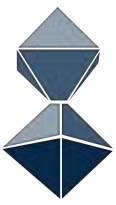


Figure 3: Rallis' Plant



Source: Company

Rallis has produced several hundred kilograms of Flavocide™ from pilot-scale batches, demonstrating high yield and consistent quality. This validates the production process at a larger scale and establishes proven standard operating procedures for future large-scale manufacturing of Flavocide. The completion of this phase positions the company to complete the remaining studies to be included in the dossier of data to support its application for regulatory approval of Flavocide™ for commercial use.

Our valuation of BGT

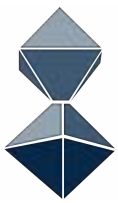
We reiterate our valuation of Bio-Gene as outlined in our initiation report.

We reiterate our valuation of Bio-Gene as outlined in our initiation report - at \$31.8m in our base case and \$42.8m in our bull case on an Enterprise Value basis (Figure 4). Accounting for the current number of shares on issue and the company's cash balance, these figures equate to 16.9c per share and 22.3c per share respectively. Flavocide™ is ~68% of our valuation of the company in both our base and bull cases, Qcide™ is 25% and the balance is the company's current cash on hand (\$2.2m as at the close of FY24).

Figure 4: Our valuation of Bio-Gene

Sum of the Parts Valuation	Base Case		Bull case	
	A\$m	A\$ps	A\$m	A\$ps
Drugs				
Flavocide	23.19	0.115	31.29	0.155
Qcide	8.63	0.043	11.50	0.057
rNPV	31.82	0.158	42.78	0.212
Cash (close of FY23)	2.99	0.015	2.99	0.015
Debt (close of FY23)	-	-	-	-
Equity Value	34.81	0.173	45.77	0.227
Current Price		0.045		0.045
Upside		284%		405%

Estimates: Pitt Street Research



We employed a Sum of the Parts approach, using projected Discounted Cash Flows for Flavocide™ and Qcide™ as well as the company’s cash balance.

Among our assumptions (Figure 4), we assumed Flavocide™ would be commercialised mid-way through FY27, and FY19 for Qcide™. We assumed a royalty-based model with BGT taking a 12% royalty on sales, and that within 5 years, Flavocide™ sales would reach US\$1.06bn, leading to US\$127m in peak royalty revenue. For Qcide™, we assume sales reach US\$579m, with peak royalty revenues of US\$70m. We assume an 0.68 AUD/USD exchange rate. Our model covered 10 years post-commercialisation, with no terminal growth beyond that period.

We utilised a WACC of 16.2%, reflecting an 8% equity premium, a 4% risk-free rate of return and a 1.5x beta. Our final NPV of both Flavocide™ and Qcide™ has been further discounted by 50% for probability.

Base and Bull case differences: Our bull cases for both Flavocide™ and Qcide™ have two key differences. First, the assumption of a 5% market capture. And second, we assume cash costs to the company are 65% of royalty-based sales. The premium to BGT shares in our bull case is 32%.

Figure 4 shows our key metrics while Figure 5 shows summary for the upside potential of the stock. The midpoint of our valuation range is A\$0.20 per share.

Figure 5: Our key valuation metrics

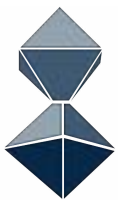
DCF Assumptions (Base case)	Flavocide	Qcide
Total market size (US\$bn)	20	11
Market share	4%	4%
Royalty	12%	12%
Market growth	2%	2%
Peak sales (US\$m)	1,062	579
Cash cost (% Royalty based sales)	70%	70%
Peak royalty revenue (US\$m)	127	70
AUD/USD	0.68	0.68
Probability Factor	50.0%	50.0%
Discount Rate	16.2%	16.2%
Tax Rate	30.00%	30.0%

Estimates: Pitt Street Research

Catalysts for BGT’s re-rating

The company’s shares have some way to go to reach our valuation range. Potential catalysts for this include (but are not necessarily limited to):

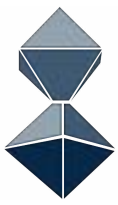
- Advancement towards regulatory filing, a step estimated in December 2025 for Flavocide™.
- Results of testing proving the ability of BGT’s compounds both in their own right and in combination with other compounds.
- The signing of further R&D collaboration agreements, particularly with industry market leaders, that could eventually become sales agreements.
- Continuation of existing commercial partnerships to later stages and expanded partnering.



Risks

We see the following key risks to our investment thesis on Bio-Gene:

- **Execution risk:** Any delays or difficulties in executing the company's strategy will impact investors' confidence in the company.
- **Competitive risk:** The market is highly competitive and success will depend on the ability of the company to prove its products are superior to alternatives on the market.
- **Key personnel risk:** There is the risk that the company could lose key individuals and be unable to replace them and/or their contribution to the business.
- **Capital risk:** There is the risk the company may need capital. Amidst higher capital costs, this will reduce the fundamental return for would-be investors and make it more difficult to raise capital. An inability to raise capital, if required, may mean the company won't be able to execute on its key initiatives.
- **R&D risk:** There is a risk that future R&D work undertaken may not be as vindicative of BGT's products as past work has done. This would potentially jeopardise the company's commercialisation plans.



Appendix I – Analysts’ Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research’s Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms.

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