



BIOTHERAPEUTICS

GENIUS BIOTHERAPEUTICS (GENIUS) (BIOCLONES (PTY) LTD)

KEY FACTS

CHIEF EXECUTIVE OFFICER	Dr Abdusamad Sidar
BOARD OF DIRECTORS	K Abdulla, I Amod, CR Ah Sing, CF Hendricks and A Sidar
EMPLOYEES	8
HEAD OFFICE	V&A Waterfront, Cape Town
FOOTPRINT	Cape Town and Centurion, Pretoria

PROFILE

Genius Biotherapeutics (Genius) focuses particularly on healthcare applications and more specifically on the production of biopharmaceutical products (those that are derived from living genetically modified cells and are of a protein or carbohydrate nature).

Biopharmaceutical products include therapeutics such as hormones, protein-based drugs and antibodies. Of critical importance in the healthcare industry is the movement away from traditional chemical-based pharmaceuticals to biotechnology-derived medicines due to the extremely inefficient success rates within the traditional pharmaceutical industry. The biopharmaceutical products are commonly thought of as the therapeutic products of the future.

The biotechnology industry is vast and covers a range of sectors in addition to the medical and healthcare applications, including genetically modified crops and foodstuffs, alcoholic beverage manufacture, mining, industrial waste treatment and water treatment. The market size opportunities for biotechnology applications is substantial.

2019 OPERATIONAL PERFORMANCE

There are multiple divisions engaged in product development phases at different stages:

- Regulatory preparation and process validation phase for the production of erythropoietin (Repotin), a biosimilar drug used to treat anaemia caused by kidney disease
- Developmental work on the dendritic cell vaccine (DCV) for cancer immunotherapy and communicable diseases such as extreme drug-resistant tuberculosis
- Further developmental activities at the Ribotech facility for a second biosimilar drug called Recogen, a granulocyte-colony stimulating factor (G-CSF) used for the treatment of neutropenia which is a condition of low white blood cell count in patients undergoing chemotherapy
- Production of protein-based reagents used mainly in research laboratories and industrial applications.

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VISION 2020 VISION – GENIUS' CONTRIBUTION

Genius' outlook for its business units and its value proposition are based on a long-term vision and value add that is linked to defined milestones.

Unlike other typical investments in other sectors, biopharmaceutical companies work towards achieving milestones in their developmental stage, hence a five-year strategic plan to the year 2020 was implemented with clear deliverables and strategic actions for each strategic lever as well as clear time frames.

The DCV project is preparing for the first phase of human clinical trials in breast cancer patients. Ribotech is immersed in research and development for the production of an additional biotech drug for humans.

PROSPECTS AND FUTURE OUTLOOK

The following prospects have been identified:

SHORT-TERM PROSPECTS

- Genius is finalising negotiations with an international partner to add four additional products to its portfolio of biosimilars.
- This partnership entails a technology transfer to facilitate more efficient production of all products and final formulation which negates the need for cold chain.
- Development support from government to develop skills in this sector and increase employment in order to provide a lower cost of health.
- All approvals have been met for phase 1 human clinical trials in breast cancer patients and trial work is scheduled.
- Pre-clinical work on other diseases has begun, such as incurable tuberculosis and lung cancer with three additional cancers to follow in 2020/21.

MEDIUM TO LONG-TERM PROSPECTS

- An international partnership will allow for scalable local production to supply Africa as well as Europe and is planned for post 2020.

- Two South African multinational pharmaceutical companies show support to market and distribute the Company's biosimilar products.
- Following the successful results of phase 1, further funding for the genomics component will strengthen the health platform offering.
- Based on the phase 1 trial results, if favourable, accelerate the listing of Genius to obtain the necessary capital to complete phase 2 and 3 trials.

PRODUCTS AND RESEARCH AND DEVELOPMENT PROJECTS

The Bioclones product and project portfolio can be divided into three key segments:

- Biosimilars which are biologically derived products having the same therapeutic effect as its competitor. It is similar to a generic, however, only the active protein effect compound is similar.
- New technologies are those which will deliver healthcare solutions through products and innovations.
- Healthcare data and genomics research which is the study of genetics and extracting information related to the functioning and optimisation of the human body while identifying markers for predispositions to diseases.

MARKET PRESENCE

Genius has two Good Manufacturing Practice (GMP) built production facilities: a cell culture division laboratory in Pretoria involved with erythropoietin production and a second facility, Ribotech located in the Western Cape.

The sales and marketing function will be outsourced to two South African pharmaceutical companies that have a footprint in South Africa and in countries in the SADC region. Based on the growth plan, Genius intends to expand its footprint to central and north African countries that are aligned to its plans to improve its production output.

COMPANY BRAND



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BUSINESS MODEL

Since inception Genius was set up as a fully integrated pharmaceutical company which is a form of vertical business model focused on developing biopharmaceutical products. In this way, the full spectrum of ownership, from discovery to development and marketing is managed in-house. In the value of an invention as in the case of the DCV project, the goal is to pursue the project as far as possible instead of selling the idea off before its full value is realised.

This lends itself to Genius raising the necessary funds to complete the project by selling equity in the business but still maintaining majority control. In the case of the biosimilars, Repotin and Recogen, the opportunity to tie up with a local distributor for the sales and marketing of the product is being considered. This is a departure from when Genius previously marketed and sold Repotin. Currently with the research and development phase reaching completion, Genius will focus its efforts on acquiring additional products while outsourcing the sales and marketing function.

Going forward is the continued development of new financing models that address the current challenges and are also flexible enough to address those in the future.

The final therapy (DCV) for cancer still has a number of years ahead before it enters the market as a form of personalised treatment for cancer.

The Company continues to:

- implement innovative procedures within the value chain to increase efficiency in line with environmental best practices, thereby reducing its carbon footprint;
- invest in reliable scientific practices that allow the Company to improve its production methodology;
- develop its employees; and
- deliver good sustainable returns to all its stakeholders.

GOVERNANCE

Genius, through the application of policies and structures implemented within the AEEI Group, complies with all sound governance and regulatory functions and has had no reported fraud or deviations in the application of these principles in the year under review. Key employees are also provided with regular training on the ever-changing regulatory environment to ensure that all employees are fully informed, and that the Group adheres to all the laws and regulations.

The Board of Genius continues working towards the

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achievement of the following governance outcomes:

OBJECTIVE	Stakeholders	<ul style="list-style-type: none"> Value creation for all stakeholders and sustainable development An ethical culture and effective leadership are maintained with positive outcomes A stakeholder-inclusive approach to balance the needs and interests of material stakeholders in the best interests of the Company
SCOPE	Company	<ul style="list-style-type: none"> The Company operates within the triple context Govern risks and opportunities, strategy, business model as well as sustainable development in a way that supports the Company achieving its strategic objectives
CHARACTER	Internal system	<ul style="list-style-type: none"> Proper internal controls are in place to approve policies and planning and to monitor and ensure accountability The assurance services and functions enable an effective control environment to support the integrity of information for internal and external decision-making The Company remunerates fairly, responsibly and transparently to promote the achievement of the strategic objectives and positive outcomes in the short, medium and long-term
MECHANISM	Conformance	<ul style="list-style-type: none"> Govern compliance with applicable laws and adopt non-binding rules, codes and standards in a way that supports the Company to be ethical and a good corporate citizen
DIRECTION	Management	<ul style="list-style-type: none"> The Board sets and steers the strategic direction of the Company and is the focal point and custodian of corporate governance and ensures accountability for the Company's performance. The Board oversees and monitors the implementation and execution by management
DISCLOSURE	Financial statements	<ul style="list-style-type: none"> Audited financial statements

STRATEGIC PLANNING AND MONITORING

Genius manages its businesses strategically, following a process that includes an annual review of past performance, product development, capacity, markets as well as a review of the internal and external environments. This review is followed by setting strategies, targets and action plans, aimed at both growth and sustainability in the short to long-term.

The Board of each business unit in Genius has an approved formal delegated authority schedule, which informs executive management of the necessary levels

of approval for all key business transactions. In this way Genius ensures that there is a senior manager or the Board itself reviewing each key business transaction/initiative to ensure that these are aligned with the Company's strategy, are lawful, contribute to the Company's sustainability and will not be harmful to any stakeholders and/or the environment.

In this manner, each business unit can monitor its financial performance against its strategies and evaluate this against the key performance areas of management and key employees. Through this process, the Company ensures the sustainability of its operations.

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ECONOMIC SUSTAINABILITY

Genius aims to deliver good and sustainable returns to all stakeholders. Genius have a defined number of targets to measure performance and continually monitors progress against its targets and, when necessary, revises them to consider changes in the business environment.

ENVIRONMENTAL SUSTAINABILITY

Genius believes that with its current strategy of focusing on innovation and transforming current healthcare needs to meet future demands to provide for the long-term sustainability of the Company, existing business will be maintained while future business is developed in new markets. This is currently being done with the production of Repotin.

Cutting-edge technology is currently being explored for production to improve yield and drive growth into new markets. The DCV project will be an innovation to personalised medical care for cancer patients when it is made available.

SOCIAL SUSTAINABILITY

Genius subscribes to a sustainable approach in conducting its business. For Genius, corporate citizenship goes beyond legislative compliance and profits. It recognises the rights and responsibilities of businesses within a broader societal context and reinforces the mission of Genius to implement a social contract between business, government and civil society.

Genius is aware of the critical role that businesses play in the upliftment and development of previously disadvantaged individuals and continues:

- to provide opportunities for skills development, training and support for employees;
- to assist with finance for start-ups of businesses;
- as a black economic empowered company, to ensure the availability of services by assisting with the development and growth of previously disadvantaged partners; and
- to provide healthcare advice and product information for patients.

KEY CHALLENGES AND RISKS

KEY CHALLENGES

At present, Genius' strategic focus is aimed at overcoming the following potential key challenges:

REGULATION AND LEGISLATION	<ul style="list-style-type: none"> • The compliance and demands placed on companies in this highly regulated industry require continuous review of business processes and strategy
COMPETITION	<ul style="list-style-type: none"> • Genius is faced with competition from both local and international companies that have critical mass and reserved funds
EMPLOYEES SKILLS AND RETENTION	<ul style="list-style-type: none"> • The industry in which Genius operates requires skilled and experienced employees thus employee retention is a key challenge • Limited resources of high-quality personnel make employee mobility one of the highest risk factors
TECHNOLOGY	<ul style="list-style-type: none"> • New and efficient technologies are constantly being developed in the biotechnology sector, and Genius ensures that they remain within the European Pharmacopoeia Standards with all new adaptations

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RISKS

Risk management is integrated into each business unit's management process. Each business unit maintains a risk register, which is compiled and maintained by the executive management, with the risk status and execution of planned actions being reviewed monthly. Executive management is responsible for the identification, classification and management of all operational risks.

Significant strategic and going concern risks are identified at all levels in each business unit. However, the responsibility for directing the actions necessary to manage these risks is the responsibility of the Board of directors of each business unit.

Strategic and going concern risks are reviewed at the quarterly Board meetings and the executive directors are charged with the execution of approved risk management actions.

Along with the risk register, executive management maintains their action plans through management meetings as several risks are being mitigated by the Company's strategy; the risks and strategy are directly mapped where applicable.

In the year under review, although a number of identified risks could not be avoided, the pre-planned management strategies for these risks were successful in mitigating or avoiding the severity of the impact on the respective companies and overall Group financial performance.

RISK IDENTIFICATION	IMPACT ON BUSINESS	RESPONSE
Funding the research and development phase of the project	There is a risk that there may be delays or they may not be successful in raising the required funds	To counter this risk, the Company is increasing the pressure to meet and engage with the government funding agency
Human resource requirements and skills	Recruitment of additional technicians, scientists and pharmacists with the appropriate background and experience is challenging	An intensive skills development and training programme will need to be implemented. The recruitment of foreign nationals with the required depth of experience is underway and this will allow for skills transfer to local scientists
Filling and formulation infrastructure	The establishment of such a facility for the first time may present technical challenges and delays	This could be mitigated in the supplier contract
Regulatory delays	The submission of the three validation results to the Medicines Control Council (MCC) for review for the re-issuing of the manufacturing licence depends on the validation runs coupled by an audit	The SAHPRA has permitted the production to proceed so long as the finished product remains in 'quarantine' and can only be released on the reissuing of the manufacturing licence
Technology	International trends in biotechnology move to more efficient production through new technologies and these changes reduce the cost of production, but investment costs are high in the early stages	Due to the regulatory delay with the SAHPRA accepting and adopting new technologies, Genius has been unable to adopt the new technologies. Once the regulatory authorities have accepted and approved the new technologies, it will be easier and cheaper for Genius to adopt the new technologies

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STAKEHOLDER MANAGEMENT

CREATING SHAREHOLDER VALUE

Genius recognises the importance of creating value for its stakeholders in the short, medium and long- term. The principal stakeholders for Genius are its shareholders, employees, customers, suppliers, communities and government.

Genius creates value for its stakeholders in the short, medium and long-term through the following:

CAPITAL	STAKEHOLDER	VALUE FOR THE ORGANISATION	VALUE FOR STAKEHOLDERS
Social	Customers	<ul style="list-style-type: none"> • Maintain reputational integrity as a leading local producer in the biosimilar market 	<ul style="list-style-type: none"> • Quality products and services • Fair prices • Correct labelling
Human	Employees	<ul style="list-style-type: none"> • Engaged and motivated employees • Ability to attract and retain key skills 	<ul style="list-style-type: none"> • Fair pay • Interesting work • Growth and development, • Equal treatment • Health and safety
Social	Communities	<ul style="list-style-type: none"> • Reputation • Brand value • Trust • Access to business opportunities 	<ul style="list-style-type: none"> • Employment/business opportunities • Environment care • Local hire • Resource use
Social	Government	<ul style="list-style-type: none"> • Favourable legislation and less interference 	<ul style="list-style-type: none"> • Contribution to taxes • Support job creation • Other strategic initiatives
Social	Suppliers	<ul style="list-style-type: none"> • Good service • Commitment • Good pricing • Good quality products 	<ul style="list-style-type: none"> • Fair allocation of business • Pay on time • Zero corruption
Financial	Owners	<ul style="list-style-type: none"> • Supply of capital at reasonable price • Healthy balance sheet 	<ul style="list-style-type: none"> • Capital growth • Dividends • Return on investment • Reduced risk
Intellectual	Customers	<ul style="list-style-type: none"> • Understanding trends and opportunities • Improved ability to compete • Reputable brands 	<ul style="list-style-type: none"> • Better products and services

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STAKEHOLDER EXPECTATIONS

Genius recognises the importance of constant engagement with stakeholders. The principal stakeholders for Genius are its shareholders, employees, customers, suppliers, regulatory authorities, government and local communities.

Genius has various procedures in place regarding stakeholder management. These are summarised as follows:

STAKEHOLDER	RELATIONSHIP	EXPECTATION	EXPECTATION MANAGED
Shareholders	Owners of the business	<ul style="list-style-type: none"> Integrity Shareholder wealth creation Ethical business practices 	<ul style="list-style-type: none"> Sound corporate governance rules are implemented in the business
Customers	Affected patients	<ul style="list-style-type: none"> Products are sold legally and are traceable Quality products that meet recognised industry standards Reliable long-term supply of products 	<ul style="list-style-type: none"> Ensure that all products supplied have met GMP and regulatory approval from the relevant authorities Ensure that they adhere to all necessary standards such as South Africa's GMP Compliance with international laws and regulations
Suppliers	Procurement of goods and services such as raw materials for their operations and other business units, etc.	<ul style="list-style-type: none"> Ethical business relationships Commitment to B-BBEE policies Prompt payment 	<ul style="list-style-type: none"> Ensure that they conduct business with reputable businesses – Code of Ethics Ensure that they support B-BBEE Negotiate, manage and conclude contracts Timeous payment
Regulatory authorities such as the South African Medicines Control Council and the Department of Health	Promulgate and monitor regulatory framework and comply with current laws and regulations	<ul style="list-style-type: none"> Compliance with laws and regulations of authorities 	<ul style="list-style-type: none"> Continuous training of management and employees responsible for compliance with various regulations by the respective authorities Internal control procedure checklist to ensure compliance with respective laws and regulations Immediate corrective action noted in the event of findings raised by authorities Participation in industry working groups Meeting with industry regulators

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STAKEHOLDER	RELATIONSHIP	EXPECTATION	EXPECTATION MANAGED
Health and Safety	Monitoring by health and safety officers	<ul style="list-style-type: none"> Compliance with health and safety standards 	<ul style="list-style-type: none"> Continuous training of employees on health and safety matters Internal control procedure checklist to ensure compliance with respective laws and regulations Immediate corrective action noted in the event of findings raised by health and safety officers
Government and regulatory authorities	Promulgate and monitor laws and regulations	<ul style="list-style-type: none"> Compliance with laws and regulations 	<ul style="list-style-type: none"> Internal control procedure checklist to ensure compliance with respective laws and regulations Immediate corrective action noted in the event of findings raised by authorities Participation in industry working groups Meeting with government representatives

REMUNERATION

Genius strives to keep remuneration in line with the pharmaceutical industry, but often settles for the lack of experience of prospective candidates entering the manufacturing sector for the first time as they still require training in the pharmaceutical industry and require laboratory experience to be familiar with the Good Manufacturing Practice Code.

( - Principles 1 to 16)