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.

VISION 2020 VISION – GENIUS' CONTRIBUTION

Genius' outlook for its business units and its value proposition are based on a long-term vision and valueadd 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 specific 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 trial 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:

- The 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 I, further funding for the genomics component which will further strengthen the health platform offering.

• Based on the phase 1 trial results, 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.

