BRINGING COVID-19, HIV, HEPATITIS B, AND CANCER CURE PROTOTYPES TO LIFE

THE PLAN

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FOREWORD

The biogeochemical cycles are proof that humans must live in harmony with their surroundings in order to better the quality of their lives. A simple change in one component of the environment can have dire consequences; recently, covid-19 pandemic hit the world and the success of this pathogen has been largely attributed to mutations in genes of an otherwise avirulent form, and bacteria have increased resistance to the common antimicrobics.

As a biotech, we strive to be the most dependable to offer long lasting solutions to problems of medical, veterinary, agricultural, environmental, and industrial concerns. This dream, which began twelve years ago, is so far manifesting in the medical field. We have embraced proteomics, particularly enzymology, as our approach in therapeutics. Our enzyme-based approach is advantageous in that treatment can be tailored to match the condition of concern and this eliminates chances of drug failure, moreover, minimizes the side effects felt by the patient. Because of our expertise in this field of therapeutics, we are fast in responding to situations of emergency. When covid-19 pandemic hit, we were the first, and still the only biotech, to announce a prototype cure.

Currently we have four prototypes that are cure candidates for HIV, Cancer, Hepatitis B, and Covid-19. We look forward to developing therapeutics for other diseases as well, be communicable or noncommunicable. This form of diversification is what we hope will make us give value to our potential investors and customers, and that they will have an excellent experience working with us or consuming our products.

Sincerely,

Robert MIJUMBI, C.E.O.

EXECUTIVE SUMMARY

We are a private limited liability company incorporated on 25th January 2013 in Uganda to provide services, which include those in the field of medical concerns. Our vision is to be the leading biotechnology company, providing forever-lasting solutions to problems of medical, veterinary, industrial, agricultural, and environmental significance. Our mission is to enhance biological research in areas of medical, veterinary, industrial, agricultural and environmental significance by providing new methods that permit quick detection of problems, and give solutions that are cheap, effective, and of minimal, if any, negative effects.

For more than four decades now, HIV pandemic has continued to torture the world. Cancer, on the other hand, has been a problem for millennia. Hepatitis B virus, though on a small scale compared to HIV, has been a persistent problem. More recently Covid-19 threatened man's existence on planet earth. For eleven years now we have been working on developing therapeutics to quell these diseases, that of covid-19 being the most recent of our developments.

Our four prototypes are candidate cures; BertoV1 for HIV, BertoCAN for cancer, BertoHEP for hepatitis B, and BertoCOV for covid-19. The advantages that our enzyme-based therapies have over other forms of treatments for these diseases are that; 1) they are designed to be single dose and effectiveness is guaranteed irrespective of the severity of the disease, 2) treatment failure is abated because of the high specificity of these enzymes, 3) side effects are negligible, and 4) quick recovery is guaranteed.

Advancing this work to make the prototypes eligible for clinical trials require publications of our science on each of them. It is for this reason that we are looking for a seed investment of **One Hundred Sixty Thousand (160,000) US dollars** to, among other things, cover the publication fees and also upgrade our current laboratory infrastructure. In exchange for this funding, we shall issue out shares in our company. These publications once complete will serve as proof of concept, which is very important in the subsequent stages.

Currently, Uganda manufactures antiretroviral drugs for HIV and is the sole supplier of East, Central and Southern Africa. In May 2023 his excellency the president signed into law a bill that is widely seen by donors to be anti-LGBTQ and the said donors have threatened to withdraw their funding for services, among which HIV and cancer treatments are included. In January 2025, USAID funding was frozen and this has created uncertainty in HIV and cancer care. This situation will make the population embrace our work, and as such a huge market awaits our products. Furthermore, the stigma associated with being HIV positive, and the pain of suffering from cancer, will make our products sell.

We have no intention of exiting the market, instead we hope to stamp our presence in the biopharmaceutical industry by developing products that match the current market trends, giving value to our investors and customers. This step that we are already making will help us develop a network in the biopharmaceutical ecosystem and as such will always be relevant.

At the moment the business being run by its two co-founders, however, talent has already been identified in the areas of laboratory, clinical and pharmaceutical practice, and will be deployed as soon as need arises and resources permit. The co-founders are biological brothers and the relationship between the co-founders and other members to join the team spans over ten years; this team cohesion will make work run smoothly and consequently success is anticipated.

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1.0 Introduction

World over, there have been changes in the communities in which people live. Most of the appreciated changes are social, political and economic in nature. However, the environmental changes are the driving forces in all the previously mentioned ones; the global climate change has altered the pattern of agricultural productivity, increased the production costs and consequently led to economic meltdown, and has resulted into new strains of pathogens.

In our rapidly changing world, where the population is increasing at the rates inversely proportional to the resources available in nations, a great danger faces the human race. There is, therefore, the need for research to improve on the conditions of life on planet earth. This research should allow easy detection of problems facing agricultural settings, industrial fields and human medical well-being, and provide biological solutions that will remedy the problems with little, if any, hazardous impacts on the environment. On this account, we were born.

Biobert Research Group (BRG) started operating in the year 2012 and became registered as a private limited liability company on 25th January 2013 (**Reg. No. 80010003843424** and **TIN 1004772132**) to provide services, which include those in the field of medical concerns. We are based in Kampala, Uganda.

- **Our vision** is to be the leading biotechnology company, providing forever-lasting solutions to problems of medical, veterinary, industrial, agricultural, and environmental significance.
- **Our mission** is to enhance biological research in areas of medical, veterinary, industrial, agricultural and environmental significance by providing new methods that permit quick detection of problems, and give solutions that are cheap, effective, and of minimal, if any, negative effects.

2.0 The problems

For more than four decades now, the HIV pandemic has ravaged the world. The estimates of those infected with the virus worldwide puts their population well over 38.4 million. In numerical value, the Republic of South Africa has over 7 million HIV positive individuals, making it the country with the world's highest population of infected people. In terms of number of infected individuals, expressed as a percentage of the overall population, the kingdom of Eswatini is a world leader (27%), followed by the kingdom of Lesotho (25%), and the Republic of Botswana (24.8%), respectively[1]. All these countries are in sub-Saharan Africa. Generally, the distribution of HIV positive humans worldwide places them in all the continents.

To this very day, there are only two people known to have been cured of HIV infection. In 2019 a story broke out of "the London patient", the second of the two to be cured of HIV. His resistance to HIV infection was a side effect of a bone marrow transplant to treat Hodgkin's lymphoma, a type of blood cancer[2]. Whereas this news brought a glimmer of hope to HIV positive individuals, that hope soon faded after learning that the surgical procedure the "London patient" underwent was more life-threatening than HIV infection itself[3]. Antiretroviral therapy is the only form of medication that is currently available for managing HIV infection; it has to be taken daily at specific intervals, a very stressful routine for people to adhere to. Moreover, there are scientific reports of certain medical problems associated with prolonged antiretroviral therapy[4].

Another medical problem that has existed for long is cancer. There are different types of cancer and each has specific methods of diagnosis and the therapeutic approach is dependent on the stage of cancer, its location within the body, and age of the patient, among other factors.

Moreover, the covid-19 pandemic and hepatitis B virus have no known cures; in 2019, the world health organization estimated the number of people living with Hepatitis B virus to be 296 million worldwide[5]. Being a biotech, these are the opportunities we look forward to salvaging for our growth and development.

3.0 Our solutions

We have embraced proteomics, particularly enzymology, as the best approach in treating diseases. Our prototypes, BertoV1, BertoCAN, BertoCOV, and BertoHEP are candidate cures for HIV, Cancer, Covid-19, and Hepatitis B, respectively.

3.1 BertoV1

It contains 460 mg polypeptide (enzyme) as the active pharmaceutical ingredient. It is dissolved in potable water at room temperature and drunk all at once; due to its design, it survives digestion by the enzymes in the gastrointestinal tract and is presented into the blood stream where it breaks the envelope of HIV, preventing the virus from attacking other otherwise susceptible T-helper lymphocytes. The viral genome resulting from its envelope lysis is then degraded by the human body in a normal biochemical fashion.

3.2 BertoCAN

It is composed of 110 mg of polypeptide (enzyme) as the active pharmaceutical ingredient. It is dissolved in potable water at room temperature and drunk all at once. It is absorbed through the villi in the gastrointestinal tract and presented into the blood stream, where it is circulated to various tissues and organs. It lyses cancerous cells, exposing their altered genetic material to normal biochemical pathways that eliminate them, which stops their proliferation.

3.3 BertoCOV

It contains 660 mg polypeptide (enzyme) as the active pharmaceutical ingredient. It is dissolved in potable water at room temperature and the resultant solution/ suspension is drunk all at once; it absorbed through the intestinal villi and presented into the blood stream where it digests the envelope of a viral particle before the virus infects a new cell. This exposes the viral enzymes and/ or surface proteins necessary for replication and attachment to an unusual environment (plasma) and thus they cannot function; moreover, exposing the viral genome to plasma leads to its metabolism in the usual biochemical fashion.

3.4 BertoHEP

It contains 460 mg polypeptide (enzyme) as the active pharmaceutical ingredient. It is dissolved in potable water at room temperature and drunk all at once; due to its design, it survives cleavage by the enzymes in the gastrointestinal tract and is presented into the blood stream where it breaks the envelope of HBV, preventing the virus from attacking other otherwise susceptible hepatocytes. Also, it digests the viral genome; moreover, exposing the viral genome to plasma leads to its metabolism in the usual biochemical fashion.

4.0 Objectives

4.1 General objective

To develop cures for Covid-19, HIV, Hepatitis B, and cancer.

4.2 Specific objectives

The following specific objectives are envisaged to help us achieve our goal.

i. To mobilize funds for the project;
ii. To publish our scientific findings on the cure prototypes;
iii. To acquire our own premise and establish a facility that is both GCLP (good clinical laboratory practice) and GMP (good manufacturing practice) compliant;
iv. To develop cheap and environmentally friendly method(s) of producing the prototypes in bulk; and
v. To conduct clinical trials of each of the four prototypes.

5.0 Methodology

The above objectives will be met using the approaches described in the logical framework matrix.

THE LOGICAL FRAMEWORK MATRIX

General objective: To develop cures for Covid-19, HIV, Hepatitis B, and cancer.			
Specific objective 1: To mobilize funds for the project.			
Approach	**Objectively Verifiable Indicators (OVI)**	**Means of Verification (MOV)**	**Questions/ Assumptions**
Activities • Writing proposals and concept notes. • Identifying potential investors and/ or funders. • Contacting the potential investors and/ or funders. • Submitting proposals and concept notes to the potential investors and/ or funders. • Marketing on the various social media platforms. • Issuing out shares. **Input** • Time. • Finances (phone calls, internet, movement). • Stationery • Computer and associated software and hardware.	• Number of potential investors and/ or funders identified. • Number of proposals and concept notes submitted to the potential investors and/ or funders. • Number of feedbacks received from the approached potential investors and/ or funders. • Presence on social media. • Number of shares bought.	• Call logs. • Acknowledgements of receipt of proposals and concept notes. • Trend in the number of followings on social media.	• Our project fits perfectly in the investment portfolio of the targeted investors and/ or funders. • We shall be able to raise the required funds within a set period. • We shall be able to attract international investors and/ or funders.

Output • Polished proposals and concept notes. • List of potential investors and/or funders.			
Specific objective 2: To publish our scientific findings on the cure prototypes.			
Approach	**Objectively Verifiable Indicators (OVI)**	**Means of Verification (MOV)**	**Questions/ Assumptions**
Activities • Writing manuscripts. • Identifying suitable journals for specific manuscripts. • Submitting manuscripts for peer review and publication. • Marketing the published papers. **Input** • Finances (article processing charge, internet). • Time. • Computer and related software and hardware. **Output** • Peer-reviewed articles.	• Number of peer-reviewed articles published. • Public perception on our publications.	• Level of coverage given by the mainstream media channels. • The trending position on social media. • The lifespan on social media. • Number of new followers acquired on social media. • Number of inquiries from the scientific community and the academia.	• For a reasonably good period, no event will occur that will take us out of the media spotlight. • We shall enjoy media presence both locally and internationally.
Specific objective 3: To acquire our own premise and establish a facility that is both GCLP (good clinical laboratory practice) and GMP (good manufacturing practice) compliant.			

Approach	Objectively Verifiable Indicators (OVI)	Means of Verification (MOV)	Questions/ Assumptions
Activity • Identifying a suitably located piece of land. • Purchasing the identified piece of land. • Identifying an engineering contractor and negotiating a contract with the firm. • Constructing and furnishing the premise. • Securing the premise. • Procuring and installing equipment. **Input** • Finances (movements, internet, phone calls, legal fees, taxes). • Time. **Output** • Contracts.	• Legally binding contracts signed. • Possession of the land. • Infrastructural development.	• Land title. • Physical inspection. • Equipment inventory.	• Finances will be available for every activity. • The engineering contractor will do their job with integrity. • Natural calamity, particularly earth quake, will not jeopardize our efforts. • The regulatory authorities shall give as the necessary approvals.
Specific objective 4: To develop cheap and environmentally friendly method(s) of producing the prototypes in bulk.			
Approach	**Objectively Verifiable Indicators (OVI)**	**Means of Verification (MOV)**	**Questions/ Assumptions**
Activities • Reviewing necessary literature on the subject matter.	• Number of new peer-reviewed publications. • Number of new patents registered.	• Laboratory reports. • Level of coverage given by the mainstream media channels.	• For a reasonably good period, no event will occur that will take us

• Procuring and assembling test materials (equipment and reagents). • Generating and testing various hypotheses. • Developing a production technology. • Publishing the science. • Marketing the publications. • Patenting the technology developed. **Input** • Finances (utilities, consumables, internet, consultancies, publications) • Time. **Output** • New publications. • Registered patents.	• Public perception on our publications.	• The trending position on social media. • The lifespan on social media. • Number of new followers acquired on social media. • Number of inquiries from the scientific community and the academia.	out of the media spotlight. • We shall enjoy media presence both locally and internationally.
Specific objective 5: To conduct clinical trials on the two prototypes.			
Approach	**Objectively Verifiable Indicators (OVI)**	**Means of Verification (MOV)**	**Questions/ Assumptions**
Activities • Creating the clinical trial protocol. • Creating the analytical plan.	• Regulatory approval. • List of potential partners. • Publications arising from clinical trials. • Public perception on the clinical trials.	• The register of clinical trials. • Positive feedback from potential partners.	• Many partners will get on board. • Industry competitors will not spread malicious information about our clinical trials.

• Identifying key partners. • Applying to, and consulting with, the regulatory authorities, both local and international. • Making a press statement on the trial. • Publishing the results of clinical trials. • Marketing the products. • Post-market surveillance. **Input** • Finances. • Time. **Output** • The clinical trial protocol. • The analytical plan. • List of potential partners.		• Level of coverage given by the mainstream media channels. • The trending position on social media. • The lifespan on social media. • Number of new followers acquired on social media. • Number of inquiries from the scientific community and the academia.	• Industry competitors will not buy out the media to limit our coverage.

6.0 Tactical Marketing

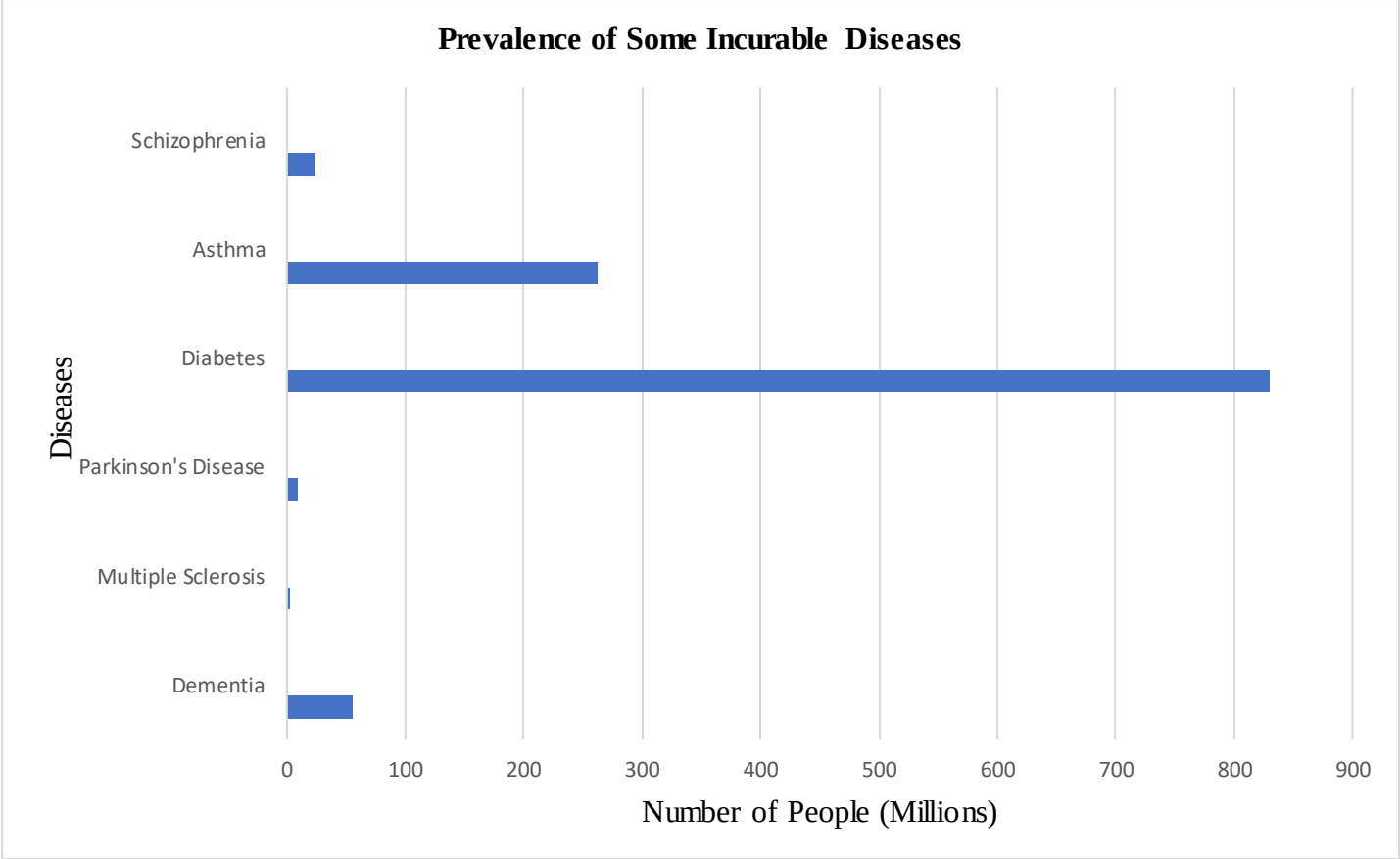
Marketing Mix

- Products: Therapeutics to treat infections with HIV, hepatitis B virus, Covid-19 virus, and cancer.
- Price: A value determined through market research that is fair to all involved stakeholders shall be adopted.
- Physical evidence: Prototypes do exist; BertoV1 for HIV, BertoCAN for cancer, BertoCOV for covid-19, and BertoHEP for hepatitis B.
- Process: Chemical synthesis of peptides, with an option of biological engineering.
- Personnel: Technical bench is fully experienced in biological, chemical, pharmaceutical and clinical procedures. Support personnel will be recruited to cover existing skills gaps.
- Place: Operations will be hybrid, in our laboratory and/or at partnering contract research organisations (CROs), contract manufacturing organisations (CMOs), and contract development and manufacturing organisations (CDMOs).
- Promotion: Scientific publications will showcase the quality of our products to target market segments.

Target Market						
	Value Perception (Reason)					
			Customer Journey			
			Planning	**Decision**	**Experience**	**Feedback**
Patients	Unexpected.	Therapeutics are highly efficacious and have negligible side effects.	The high quality of scientific publications will draw attention.	The stress of routine medication and the desire to try new stuff is our usher.	They will use the products as prescribed and offer feedback.	Online and offline touch points will be used to collect views for further growth.
CROs		An early stage asset with prototypes that are first of their kinds in their areas of therapy, moreover with adaptability to other indications.	Loss of exclusivity has led to many entities producing what used to be restricted to a select few in the biopharma industry. There is thus a stiff competition for few assets developing new products.	Currently the market does not have a product with an ability akin to any of our prototypes in their therapeutic areas. There is thus a chance of increasing profit margins by pioneering the production of them.	They will produce, clinically trial and market the products. This could imply adaptation of existing technologies or developing entirely new production lines to match scientific and financial load.	There will be continuous refinement of each of the products to match market needs and remain on the lead. Feedback will also be used to gauge the complementary products to make to give value to clients.

7.0 Strategic Marketing

Our long-term plan is to be the world's most sought-after biotech for solutions to emerging problems or those that are still unresolved. Some of the current medical conditions for which we intend to develop game-changing solutions in the future are Dementia, Multiple Sclerosis (MS), Muscular Dystrophy (MD), Amyotrophic Lateral Sclerosis (ALS), Huntington's Disease (HD), Parkinson's Disease (PD), Diabetes, Asthma, Creutzfeldt-Jakob disease (CJD), Fibrodysplasia Ossificans Progressive (FOP), Hutchinson-Gilford Progeria Syndrome (HGPS), and Schizophrenia. The global prevalence of the most common of these diseases is depicted below.



8.0 Market Analysis

8.1 The Market Size

HIV and cancer are diseases of global concern. Africa has the biggest population of HIV infected individuals, contributing to about 69% of the global infections; moreover, the continent still leads in the number of new infections registered yearly. The other markets are Europe, Asia, and the Americas. On the whole, there are more than 37 million people who could benefit from BertoV1; this is a ready market to tap. Also, global estimates of people suffering from cancer put their population above 19 million, a market for BertoCAN to tap in. As of 2019 WHO estimated world hepatitis B infection to be 296 million, a ready market for BertoHEP. Currently, there is no known/ approved cure for covid-19 infection, a virgin market for BertoCOV.

8.1.1 HIV Statistics for Uganda

According to the Uganda Aids Commission (2022), Uganda has 1.4 million people living with HIV (PLHIV). Figures 1 and 2 summarize the HIV trend in Uganda.

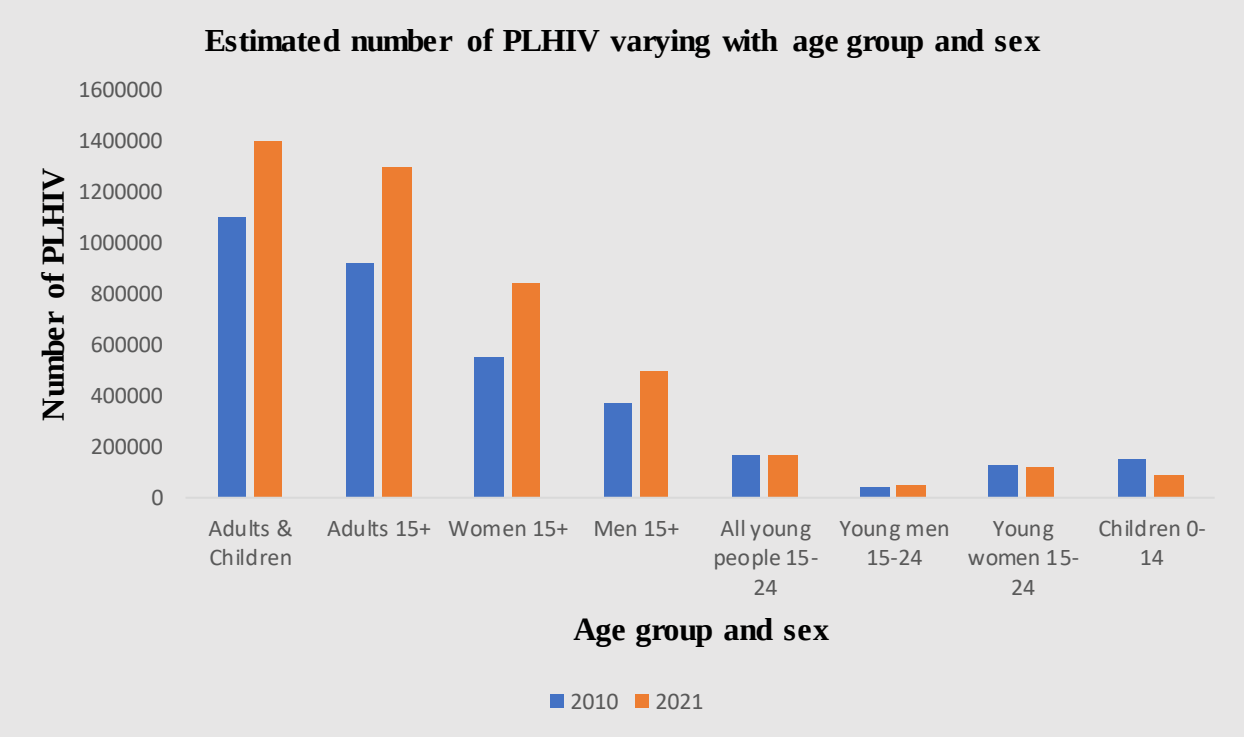


Figure 1: Estimated number of people living with HIV disaggregated by age group and sex.

Source: Uganda Aids Commission, 2022 Fact Sheet.

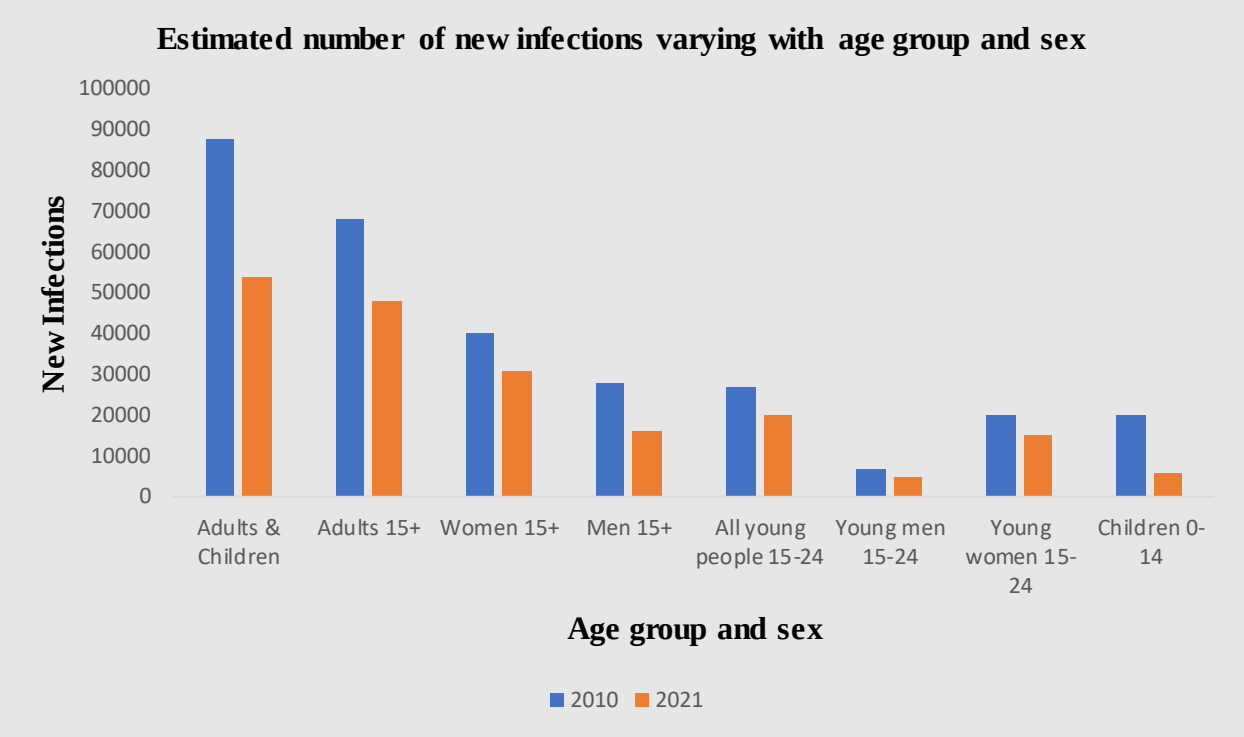


Figure 2: Number of new HIV infections disaggregated by age group and sex.

Source: Uganda Aids Commission, 2022 Fact Sheet.

8.1.2 Cancer Statistics for Uganda

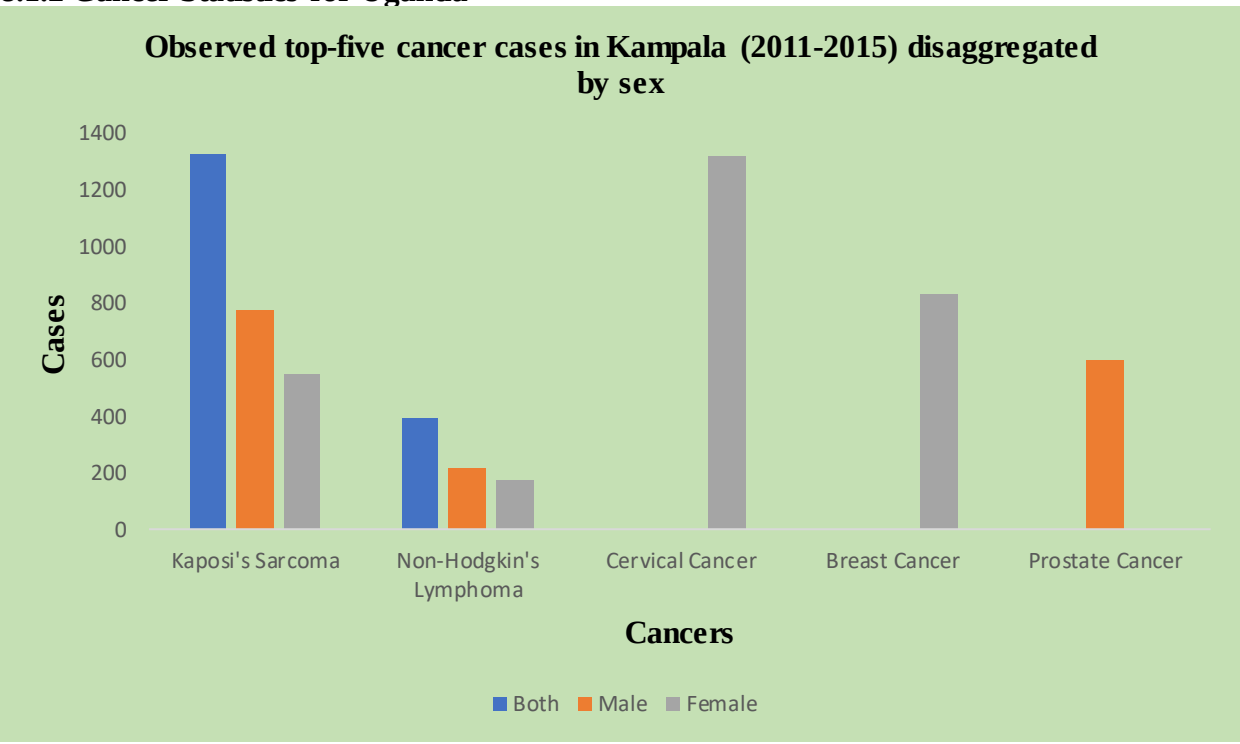


Figure 3: Observed top-five cancer cases in Kampala (2011-2015) disaggregated by sex.

Source: Asasira J., Lee S., Tran TXM. *et al.* (2022).

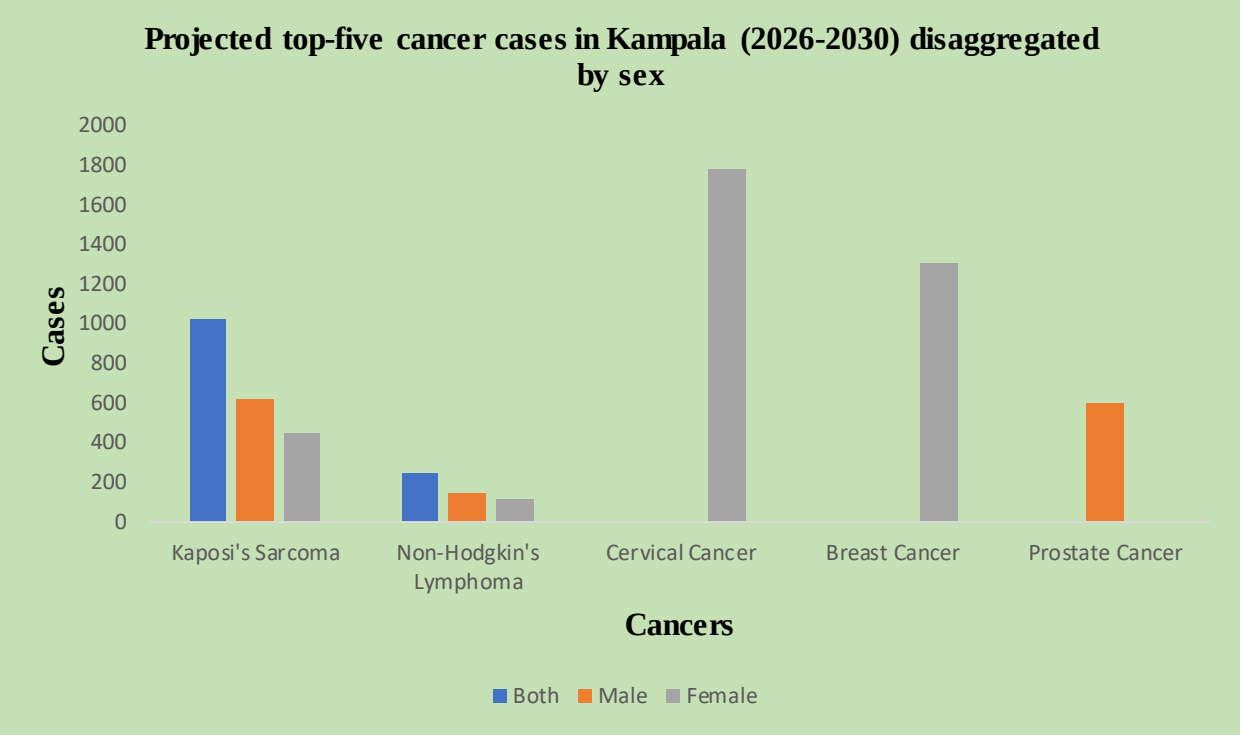


Figure 4: Projected top-five cancer cases in Kampala (2026-2030) disaggregated by sex.

Source: Asasira J., Lee S., Tran TXM. *et al.* (2022).

8.2 Segmentation and Targeting

8.2.1 HIV Segment

Criteria		Target Group	Reason
Psychographic	Commercial sex workers	Both sex workers and their clients.	• BertoV1 will be consumed by both prostitutes and their clients either as a pre-exposure prophylactic or a post-exposure prophylactic, which leads to a recurrence of sales and consequently growth.
	Homosexuals	All.	• In areas where gay sex is criminalized or considered a cultural abomination, gay men are listed among the most-at-risk-people to contract HIV and as such this is a potential market for BertoV1 either as a pre-exposure prophylactic or a post-exposure prophylactic, which leads to a recurrence of sales and consequently growth.
	Users of psychoactive injectable drugs	All.	• Sharing injection needles by drug addicts is one of the documented forms of HIV transmission. This is a market that BertoV1 will tap in.
Demographic	Age	All.	• The product is designed to be safe, with minor, it all any noticeable effects. Since some children are born HIV positive, BertoV1 can be used across all ages, from infants to the elderly.
	Gender	All.	• The product fits all genders and as such has a wide market.
	Pregnancy/ lactating	Both.	• The product is designed to be safe, with minor, it all any noticeable effects. Further studies are being done to ensure it has no harm on the

			foetus and that lactation is not affected (quality and quantity of milk).
	Co-morbidity	All.	• Because the product is designed to be safe, those with other co-morbidities can consume it without fear of having an aggravated side effect. Moreover, the most common medicines are not antagonistic to BertoV1 and as such the product can be taken along with other forms of medication.
	Income levels	All.	• The final product will be priced at a value fair enough for even the poor to afford. This will widen the market.
Geographic	Worldwide	Worldwide.	• BertoV1 is designed to match the various serotypes of HIV with the same level of efficacy and as such will be sold world over.
Benefit	Stress of repetitive medication	Those on other forms of HIV treatment.	• Currently, antiretroviral regimens are taken either daily or at regular intervals for the rest of a patient's life. The patients stressed of taking routine medication will most likely welcome BertoV1 and try it out.
	Travel	Travelers interested in crossing country borders.	• Certain countries screen travelers for HIV and those found to be positive are denied entry. For reasons such as education and search for better life opportunities, BertoV1 will find market among the HIV infected.
	Marriage	Both the married and unmarried.	• HIV discordance is when one partner in a marriage is positive and the other is negative. In this scenario, there will be a need to either protect the HIV negative party or conceal the matter by clandestinely treating the problem, hence BertoV1 will be sought out.

			• HIV test is one of the key events in courtship and certain religious institutions require test results before wedding couples. For individuals born HIV positive or infected by other means, this is a stumbling block and as such will most likely consume BertoV1.

8.2.2 Cancer Segment

Criteria		Target Group	Reason
Demographic	Age	All.	• The product is designed to be safe, with minor, if at all any noticeable effects. Since some children are born with cancer or develop it earlier on in life, BertoCAN can be used across all ages, from infants to the elderly.
	Gender	All.	• The product fits all genders and as such has a wide market.
	Pregnancy/ lactating	Both.	• The product is designed to be safe, with minor, if at all any noticeable effects. Further studies are being done to ensure it has no harm on the foetus and that lactation is not affected (quality and quantity of milk).
	Co-morbidity	All.	• Because the product is designed to be safe, those with other co-morbidities can consume it without fear of having an aggravated side effect. Moreover, the most common medicines are not antagonistic to BertoCAN and as such the product can be taken along with other forms of medication.
	Type and stage of cancer	All.	• BertoCAN is designed to be efficacious against all types and stages of cancer, which implies wide market.

	Income levels	All.	• The final product will be priced at a value fair enough for even the poor to afford. This will widen the market.
Geographic	Worldwide	Worldwide.	• BertoCAN is designed to match the various types of cancer with the same level of efficacy and as such will be sold world over.
Benefit	Stress of repetitive medication	Those on other forms of cancer treatment.	• Currently, most cancer regimens are taken either daily or at regular intervals. The patients stressed of taking routine medication will most likely welcome BertoCAN and try it out.

Note: BertoHEP and BertoCOV are akin to BertoV1 in segmentation.

8.3 The Competition

COVID-19 Treatment										
No.	**Parameter**	**Product**								
		BertoCOV	Paxlovid	Lagevrio	Remdesivir	Comirnaty (Pfizer)	mRNA-1273 (Moderna)	ChAdOx1-S (Oxford)	Ad26.COV2.S (Janssen)	CoronaVac (Sinovac)
1	Category	Drug	Drug	Drug	Drug	Vaccine	Vaccine	Vaccine	Vaccine	Vaccine
2	Nature of API	Polypeptide	Organic	Organic	Organic	mRNA	mRNA	mRNA	Adenovirus	Inactivated SARS-COV-2
3	Administration	Oral	Oral	Oral	Intravenous	IM	IM	IM	IM	IM
4	Smell	Odourless	Unpleasant	Unpleasant						
5	Taste	Salty	Bitter	Bitter						
6	Comfort		Bitterness	Bitterness	Painful	Painful	Painful	Painful	Painful	Painful
7	Point of use	Unrestricted	Unrestricted	Unrestricted	Clinic	Clinic	Clinic	Clinic	Clinic	Clinic
8	Dosage	Single	Twice daily for 5 days	Twice daily for 5 days	3-10 days	2 doses in 4 weeks	2 doses in 4 weeks	2 doses in 4 weeks	Single	2 doses in 4 weeks
9	Need for vaccine	No	Yes	Yes	Yes					
10	Need for vaccine booster		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
11	Virus rebound	No								
12	Efficacy		89%	30%		95%	94.1%	76%	94%	65%
13	Treatment duration	≤ 3 minutes	> 10 minutes	> 10 minutes	30 minutes to 2 hours	≥ 5 minutes	≥ 5 minutes	≥ 5 minutes	≥ 5 minutes	≥ 5 minutes
14	Variants	All								
15	Age restriction	None	≥ 12 years	≥ 65 years	≥ 65 years	≥ 5 years	≥ 12 years	≥ 18 years	≥ 18 years	≥ 18 years
16	Eligibility	All	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity

17	Exclusion		Kidney/ liver disease, organ transplants.	Pregnancy, children, and nursing individuals.		Severe allergy to components of vaccine.	Severe allergy to components of vaccine.	Severe allergy to components of vaccine.	Severe allergy to components of vaccine, and body temperature ≥ 38.5°C.	Severe allergy to components of vaccine, acute illness, and temperature ≥ 38.5°C.
18	Side effects		Altered taste, diarrhea, muscle ache, and increased blood pressure.	Diarrhoea, nausea/ vomiting, and dizziness.	Nausea/ vomiting, back pain, head ache, itching, flushing, dark urine, chest tightness, and light-coloured stool	Myocarditis/ pericarditis, fever, chills, fatigue, and head ache.	Fever, chills, fatigue, and head ache.	Thrombosis and Guillain-Barre syndrome are suspected.	Thrombosis and Guillain-Barre syndrome are suspected.	Fatigue, diarrhea, muscle pain, and pain at injection site.
19	When required	Any time of infection	Within 5 days of symptom onset.	Within 5 days of symptom onset, and non-severe disease.	Severe disease and comorbidity.	Before infection/ after recovery from the disease.	Before infection/ after recovery from the disease.	Before infection/ after recovery from the disease.	Before infection/ after recovery from the disease.	Before infection/ after recovery from the disease.
20	Recovery period	2 days after treatment								

HIV Treatment

No.	Parameter	Product		
		BertoV1	Antiretroviral Therapy (ART)	Bone Marrow Transplant
1	Nature of API	Polypeptide	Other organic	
2	Curative	Yes	No	Yes
3	Duration	Single dose	Lifetime	Once/ varies

4	Point of use	Unrestricted	Unrestricted	Clinic
5	Administration	Oral	Oral	Surgical
6	Recovery time	4 weeks		
7	Smell	Odourless	Unpleasant	
8	Taste	Slightly salty	Depends on brand/ Constituents	
9	Side effects		• Hypersensitivity reaction • Increase in cholesterol • Risk of heart disease • Nausea • Vomiting • Abdominal pain • Peripheral neuropathy • Pancreatitis, • Lactic acidosis, • Fat loss in arms, legs, or face • Skin rash • Darkening of the skin of palms/ soles • Kidney and bone damage • Weight gain • Anaemia	• Death • Infertility • Cataract • New cancers • Organ damage • Graft-versus-host disease • Infections • Graft failure

HEPATITIS B Treatment (please refer to the HIV treatment comparison, BertoHEP is akin to that)

CANCER Treatment

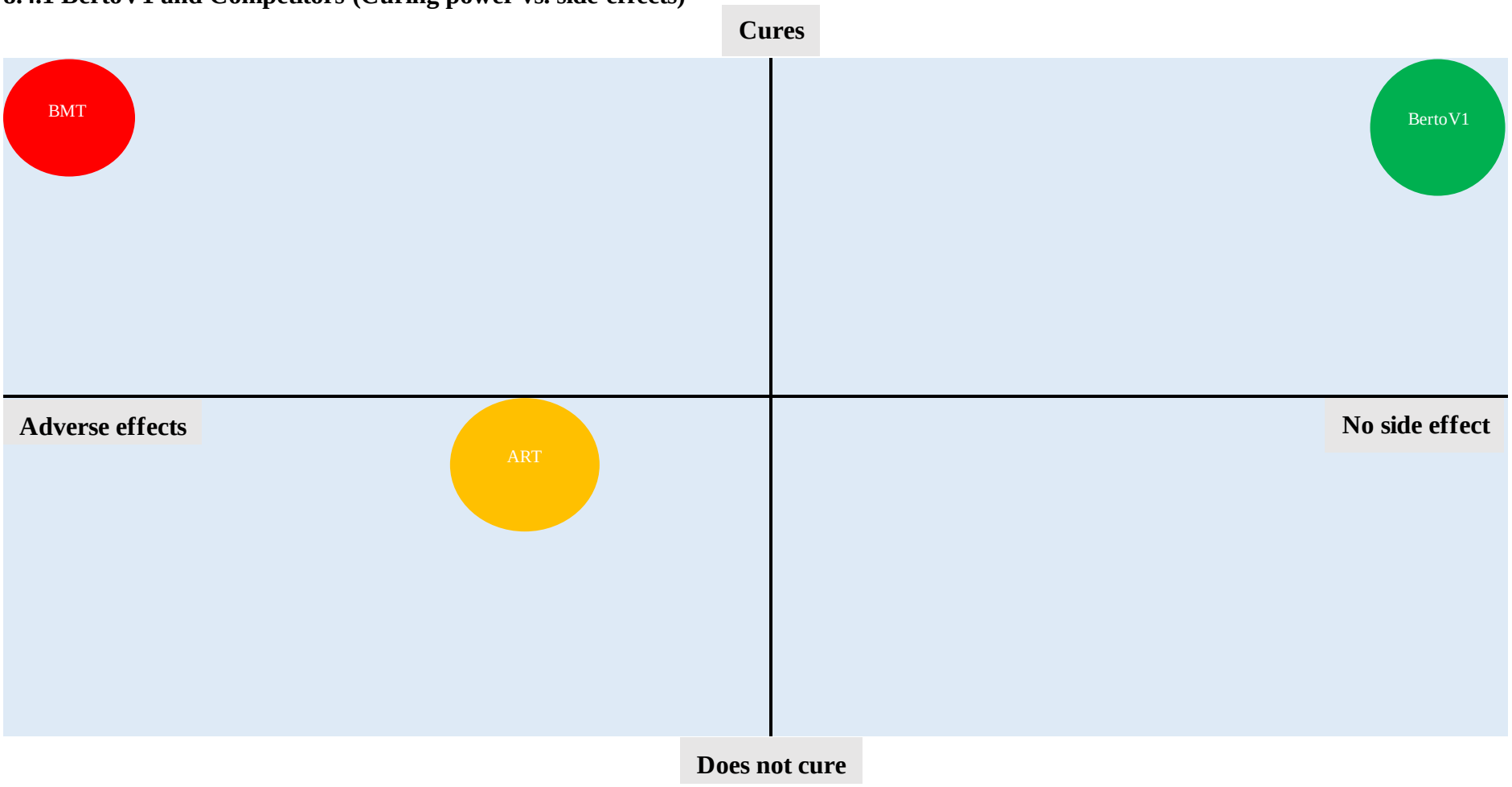
No.	Parameter	Product				
		BertoCAN	Immunotherapy	Chemotherapy	Radiotherapy	Bone Marrow transplant
1	Nature of API	Polypeptide	Other organic/ cells	Other organic		
2	Administration	Oral	Intramuscular	Oral/ intravenous	Topical	Surgical
3	Point of use	Unrestricted	Clinic	Clinic	Clinic	Clinic
4	Curative	Yes	Depends on type/ stage	Depends on type/ stage	Depends on type/ stage	Depends on type/ stage
5	Stage of effectiveness	All	Varies	Varies	Varies	Varies
6	Type of cancer	All	Some	All	Some	Some

7	Recovery time	4 weeks				
8	Smell	Odourless		Dependent on drug		
9	Taste	Tasteless		Dependent on drug		
10	Special requirement	None	• Increasing dietary fibre intake improves effectiveness.			
11	Side effects		• Chills • Localized blisters • Constipation • Coughing • Loss of appetite • Headache • Itching • Fever • Diarrhoea • Fatigue • Pain at injection site	• Fatigue • Feeling and being sick • Loss of appetite • Anaemia • Hair loss • Soreness of mouth • Infections • Bruising and bleeding	• Diarrhoea • Loss of hair • Soreness, dryness, reddening, and darkening of skin • Stiffening of joints and muscles • Difficulty in swallowing • Sickliness • Impaired sexual life • Infertility issues • Fatigue	• Death • Infertility • Cataract • New cancers • Organ damage • Graft-versus-host disease • Infections • Graft failure

NOTE: This comparative analysis of our prototypes and their competitors is based on the prevailing scientific data available on public domain and since research is always being conducted new data may emerge, leading to changes in certain parameters against which we compared our prototypes to their competitors. We used secondary sources to do this analysis and, therefore, make no claims for primary reports/ data.

8.4 Positioning of Products

8.4.1 BertoV1 and Competitors (Curing power vs. side effects)



Note: BMT stands for bone marrow transplant whereas ART stands for antiretroviral therapy.

In 2018 bone marrow transplant was successfully carried out in an HIV positive patient and whereas the intention was to rid the patient of a blood cancer, the patient also got cured of HIV. However, very stringent conditions are required in order for this operation to be successful and there are high chances (95%) of mortality than survival, hence BMT takes the assigned position in this map.

ART has been used for decades in the fight against HIV and is proven to be effective in suppressing the viral load to a level that does not cause acquired immunodeficiency syndrome (AIDS). However, this treatment does not clear the provirus that remains harboured in the lymphoid tissue, brain, spleen, and bone marrow, which therefore means that treatment must be adhered to for the rest of a patient's life. Also, several side effects of ART have been reported by patients. These effects vary from one patient to another, depending on the demography and the regimen, and could be mild or adverse such as hallucinations, dizziness, weakness of the body, and enlargement of the liver. Therefore, ART takes the assigned position in this map.

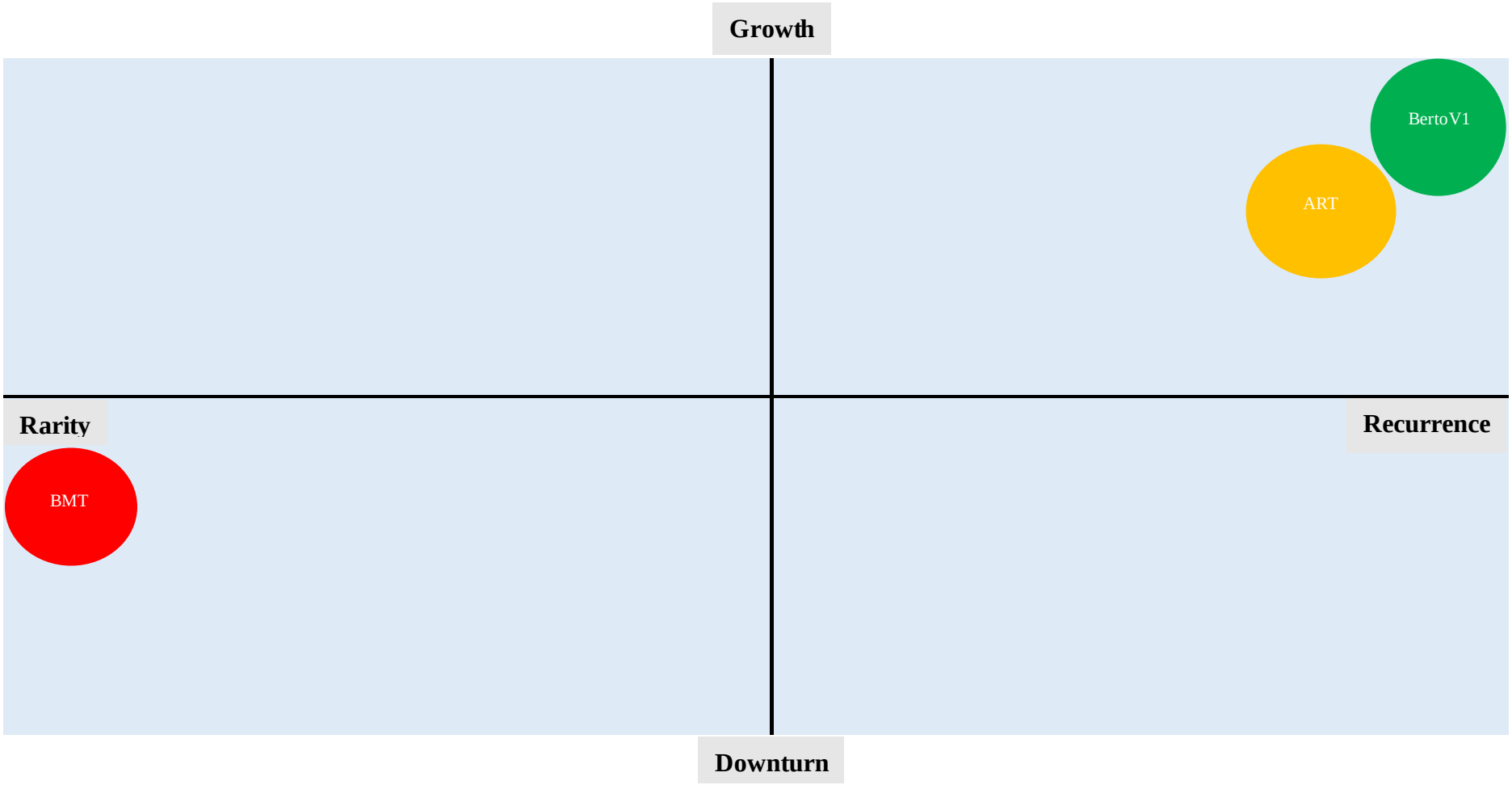
On the other hand, BertoV1 is designed to be a single-dose regimen effective against all genotypes of HIV and has modifications to adapt for oral, intravenous and intramuscular routes of administration. Moreover, its side effects are projected to be negligible, if at all any. Our product, thus, takes the assigned position in this map.

8.4.2 BertoV1 and Competitors (Growth vs. recurrence)

ART does not cure HIV infection because the virus remains harboured in its inactive form in the lymphoid tissue, spleen, brain, and bone marrow. It is thus used to control the viral load to a level that makes the infection manageable. Since a patient has to be on this medication for the rest of his/ her life, ART has a good recurrence and consequently leads to growth of a business dealing in it.

BMT, in contrast to ART, is only done in circumstances that other forms of treatment have failed. In the case of "the London patient", the treatment was not done primarily to treat HIV infection but to rid the patient of a type of blood cancer. Since this therapy has a high chance of mortality occurring, most doctors would discourage it and only recommend as the last option available. BMT thus has no recurrence and a business dealing in it cannot have a significant growth, hence its assigned position in the map.

BertoV1, on the other hand, is designed to cure HIV infection and within a short period of four (4) weeks. Moreover, it is expected to have negligible, if at all any, side effects. Also, the product can be used as both a pre-exposure prophylactic and a post-exposure prophylactic; and adjustments are being made to increase its range of viruses against which it can be efficacious. These qualities, therefore, imply that BertoV1 will have a great recurrence and as such will attain the assigned position against its competitors in this map.



Note: BMT stands for bone marrow transplant whereas ART stands for antiretroviral therapy.

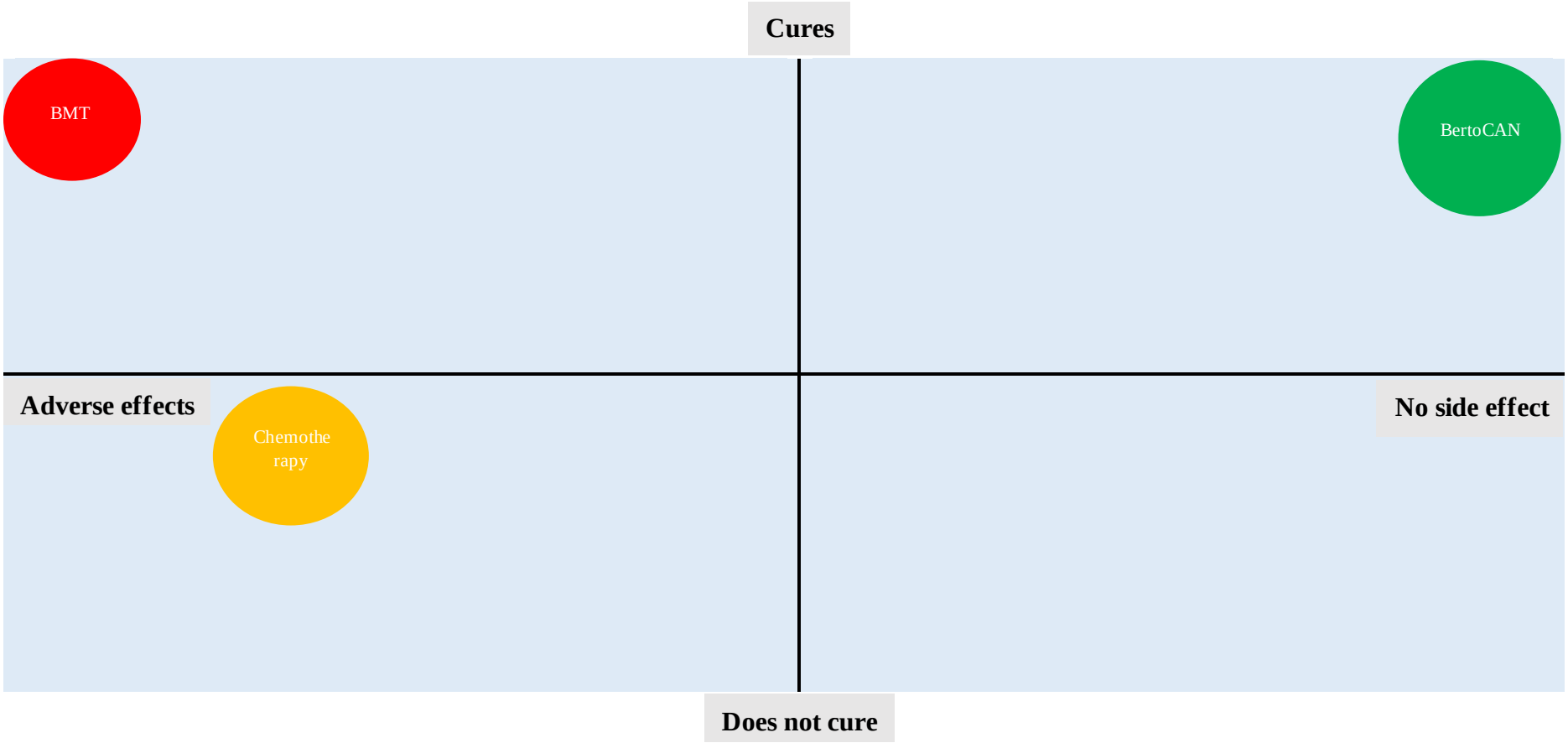
8.4.3 BertoCAN and competitors (Curing power vs. side effects)

BMT is done when the other treatment options have been exhausted and the results are still not desirable. This is because of the high chance of mortality associated with this type of surgery, and the strict environmental conditions required for the success of this operation. This, thus, makes BMT take the assigned position in this map.

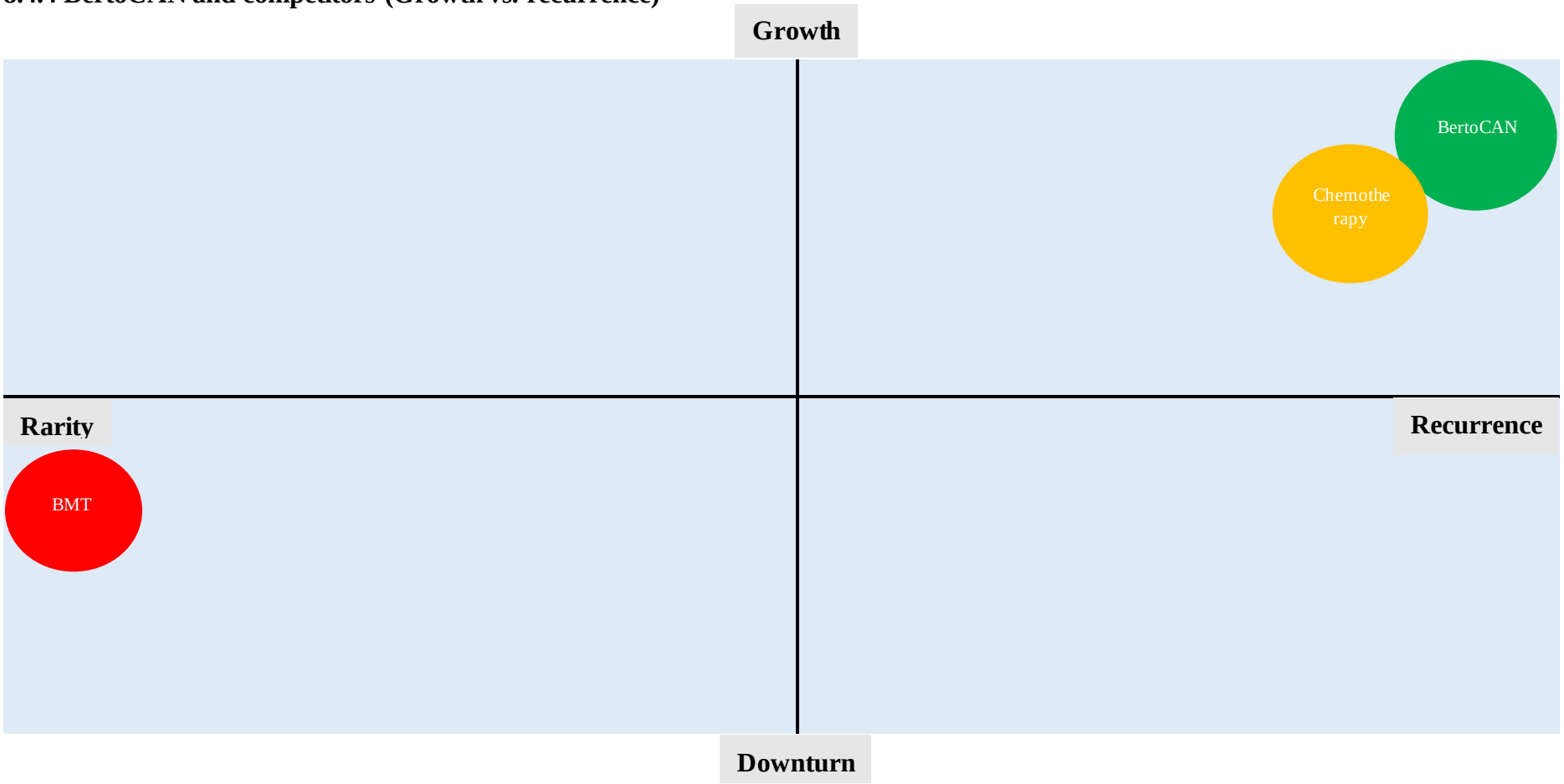
Chemotherapy when started early and when cancer is in its initial stages has been reported to cure the disease in some cases. However, with progression of the disease, chemotherapy has often been combined with other forms of treatment such as radiotherapy, surgery and bone marrow transplant. Several side effects have been reported and the magnitude varies depending on the patient demographics and the exact regimen the patient is on. For these reasons, chemotherapy takes the assigned position in this map.

BertoCAN, on the other hand, is designed to be effective against all types of cancers irrespective of the stage of the disease. It is expected to have negligible, if at all any, side effects. The product, thus, takes the assigned position in this map.

Note: BMT stands for bone marrow transplant.



8.4.4 BertoCAN and competitors (Growth vs. recurrence)



Note: BMT stands for bone marrow transplant.

BMT is only done as a last resort because of the adverse effects associated with it and the high cost of maintaining the environmental conditions required for its success. Once done and successful, there is no need for a repeat procedure. BMT, for these reasons, has a low recurrence and as such takes the assigned position in the map. Chemotherapy is taken routinely and the frequency is dependent on the type and stage of cancer. It thus has a high recurrence, which is the reason for its assigned position in the map.

BertoCAN, on the other hand is designed to be effective against all types of cancer irrespective of the stage of the disease. Also, it is designed to have negligible, if at all any, side effects. For these reasons, the product is anticipated to sell well among the target customers and as such takes the assigned position in the map.

8.5 SWOT and Risk Analyses

Strengths	Weaknesses	Opportunities	Threat
Prototypes • Single dose, one-off treatment. • Quick acting, results within 28 days (2 days for covid-19). • Negligible, if any, side effects. • Tasteless. • Odourless. • Easy to consume. • Easy to store. • Long shelf life. • We are pioneers in this science. • Potential customers like what we are doing and are eagerly waiting for the products. **Personnel** • In 2020 when the C.E.O. was arrested over the claims of these prototypes, he made it on record that the claims could be verified scientifically. This drew a lot of support from other scientists and sympathizers and as such people will be eager to see these products undergo clinical trials. • Technically gifted staff. • Good understanding of the business environment. • The co-founders are biological brothers. • The co-founders and other key staff have known each other for at least 9 years.	• Drugs are yet to be clinically tried for approval. • Lack own premises. • Financially handicapped. • Lack global representation.	• Currently there are no known cures for HIV, cancer, hepatitis B, and covid-19, thus no competitor in the market. • Over 38.4 million HIV positive individuals worldwide, a ready market to tap. • Over 19 million cancer patients worldwide, another ready market to tap. • 296 million hepatitis B positive individuals, a massive market to explore. • Covid-19 is a threat to the entire world population, an immensely huge market to explore. • New technologies will generate revenue through patent rights. • Science can be adapted to generate solutions for other diseases, creating new markets.	Sabotage by the pharmaceutical establishments making products for the management of HIV, Cancer, Covid-19, and Hepatitis B.

Risks

- Will this new approach to therapeutics be accepted by the wider public?
- Won't our science and/ or patents get stolen by the pharmaceutical establishments?
- Will the investor(s) stick with us till the very end of the project?

8.6 P.E.S.T. Analysis

8.6.1 Political

- Prof. Patrick Loch Otieno Lumumba had a meeting with His Excellency Lazarus McCarthy Chakwera, the president of the Republic of Malawi, in 2021. During their conversation, the latter pointed out the challenges met by African nations in accessing covid-19 vaccines and both parties agreed that for Africa to progress scientists must be empowered to conduct impactful research[6]. Since the president of a nation is aware of the need to promote science in Africa, we envisage the continent of Africa embracing our work.
- The French President, His Excellency Emmanuel Jean-Michel Frédéric Macron, met with certain leaders of Africa in 2023. In his address to the French President and other dignitaries, His Excellency Matamela Cyril Ramaphosa, the President of the Republic of South Africa, expressed his disappointment over the manner in which covid-19 vaccines were hoarded by the "northern countries" as though lives of people in "the global south" did not matter; moreover, he pointed out that Africa was not permitted by the WTO to manufacture own vaccines[7]. With this kind of resentment among African leaders, we anticipate that our work will be embraced in many African countries.
- In May 2023 His Excellency Gen. Yoweri Kaguta Tibuhaburwa Museveni, the President of the Republic of Uganda, signed into a law a bill that criminalizes homosexuality; part of this law penalizes a criminal with death in case of an aggravated act of homosexuality. This law drew a lot of criticism and threats from donors who warned they would withdraw their support to the country[8]. HIV and cancer treatment services are heavily dependent on donor funding; The U.S. President's Emergency Plan for Aids Relief (PEPFAR), for example, has supported HIV treatment and associated services for decades and remains one of the biggest donors in this sector, the Global Fund is another such donor. Withdrawal of this kind of support will mean lack or insufficiency of antiretrovirals used to manage HIV and as such we foresee the patients embracing our product, BertoV1. Moreover, this donor threat will make the government promote country-built technologies in order to foster self-reliance and as such we anticipate that our work will be supported by the government. In January 2025, Donald Junior Trump, the 47th President of the United States of America, signed an executive order that froze United States Agency for International Development (USAID) funding for 90 days, pending review[9]. This has disrupted roll out of medical services in HIV and Cancer care, among others; whether funding gets restored or not, this experience will push the populace to embrace our work.
- The government of the Republic of Uganda has embraced the UNAIDS ambitious target of ending Aids by 2030. Since our product is a candidate cure for this disease, we anticipate that the government will support our efforts in bringing this prototype to reality.

- We are a private limited liability company and are impartial to politics.
- Our directors are law-abiding and are not faced with any sanctions, be locally or internationally.
- Uganda is politically stable, there are no ongoing wars or civil unrests.
- Uganda's relationship with her neighbours is very good. There are no trade embargos imposed on her.
- The government has incorporated science in its development model, thus promoting it.
- The regulatory framework governing scientific activities is well laid out.
- Uganda welcomes foreign direct investments.

8.6.2 Economic

- Africa is home to approximately 69% of world HIV positive individuals.
- Uganda is home to approximately 1.4 million people living with HIV.
- Uganda manufactures antiretroviral drugs and supplies Eastern, Central and Southern regions of Africa.
- The incidence of cancer in Uganda is estimated at 48 individuals per 100,000.
- National prevalence of hepatitis B infection in Uganda is at 10%.
- Both HIV and cancer patients have given us good feedback on their thoughts about what we are doing.
- We do not yet know of any biotech, in Uganda or Africa as a whole, developing therapeutics for these diseases.

8.6.3 Social

- The stigma of being HIV positive has made many adults not to marry for fear of disclosing status to spouses. Such individuals, therefore, burn with sexual desires that are unmet. Having a product that cures HIV will thus bring relief to such individuals and because of the desire to gain their sexual activities they are most likely going to buy our product. Moreover, there are countries where HIV screening is done before one is allowed in. For cases of employment-related migrations, our product will offer a huge sigh of relief and this category of people will most likely buy. Those suffering from covid-19 or hepatitis B infections will have a similar behaviour towards our products in those lines of treatment.
- The psychological trauma people get when diagnosed with cancer, because it is known to be incurable in most cases, and the pain that those suffering from cancer go through, including the side effects of their various treatments, will make them try out our product.
- Our products will improve the quality of lives of those infected with HIV, hepatitis B, covid-9, or suffering from cancer, and their relatives.
- We shall create employment opportunities to both the skilled and unskilled labour force, directly and indirectly.
- Our publications will improve on the training of learners/ scientists at tertiary institutions.
- Our establishment will contribute to improvement of security in the neighbourhood of our premises.
- Our establishment will contribute to infrastructural development in our immediate neighbourhood.

8.6.4 Technological

- We are pioneers in our approach to therapeutics.
- The course of research and development will generate newer technologies that can be patented.
- Our patents will be a great source of intellectual capital.
- Our science can be adapted to meet new challenges, say an emerging disease.
- We reuse bottles of medicine to package raw materials and reagents in order to reduce on the plastic wastes released to the environment.

8.7 VRIO Framework

Parameter	Qualification	Competitive Stand
Valuable	• Both cancer and HIV have no known cure. The available treatments for cancer (chemotherapy and radiotherapy) are only effective in controlling the progression of the disease, which depends on the type and stage of cancer, and have very many undesirable side effects. ART only controls HIV by bringing down a patient's viral load to a manageable level; HIV patients, therefore, are conditioned to taking this medication for the rest of their lives. • The pain cancer patients go through, and the psycho-social trauma HIV positive individuals face will drive demand for the cures of these diseases. BertoCAN and BertoV1 will therefore be of great value to the target customers.	• We stand at a point of sustained competitive advantage because our products are projected to be well received by the target customers, are rare, the competitors cannot imitate, and we have a team with the capabilities to bring these prototypes and new products to life.
Rarity	• Our enzyme-based therapy is the first of its kind in the world and has adaptations for oral, intravenous and intramuscular administration. The only protein used commercially as a therapeutic is insulin, a hormone, and is administered intramuscularly. We are therefore pioneering/ setting a trend in the area of proteomics with enzymology being our approach. Our products are custom-built and as such cannot be found in other laboratories.	
Inimitability	• We custom-build enzymes to match genotypes of target pathogens and/ or abnormal cells. The methodology applied in the design of enzymes are unique to us because they are original concepts. Moreover, the protypes are encrypted and as such they cannot be deconstructed by competitors. Our style, therefore, cannot be copied by the competitors.	
Organization	• The technical bench of our research and development team is talented in the disciplines of biochemistry, pharmaceutical practice, and clinical practice. This will ensure the prototypes are of the desired quality and reproducible. • There is an excellent management plan to ensure acquisition and retention of all the resources necessary to bring these prototypes to life.	

8.8 Value Chain

Activities	Departments/ Functions	Description	
Primary activities	**Inbound logistics**	• Some raw materials used in our production process are locally available whereas others and equipment have to be imported. Once acquired, they will be stored appropriately to preserve quality.	Profits/ Margin
	Operations	• The prototypes are custom-built in our laboratory. The main steps include genotyping, enzyme construction, efficacy testing, and tests for safety.	
	Outbound logistics	• The prototypes will be packaged in a customized container and dispatched to the intended customer. They are built to remain stable even at 43^{o}C to ensure no value is lost because of changes in environmental temperatures during transportation or storage.	
	Sales and marketing	• Both digital and traditional media will be employed to promote the products. Our exciting publications will grant us huge presence in the scientific community for conferences and this will help us win the trust of our target customers.	
	Service	• The products will be adapted to suit the needs of the customers. • Customers will be trained on how to produce the products, correct production errors, and use it effectively.	
Support activities	**Procurement**	• The right equipment and raw materials will be made available at the right time to ensure smooth flow of work.	
	Technology development	• Our process will get automated to ensure consistence of quality and quantity of the products produced. In-house development of such technologies will generate revenue through patent rights.	
	Human resource management	• There is an excellent plan to identify the best talents, recruit, train, motivate, and retain them.	
	Firm organization	• There is an effective management plan to ensure that the right resources are acquired at the right time, deployed tactfully, and are all working in harmony to ensure that there is both **optimization** and **coordination**, which are prerequisites for increased margins/ profits of the company so that the investors are pleased and further investments are attracted.	

8.9 Porter's Five Forces

<table>
<tr>
<td><u>Power of suppliers</u>
The key raw material required is locally available and in an event of a production outside Uganda it can still be sourced within such local communities. The other raw materials that need importation have many suppliers from which they can be sourced. There is, therefore, an assurance of having a consistent supply of the required raw materials and a friendly price.
The equipment, though require importation, are one-off purchases with long shelf-lives if properly maintained and as such the suppliers cannot have a direct influence on our operations.
There are several manufacturers of packaging materials and this will make us acquire such at favourable prices that will sustain our production.</td>
<td><u>New entrants</u>
Proteomics is a rapidly growing area of biology and several biotechs have sprung up offering solutions of diverse kind. HIV has existed for now four (decades) and cancer for centuries yet the scientists failed to cruck their codes. The uniqueness of our science makes it impossible to imitate and as such our products will maintain superiority compared to rivals in an event that new entrants emerge.
Also, we shall keep updating the products so as to match the prevailing market trends (new strains/ subvariants) and such new entrants will find it very difficult to gain market share.
Besides HIV and cancer, we intend to produce medicines for other diseases, both communicable and noncommunicable, which will give us great market presence as we diversify and subsequently increase revenue.
<u>Rivalry among competitors</u>
Currently, there are no known cures for both HIV and cancer. ART used in managing HIV, and chemotherapy and radiotherapy that are used in managing cancer have to be used for a long period of time. BertoV1 and BertoCAN, therefore, will be favoured by the patients.</td>
<td><u>Power of buyers</u>
HIV and cancer have no known cures and yet there are millions of people worldwide suffering from these diseases. The trauma caused by these diseases makes the idea of a cure a "dream come true" and as such we project an overfull demand. Once the prototypes are fully developed, the production technology will be automated to ensure consistence in quality and quantity of products so as to match the demand.
The pharmaceutical industry, our target customers, will be very much interested in buying our products because they will want to remain relevant in the HIV and cancer market segment.</td>
</tr>
<tr>
<td colspan="3"><u>Threat of substitutes</u>
Our products will be constantly updated to match the current market needs. This implies that at all times they will remain relevant. Moreover, the uniqueness of our design will hinder any attempts by pirates to make close copies of the products.</td>
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9.0 Fundraising

Stages, Reasons and Target Source		
Idea	**Seed**	**Growth**
• The idea of developing therapeutics was conceived in late 2011 and by the middle of 2012 several attempts were made to verify plausibility of the various postulates. By December 2012 experimentations begun, however, the work flow was not smooth because we lacked own laboratory to operate in and as such relied on very good friends and acquaintances who were generous enough to let us use their laboratories (space, equipment and reagents). This, though kick-started our development process, was very inconveniencing in that we had to adjust to the schedules of the various laboratories. • Because of the above reason, we paused the project in 2014 and the co-founders had to take on several jobs to raise funds for the business. By the middle of 2017 we had assembled all the necessary equipment and re-started our project. • We currently have four (4) prototypes: BertoV1 for HIV; BertoCAN for cancer; BertoCOV for covid-19; and BertoHEP for hepatitis B virus. • We are now looking forward to bringing these prototypes to life.	• Bringing our prototypes to life require conducting a clinical trial on each of them. The conditions for approval to conduct a clinical trial are strict and require massive financial investment to meet them, which we the founders can no longer raise on our own and for this reason we are seeking investment. • Our first step in this direction is to upgrade the present laboratory infrastructure, and publish our science. The significance of the publications is that they will prove our concepts. For this stage, we are in need of **one hundred sixty thousand (160,000) US dollars**. • Our ideal investor will be one that is willing to walk with us in our journey to conquer the field of medical therapeutics, helping in publicity and connecting us with the key players in the industry. • We shall issue out shares in exchange for the investment.	• Once the publications are done, the next stages will involve acquiring necessary licenses for clinical trials. This entails hiring the right talents in the fields of medical and pharmaceutical practice; further upgrading the manufacturing setting to be compliant with industry regulations; insuring the trial subjects; and publicizing the work. All these require additional financing, the exact amount varying depending on the number of trial subjects and the country in which the trial will be done. This will take us to **Series A**. • This funding will also be used to register patents and trademarks. • In this stage we would wish to continue with the seed investor as the sole funder. However, if not possible for the same investor to fund this stage we shall opt for that investor with whom the seed investor feels happy to deal with. • Just as at the seed stage, shares will be traded for the funds and subsequent series will be raised depending on the needs that arise.

10.0 Exit

We have no intentions of exiting the market but rather plan to build a firepower in the biopharmaceutical industry. However, we would like to show our potential investors and shareholders how they will be able to get returns on their investments.

10.1 Biopharma Mergers and Acquisitions in 2022

Key Players in the Biopharmaceutical Industry	**Recent Exits in the Biopharmaceutical Industry**[10]
The following list is generalized, does not represent the ranking of an entity but simply presents each as an active player in the industry. 1. Amgen 2. Pfizer 3. Bristol Myers Squibb 4. Biocon 5. GSK (GlaxoSmithKline) 6. Johnson & Johnson 7. Bayer 8. Roche 9. Syngenta 10. UCB	1. Amgen acquired Horizon Therapeutics in a deal valued at $27.8 billion. 2. Pfizer bought Biohaven's calcitonin gene-related peptide (CGRP) drug franchise and the latter's approved therapy, Nurtec ODT, at $11.6 billion. 3. Pfizer acquired Global Blood Therapeutics in a deal valued at $5.4 billion. 4. Bristol Myers Squibb acquired Turning Point Therapeutics in a deal valued at $4.1 billion. 5. Amgen bought Chemocentryx at $3.7 billion. 6. Biocon Biologics bought Viatris' biosimilars at $3 billion. 7. GSK bought affinivax at $2.1 billion. 8. UCB bought Zogenix at $1.76 billion. 9. GSK bought Sierra Oncology at $1.9 billion. 10. Sumitomo Dainippon bought Myovant at $1.7 billion.

Macro Trends in the Biopharmaceutical Industry

Ernst & Young (2023) report that most biotechs and associated pharmaceutical businesses profited from the covid-19 pandemic through the sale of vaccines, therapeutics, and testing materials. However, with the waning away of this pandemic, most biopharma establishments must now focus on new strategies to raise and/ or maintain revenue. Moreover, the start of 2023 saw a landmark loss of exclusivity even; Amgen launched its first biosimilar version of AbbVie's Humira, and by the end of this year four monoclonal antibodies that generated 14 billion USD in revenue last year will also face the loss of exclusivity situation. In the next five years, 17 products that currently generate 145 billion USD in annual revenue will lose their patent protection.

In order to overturn the deficit caused by the loss of exclusivity, pharmaceutical establishments will heavily rely on the innovations of biotechs to create new products. They summarize their report by saying:

Ultimately, while biotechs must evolve their operating models due to the current changing landscape, innovation will remain the core strength of the industry and the heart of the biotech business model. The challenge of the patent cliff could be an inflection point for the industry, as biotech's innovation renaissance becomes the critical revenue driver for the wider biopharmaceutical driver. As biotechs adjust their strategies and operations to focus on their fundamentals, they must fuse their innovative energies with a greater focus on discipline and efficiency. If they do, the industry has an opportunity to become an even more essential – and resilient – component of the biopharma ecosystem.

This is exactly our mindset as we launch deep in the industry and with our level of commitment, we foresee ourselves contributing to the big events that will shake the industry.

Buying-back Shares

We intend to retain full ownership of the business and keep our brand. Following profitability, an investor that intends to leave the company will have his/ her/ their shares bought back at a mutually agreed market value so that we retain full control of the business.

Brand Survival Strategy

- As Biobert Research Group, our name embodies our key survival attribute, research. With the changing climate, economic conditions, and psychosocial behaviour change among humans, new problems are arising and these require tailored solutions to effectively deal with them.
- Whether in the field of human medicine, veterinary medicine, agriculture, environment, or industry, we are committed to developing new solutions, be therapeutics, vaccines or processes, that will meet the poised challenges while impressing our investors by generating revenue so that all our stakeholders are made happy.
- We shall nurture and attract top talents with the skills vital in our disciplines of practice and ensure that we are the destination of choice for every aspiring biological scientist in Uganda, for now, then later on worldwide. The boldness with which we are pushing our prototypes is our first step in the creation of this attractiveness and is an announcement of our presence in the industry.
- By continually refining our technologies and studying the emerging market trends, we shall tailor our products to match the new demands and diversify to offer a range of products for newer markets.

10 Top Biotechnology Innovations in 2023[11]

The ranking factors used by IN-PART to uncover the top biotechnology innovations with the biggest impact on science, medicine, engineering and agriculture are; 1) the number of requests from research and development professionals; 2) positive feedbacks from the reviewers; and 3) total number of article readers.

1. Naturally occurring biocompatible proteins for tunable proton conduction.
2. Universal plant gene modification for more efficient growth.
3. Genetically-modified fibre crops to make waterproof materials.
4. Recycling plastics with synthetic organisms.
5. New methods for controlling gene expression in agricultural biotechnology.
6. Broad range biodegradable biosurfactants.
7. New strain of *E. coli* for the synthesis of superior PHA.
8. Reproductive hormone from cows, for cows.
9. Cell-free protein production platform.
10. Genetically engineered plants to resist environmental stresses.

10.2 Biopharma Mergers and Acquisitions in 2023

Key Players in the Biopharmaceutical Industry	**Exits in the Biopharmaceutical Industry**[12]
The following list is generalized, does not represent the ranking of an entity but simply presents each as an active player in the industry. 11. Pfizer 12. Seagen 13. Bristol Myers Squibb 14. Merck 15. AbbVie 16. Biogen 17. Roche 18. Astellas 19. Reata Pharmaceuticals 20. Cerevel Therapeutics	11. Pfizer merged with Seagen in a deal worth $43 billion. 12. Bristol Myers Squibb bought Karuna Therapeutics at $14 billion. 13. Merck took over Prometheus Biosciences in a deal valued at $10.8 billion. 14. AbbVie bought Immunogen at $10.1 billion. 15. AbbVie bought Cerevel Therapeutics at $8.7 billion. 16. Biogen acquired Reata Pharmaceuticals at $7.3 billion. 17. Roche bought Telavant at $7.1 billion. 18. Astellas acquired Iveric Bio at $5.9 billion. 19. Bristol Myer Squibb bought Mirati Therapeutics in a deal worth $4.8 billion. 20. Bristol Myers Squibb acquired RayzeBio in a deal valued at $4.1 billion.

Macro Trends in the Biopharmaceutical Industry

KPMG biopharma deal trend outlook for 2023 reported that:

> The overall biopharmaceutical deal market slowed down in 2023. The main drivers of reduced deal activity lied on fewer licensing deals and strategic R&D collaborations. Several large biopharmaceutical companies face an interesting dilemma: on the one hand, many companies have publicly stated ambitions to increase growth while also improving near- and long-term competitive position across specific therapeutic categories in their pipeline, while other biopharmaceutical companies are facing significant patent cliffs in 2025-2027 period. The need to build pipelines inorganically is changing for this latter category. In recent years, oncology has been the most therapeutic area of deal making; however, in 2022 from a product acquisition standpoint, assets with the potential for multiple indications (non-oncology) outperformed oncology deals. While the demand for adding new oncology assets to pipeline portfolios remains a top priority for many large to mid-sized pharmaceutical companies, the availability of quality assets has become increasingly scarce because the competition for these assets has largely consumed all the quality mid- to late-stage oncology assets from the global pipeline. The only way to access quality mid- to late-stage oncology assets is through co-promotions or a very large acquisition. This gap has caused other therapeutic areas to attract attention. The data for 2022 demonstrates this trend with deals focused on ophthalmology, neurology, and immunology. Also, cell and gene therapy, which mainly focus on rare diseases, have received significant deal flow in the biopharmaca industry.[13]

10.3 Biopharma Mergers and Acquisitions in 2024

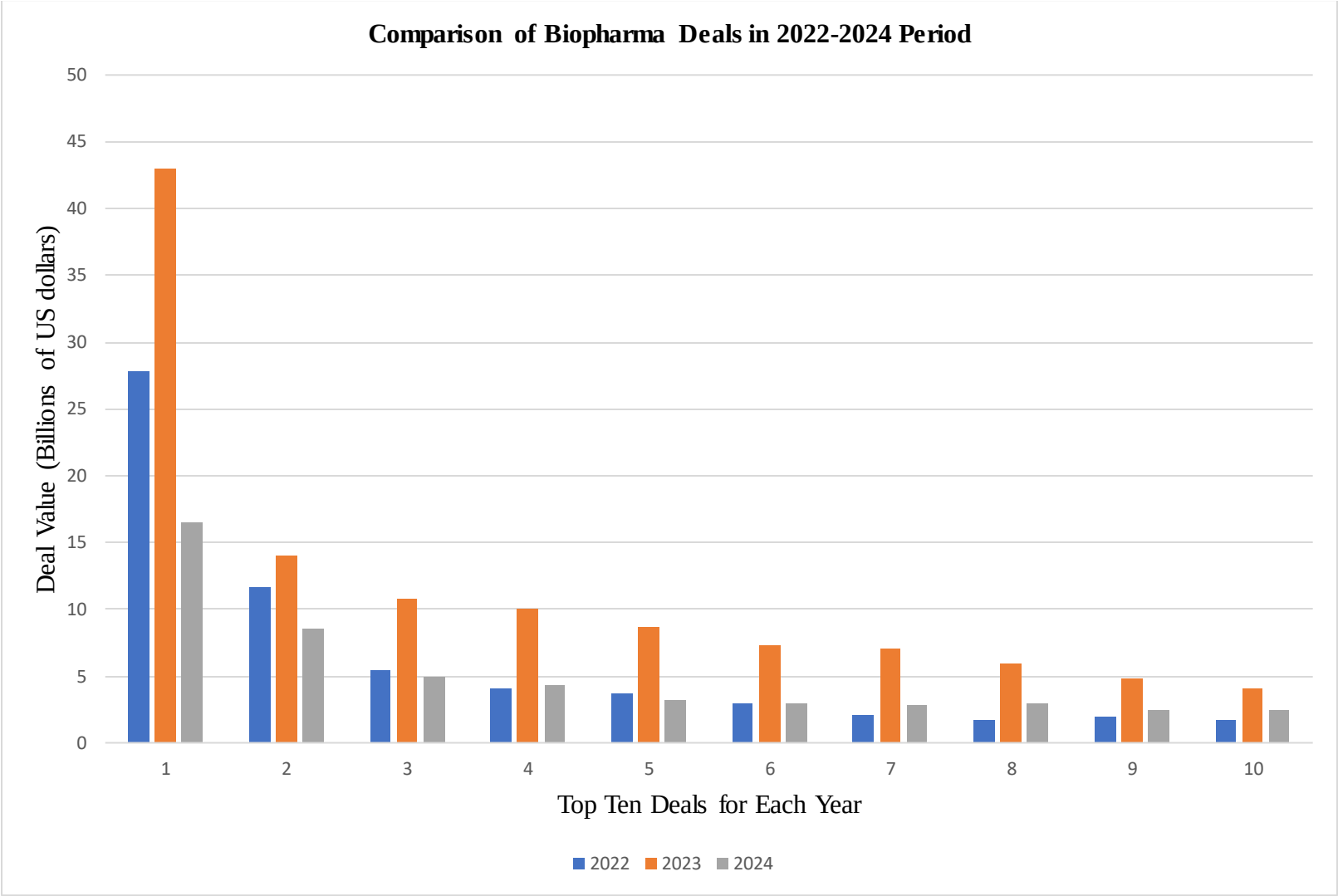
Key Players in the Biopharmaceutical Industry	**Exits in the Biopharmaceutical Industry**[14]
The following list is generalized, does not represent the ranking of an entity but simply presents each as an active player in the industry. 21. Novo Holdings 22. Clayton, Dubilier and Rice 23. Vertex Pharmaceuticals 24. Gilead Sciences 25. Eli Lilly 26. Merck 27. Roquette 28. Norvatis 29. Lundbeck 30. Ono Pharmaceutical	21. Novo Holdings bought Catalent, a CDMO giant, at $16.5 billion. 22. Clayton, Dubilier and Rice bought a 50% controlling stake in Sanofi's consumer health business, Opella, at 8 billion euros. 23. Vertex Pharmaceuticals bought Alpine Immune Sciences at $4.9 billion. 24. Gilead Sciences bought CymaBay Therapeutics in a deal worth $4.3 billion. 25. Eli Lilly bought Morphic Therapeutics at $3.2 billion. 26. Merck bought EyeBio at $3 billion. 27. Roquette bought International Flavors & Fragrance's pharma solution business at $2.85 billion. 28. Novartis bought MorphoSys' BET inhibitor (pelabresib) and EZH2/EZH1 proteins at 2.7 billion euros. 29. Lundbeck bought Longboard Pharmaceuticals at $2.5 billion. 30. Ono Pharmaceutical bought Deciphera Pharmaceuticals in a deal valued at $2.4 billion.

Macro Trends in the Biopharmaceutical Industry

PwC (2025) report says:

> Across the health ecosystem, value creation is moving in the direction of prevention, with more focus on addressing the risk factors of health decline; personalization, with data-driven, customized treatments based on factors like genetics and behavior; prediction, with active analysis of well-being and early intervention to improve health outcomes and point of care, with more accessible and convenient settings for delivery of care. Macro and micro forces are driving a surge in scientific breakthroughs, while innovations and the pace of business is accelerating. Amid these disruptive forces and the ongoing value creation challenges facing the sector, it's no wonder CEOs are questioning whether their business models are built to last. Artificial Intelligence has transformed how work is conducted and how decisions are made. Results are tailored to include better predictions, faster actions and greater outcomes. AI can help power the organizations of the future.[15]

10.4 Trends in Biopharma Deals



Source: Graph has been plotted using deal figures for each year, referred to earlier.

11.0 Workplan and Budget

Order	**1**	**2**	**3**	**4**	**5**
Stage	Fundraising	Refurbishing the current laboratory infrastructure	Publication of the scientific work	Fundraising	Clinical trials
Activities	• Writing documents for investors (executive summary, business plan, pitch deck, and pro-forma statement). • Creating a website for purposes of marketing. • Pitching the business at an angel investment network.	• Connecting to the national power grid. • Connecting to the national water supply. • Acquiring appropriate furniture and fittings. • General brick masonry. • Constructing incinerator. • Fencing the premise. • Accreditation.	• Local registration of trademarks. • Purchase of laboratory consumables. • Repeating experiments where required. • Submission of manuscripts for peer review.	• Writing documents for investors (executive summary, business plan, pitch deck, and pro-forma statement). • Updating the website for purposes of marketing. • Pitching the business at an angel investment network.	• Hiring talents with the necessary skills. • Establishing a good manufacturing practice (GMP) compliant facility. • Establishing partnerships with key players. • Applying for clearance to conduct clinical trials. • Recruiting clinical trial participants. • Publishing results of clinical trials.
Cost (US dollars)		160,000			
Time (Months)		12			

Note: This workplan is simply to guide our potential investors on the steps that the business will have to take in order to develop the prototypes into fully approved drugs ready for human consumption. The timelines, therefore, are controlled by several factors and as such can only be definite subject to the availability and level of funding. Also, clinical trials stage is much more detailed than presented here. The funding required at this moment is specifically for stages 2 and 3, there is a possibility of conducting clinical trials in collaboration with individuals/ entities in various geographical locations; therefore, a detailed work chart can only be made once all required factors have been identified and are in place.

12.0 The Team

<table>
<tr><th colspan="2">Current Management</th></tr>
<tr><td><u>Robert MIJUMBI</u>
A graduate of bachelor of science technology (biology) - Kyambogo University - is our chief executive officer, chief scientist, co-founder and director. His eleven years of laboratory practice has yielded expertise in proteomics, nucleic acid techniques, and general research. Currently has one hundred thirty-four manuscripts to publish in biological science disciplines that cut across biochemistry, bacteriology, virology, histopathology and physiology, and chemistry. Designing enzymes for specific therapeutic purposes, with adaptations for various routes of administration, is a skill he prides in.
He has been in the education sector for a cumulative total of three years now and has developed a lot of skill and experience in people training, evaluation and management; organizational management; project design, implementation, monitoring, and evaluation.
He is fully acquainted with the regulatory frameworks, locally and internationally, that govern the development of biopharmaceutical products, right from performing laboratory experiments to conducting clinical trials on human subjects.
He is a pragmatic leader that approaches situations with open-mindedness and calmness, which results in effective solutions raised for whatever problems arise; and a good reader of environmental trends, which leads to better planning and consequently better strategies that are vital not just for beating the competition but for long term survival of the business.
In 2020 when he was arrested over the claims of these prototypes, he made it on record that the claims could be verified scientifically. This drew a lot of support from other scientists and sympathizers.</td><td><u>Samuel BYENKYA</u>
He is our co-founder and director. He holds a post-graduate diploma in information systems management – Uganda Management Institute, diploma in records keeping and information management – Management Training and Advisory Centre, and Bachelor of Library and Information Science – Uganda Christian University.
His now thirteen years of experience in records management makes him a valuable asset as an archivist, we trust him to handle all aspects of records generated in the course of our work.
Also, because of the numerous administrative roles he has held in the private sector, we shall benefit immensely from this experience as we scale up our operations.</td></tr>
<tr><th colspan="2">Technical Bench</th></tr>
<tr><td colspan="2">Top talents in the fields of laboratory, clinical and pharmaceutical practices have already been identified and are ready to deploy once the appropriate time approaches where the business will have the finances to sustain their employment.
The management and members of the technical bench have an excellent relationship that spans at least 10 years and as such there is cohesion in the team, which means a healthy team and as such desired performance, a key attribute for success. Moreover, the co-founders are biological brothers.</td></tr>
</table>

REFERENCES

1. UNAIDS (2022). Global HIV and AIDS Statistics-Fact Sheet. Available at https://www.unaids.org/en/resources/fact-sheet (Accessed 18th May 2023)

2. Apoorva Mandavilli. "The 'London Patient,' Cured of HIV, Reveals His Identity." The New York Times, 29th November 2020. Available at https://www.nytimes.com/2020/03/09/health/hiv-aids-london-patient-castillejo.html (Accessed 17th May 2023)

3. Mayo Clinic (2022, July 20). *Bone marrow transplant.* Mayo Clinic. Available at https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/about/pac-20384854 (Accessed 18th May 2023)

4. NIH (2023, May 26). *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV: Adverse Effects of Antiretroviral Agents*. NIH. Available at https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/adverse-effects-antiretroviral-agents (Accessed 27th June 2023)

5. WHO (2022, June 24). *Hepatitis B*. WHO. Available at https://www.who.int/news-room/fact-sheets/detail/hepatitis-b (Accessed 27th June 2023).

6. Pan-African Daily TV (May 11, 2021). *Must Watch! Prof. PLO Lumumba with Malawian President Lazarus Chakwera; Talks about the New Africa* [Video]. YouTube. Available at https://www.youtube.com/watch?v=B6Cusm8DoFg (Accessed 26th July 2023). Timestamp 10:29

7. Make Africa Great (June 23, 2023). *Breaking: African Leaders' Reaction in France, Ramaphosa Told Macron "Africa We Are Not Beggars!"* [Video]. YouTube. Available at https://www.youtube.com/watch?v=KROVtwrjzsY (Accessed 26th July 2023). Timestamp 4:06

8. WION (May 30, 2023). *Africa: Uganda Enacts Tough Anti-LGBTQ Law, Move Draws Western Condemnation* [Video]. YouTube. Available at https://www.youtube.com/watch?v=tQqnPPNStek (Accessed 26th July 2023).

9. Morris, M. (2025, February 6). *Trump freezes funds and Africa counts the costs: As programmes pause, health officials and programme leaders wait for the fallout*. Nature Africa. Available at https://www.nature.com/articles/d44148-025-00031-6 (Accessed 1st April 2025)

10. Sagonowsky, E., Dunleavy, K., Kansteiner, F., Liu, A. and Becker, Z. (2023, January 30). *The Top 10 Biopharma M&A Deals of 2022*. Fierce Pharma. Available at https://www.fiercepharma.com/pharma/top-10-ma-deals-2022 (Accessed 20th June 2023)

11. Wilkinson, F. (2023, February 28). *10 Top Biotechnology Innovations 2023*. In-part. Available at https://in-part.com/blog/top-biotechnology-innovations/ (Accessed 27th June 2023)

12. Kansteiner, F., Becker, Z., Liu, A., Dunleavy, K., and Sagonowsky, E. (2024, February 15). *The Top 10 Biopharma M&A Deals of 2023*. Fierce Pharma. Available at https://www.fiercepharma.com/special-reports/top-10-biopharma-ma-deals-2023 (Accessed 29th March 2025)

13. KPMG (2023). *Biopharma deal trends outlook for 2023: Near-term headwinds, with possible run on small biotechs on the horizon*. KPMG. Available at https://kpmg.com/kpmg-us/content/dam/kpmg/pdf/2023/12800-biopharma-deal-trends-outlook.pdf (Accessed 29th March 2025)

14. Kansteiner, F., Becker, Z., Liu, A., Dunleavy, K., and Sagonowsky, E. (2025, January 13). *The Top 10 Biopharma M&A Deals of 2024*. Fierce Pharma. Available at https://www.fiercepharma.com/pharma/top-10-biopharma-ma-deals-2024 (Accessed 29th March 2025)

15. PwC (2025). *Next in pharma 2025: The future is now*. PwC. Available at https://www.pwc.com/us/en/industries/pharma-life-sciences/pharmaceutical-industry-trends.html (Accessed 29th March 2025)

16. Ernst & Young (2023). *Beyond Borders: EY Biotechnology Report 2023*. Ernst & Young. Available at https://www.ey.com/en_us/life-sciences/beyond-borders#marketoform (Accessed 20th June 2023)

17. Uganda Aids Commission (2022). Fact Sheets on HIV & AIDS Epidemic in Uganda. Available at https://uac.go.ug/media/attachments/2023/01/12/hiv-aids-factsheet-2022.pdf (Accessed 18th May 2023)

18. Asasira, J., Lee, S., Tran, TXM., *et al.* (2022). Infection-related and lifestyle-related cancer burden in Kampala, Uganda: projection of the future cancer incidence up to 2030. BMJ Open 2022; 12: e056722. Doi: 10.1136/ bmjopen-2021-056722