

# **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 enzymebased 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 well. be communicable as 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 25<sup>th</sup> 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 **Seventy Thousand (70,000) US dollars** to 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. 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 25<sup>th</sup> 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<sup>1</sup>. 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<sup>2</sup>. 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<sup>3</sup>. 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<sup>4</sup>.

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<sup>5</sup>. 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.

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

# THE LOGICAL FRAMEWORK MATRIX

Output						
Polished proposals ar	d					
concept notes.						
• List of potential						
investors and/ or						
funders.						
Specific objective 2: To pub	lish our scientific findings on the cure proto	types.				
Approach	Objectively Verifiable Indicators (OVI)	Means of Verification (MOV)	Questions/ Assumptions			
<ul> <li>Activities         <ul> <li>Writing manuscripts.</li> <li>Identifying suitable journals for specific manuscripts.</li> <li>Submitting manuscript for peer review and publication.</li> <li>Marketing the published papers.</li> </ul> </li> <li>Input         <ul> <li>Finances (article processing charge, internet).</li> <li>Time.</li> <li>Computer and related software and hardware of the processing charge of the procese of the proces of the processing charge o</li></ul></li></ul>	<ul> <li>Number of peer-reviewed articles published.</li> <li>Public perception on our publications.</li> </ul>	<ul> <li>Level of coverage given by the mainstream media channels.</li> <li>The trending position on social media.</li> <li>The lifespan on social media.</li> <li>Number of new followers acquired on social media.</li> <li>Number of inquiries from the scientific community and the academia.</li> </ul>	<ul> <li>For a reasonably good period, no event will occur that will take us out of the media spotlight.</li> <li>We shall enjoy media presence both locally and internationally.</li> </ul>			
Specific objective 3: To acq	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	Means of Verification (MOV)	Questions/ Assumptions
<ul> <li>Activity <ul> <li>Identifying a suitably located piece of land.</li> <li>Purchasing the identified piece of land.</li> <li>Identifying an engineering contractor and negotiating a contract with the firm.</li> <li>Constructing and furnishing the premise.</li> <li>Securing the premise.</li> <li>Procuring and installing equipment.</li> </ul> </li> <li>Input <ul> <li>Finances (movements, internet, phone calls, legal fees, taxes).</li> <li>Time.</li> </ul> </li> </ul>	<ul> <li>Legally binding contracts signed.</li> <li>Possession of the land.</li> <li>Infrastructural development.</li> </ul>	<ul> <li>Land title.</li> <li>Physical inspection.</li> <li>Equipment inventory.</li> </ul>	<ul> <li>Finances will be available for every activity.</li> <li>The engineering contractor will do their job with integrity.</li> <li>Natural calamity, particularly earth quake, will not jeopardize our efforts.</li> <li>The regulatory authorities shall give as the necessary approvals.</li> </ul>
Specific objective 4: To develop	cheap and environmentally friendly me	thod(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.	<ul> <li>Number of new peer-reviewed publications.</li> <li>Number of new patents registered.</li> </ul>	<ul> <li>Laboratory reports.</li> <li>Level of coverage given by the mainstream media channels.</li> </ul>	• For a reasonably good period, no event will occur that will take us

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

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

# 6.1 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.

# 6.1.1 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.



# 6.1.2 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).

# 6.2 Segmentation and Targeting

# 6.2.1 HIV Segment

	Criteria	Target Group	Reason
Psychographic	Commercial sex workers	Both sex workers and their clients.	<ul> <li>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.</li> </ul>
	Homosexuals	All.	<ul> <li>In areas where gay sex is criminalized or considered a cultural abomination, gay mer 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.</li> </ul>
	Users of psychoactive injectable drugs	All.	<ul> <li>Sharing injection needles by drug addicts is one of the documented forms of HIV transmission. This is a market that BertoVI will tap in.</li> </ul>
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 car 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.

# 6.2.2 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.

6.2.3 Buyer Personas and Em
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Category	Persona	Empathy
	Angela is 23-45 years old. She is a professional	Angela's mother was infected with HIV by an unfaithful husband. At the time
	corporation that has offices in the major cities of	possible infection and as such she was born infected.
	each continent. She works Monday-Friday and	
	sometimes works remotely at home. She spends	While in a boarding school, she had to hide herself from peers while taking
	aspects of her life is always shared on X,	the medication had very undesirable side effects that affected her concentration
	Facebook, Instagram, and once in a while,	at school. Since her medical counsellor encourages her to take ART regularly
	YouTube.	as prescribed, Angela has come to a conclusion that HIV infection is a "life sentence".
	Her peers perceive her to be a happy person and	
	many admire her lifestyle, career achievements	Prior to graduation, her peers set marriage goals and most have either attained
>	and amolitions.	beautiful and a practicing professional, is still single: she turns away every man
H		that approaches her for a relationship because she fears disclosing her HIV
		status and being rejected. Whereas her mother is aware of her situation, other relatives cannot figure out why a beautiful woman is not yet married.
		Recently, she got a promoted by her employer. Her new role entails
		supervising overseas operations and as such she must travel to various
		cannot get allowed into because of her HIV status.
		Angela has had news of some HIV patients getting cured of the infection after
		bone marrow transplant, however, the procedure is so risky that her medical
		counsellors have discouraged; moreover, it is very expensive. She prays and hopes that one day there will be a solution to her predicament.
	Source: Marriage Confessions (2023); The Orion	Production (2023); and Relebogile Mabotja (2021a and 2021b)

	Meet Bruce, an only child of his mother. He	One day Bruce woke up feeling unusually fatigued, headache then followed					
	recently celebrated his 16 <sup>th</sup> birthday with a party	suit. A visit to the doctor got him pain killers that relieved him of the headache,					
	attended by childhood friends and school mates.	however, these symptoms persisted. One day his doctor ordered for an MRI					
	He is a jolly young man liked by many of his	scan, which revealed a tumor in his brain.					
	peers at school. He is a sportsman with huge						
	followings on social media, where he makes	Despite several counselling sessions, Bruce had to cope up with the fact that					
	regular posts of his games.	his sporting career needed a forced break and that he would now have to get					
		on chemotherapy, which has several documented undesirable side effects.					
	He is single and plans to move out of his	Moreover, he kept imagining his mother's sadness watching him undergo this					
	mother's house once he turns 18 years old then	treatment, which stressed him further.					
	marry. At this point he anticipates he will now be						
	playing in a professional league.	Once treatment started, he experienced firsthand the side effects of					
		chemotherapy and because of stress he stayed away from social media, which					
		left his friends asking "what's up with Bruce?" His friends visited him at home					
er		and noticed an unusual lack of hair on his head, sunken eyes and a slimmer-					
anc		than-usual Bruce. He could no longer hide this problem and gave an					
Ü		explanation for his absence from school and social media. The news of his					
		disease went viral among peers and stressed him more because the messaging					
		gave an impression that his days were numbered.					
		As the disease progressed, he got a ray of hope when one specialist doctor					
		recommended bone marrow transplant. This surgical procedure successfully					
		took place and within a few weeks Bruce was relieved of his pains and resumed					
		normal life. However, 6 months later he woke up with the symptoms more					
		severe than the ones he had before. A visit to his doctor revealed the cancer					
		was wide spread and two options were presented to him, either undergo a risky					
		surgical procedure that would grant him a few more months of life or give up					
		and face death. Being a fighter, he chose the surgical procedure, which					
		lengthened his life for a few more months.					
Source: BBC (2021); The New York Times (2017); The Guardian (2019); Yomiuri Telecasting Corporation (2							
	Public Broadcasting (2019); and NorthDevon Hospice (2021).						

	Meet Jon, a 55-year-old long distance truck driver. He is married and is a father of 3 youthful children, 2 sons and 1 daughter. Because of his job, he is often far away from home and utilizes social media to connect with family and friends. He is always meeting new people at each new location he gets to and his truck carries back commodities from various sources.	When news broke out that there was a new disease called covid-19, Jon thought his location was spared. However, one morning he felt weak as he carried on his routine and his symptoms included those said to be of covid-19. A visit to a nearby clinic proved to be his best bet at life as his symptoms worsen on arrival and was immediately put in the ICU. Laboratory results indicated he was positive for covid-19 and as such was isolated from other patients. After a few weeks, he recovered from the disease but had to isolate from family and friends for fear of either infecting them or being re-infected. This isolation, coupled with loss of man-hours at work that meant reduced pay, took a heavy toll on Jon.
Covid-19		In about 100 days of the covid-19 disease, certain pharmaceutical manufacturing companies announced their vaccine candidates and regulatory approvals were fast-tracked for their clinical trials. Whereas the companies provided data that showed their vaccines were effective, there were serious ethical issues reported against some of them. However, the government made vaccination against the disease mandatory for entities that had a lot of employees and also a travel requirement. Given the nature of Jon's work, he either had to take the jab or quit his only source of livelihood.
		Jon took the jab but had to endure severe side effects, which lasted more than 6 months; some individuals, who took the same brand of the vaccine as Jon, even died. As time passed, scientists reported that vaccine protection only lasted 6 months and that to be safe the fully vaccinated persons needed booster vaccinations. Moreover, new strains of the covid-19 virus emerged and are still emerging, and the vaccines need to be updated for each variant. This makes Jon feel is an experimental rat and fears for his safety and that of his family and friends.
	Source: MedSimplified (2021); Hawan State Dep MedCram (2022 & 2023): The Hill (2022 & 2023)	B): Anderson Podiatry Center (2022); and Wayne Goss (2021)

Hepatitis B	Please refer to HIV persona and empathy.

6.3	The	Com	petition
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COV	COVID-19 Treatment									
No.	Parameter		Product							
		BertoCOV	Paxlovid	Lagevrio	Remdesivir	Comirnaty	mRNA-	ChAdOx1-S	Ad26.COV2.S	CoronaVac
						(Pfizer)	1273	(Oxford)	(Janssen)	(Sinovac)
							(Moderna)			
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	Twice daily	3-10 days	2 doses in 4	2 doses in 4	2 doses in 4	Single	2 doses in 4
			for 5 days	for 5 days		weeks	weeks	weeks		weeks
9	Need for	No	Yes	Yes	Yes					
	vaccine									
10	Need for		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	vaccine									
	booster									
11	Virus rebound	No								
12	Efficacy		89%	30%		95%	94.1%	76%	94%	65%
13	Treatment	$\leq$ 3 minutes	> 10	> 10	30 minutes	$\geq$ 5 minutes	$\geq$ 5 minutes	$\geq$ 5 minutes	$\geq$ 5 minutes	$\geq$ 5 minutes
	duration		minutes	minutes	to 2 hours					
14	Variants	All								
15	Age restriction	None	$\geq$ 12 years	$\geq$ 65 years	$\geq$ 65 years	$\geq$ 5 years	$\geq$ 12 years	$\geq$ 18 years	$\geq$ 18 years	$\geq$ 18 years
16	Eligibility	All	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity	Comorbidity

17	Exclusion		Kidney/	Pregnancy,		Severe	Severe	Severe	Severe allergy	Severe	
			liver	children,		allergy to	allergy to	allergy to	to components	allergy to	
			disease,	and nursing		components	components	components	of vaccine,	components	
			organ	individuals.		of vaccine.	of vaccine.	of vaccine.	and body	of vaccine,	
			transplants.						temperature $\geq$	acute	
									38.5°C.	illness, and	
										temperature	
										$\geq$ 38.5°C.	
18	Side effects		Altered	Diarrhoea,	Nausea/	Myocarditis/	Fever,	Thrombosis	Thrombosis	Fatigue,	
			taste,	nausea/	vomiting,	pericarditis,	chills,	and	and Guillain-	diarrhea,	
			diarrhea,	vomiting,	back pain,	fever, chills,	fatigue, and	Guillain-	Barre	muscle pain,	
			muscle	and	head ache,	fatigue, and	head ache.	Barre	syndrome are	and pain at	
			ache, and	dizziness.	itching,	head ache.		syndrome	suspected.	injection	
			increased		flushing,			are		site.	
			blood		dark urine,			suspected.			
			pressure.		chest						
					tightness,						
					and light-						
					coloured						
					stool						
19	When required	Any time of	Within 5	Within 5	Severe	Before	Before	Before	Before	Before	
		infection	days of	days of	disease and	infection/	infection/	infection/	infection/	infection/	
			symptom	symptom	comorbidity.	after	after	after	after recovery	after	
			onset.	onset, and		recovery	recovery	recovery	from the	recovery	
				non-severe		from the	from the	from the	disease.	from the	
				disease.		disease.	disease.	disease.		disease.	
20	Recovery	2 days after									
	period	treatment									
HIV	HIV Treatment										
No.	Parameter				Product						
L		BertoV1			Antiretroviral Therapy (ART)			Bo	Bone Marrow Transplant		
1	Nature of API	Polypeptide			Other organic						
2	Curative	Yes			No	No					
3	Duration	Single dose			Lifetime	Lifetime			Once/ varies		

4	Point of use	Unrestricted	Un	Unrestricted		Clinic		
5	Administration	Oral		Oral			Surgical	
6	Recovery time	4 weeks						
7	Smell	Odourless	Un	npleasant				
8	Taste	Slightly salty	De	epends on l	brand/ Constituents			
9	Side effects			<ul> <li>Hypersensitivity reaction</li> <li>Increase in cholesterol</li> <li>Risk of heart disease</li> <li>Nausea</li> <li>Vomiting</li> <li>Abdominal pain</li> <li>Peripheral neuropathy</li> <li>Pancreatitis,</li> <li>Lactic acidosis,</li> <li>Fat loss in arms, legs, or face</li> <li>Skin rash</li> <li>Darkening of the skin of palms/ soles</li> <li>Kidney and bone damage</li> <li>Weight gain</li> </ul>			<ul> <li>Death</li> <li>Infertility</li> <li>Cataract</li> <li>New cand</li> <li>Organ da</li> <li>Graft-ver</li> <li>Infections</li> <li>Graft fail</li> </ul>	zers mage rsus-host disease s ure
HEP	PATITIS B Treat	tment (please refer to the H	IV treatment comparis	son, Bertol	HEP is akin to that)			
CAN	ICER Treatment	t						
No.	Parameter	Product						
		BertoCAN	Immunotherapy	7	Chemotherapy	Ra	diotherapy	Bone Marrow transplant
1	Nature of API	Polypeptide	Other organic/ cells	Oth	ner organic			
2	Administration	Oral	Intramuscular	Ora	al/ intravenous	Topical		Surgical
3	Point of use	Unrestricted	Clinic	Clir	nic	Clinic		Clinic
4	Curative	Yes	Depends on type/ sta	age Dep	pends on type/ stage	Depends	on type/ stage	Depends on type/ stage
5	Stage of	All	Varies	Var	ries	Varies		Varies
	effectiveness							
6	Type of cancer	All	Some	All		Some		Some

8       Smell       Odourless       Dependent on drug       Image: Construction of the provided in the proves of the provided in the provid	7	Recovery time	4 weeks				
9       Taste       Tasteless       Dependent on drug       Increasing dietary fibre intake improves effectiveness.       Dependent on drug       Increasing dietary fibre intake improves effectiveness.       Increasing dietary fibre being sick       Infibre Diarrhoea       Infections         11       Side effects       Infections       Infections       Infections       Infections       Infections         11       Side effects       Infections       Infections       Soreness of mouth       Infections       Infections       Infections         11       Fatigue       Pain at injection site       Infections       Infections       Stiffening of gioints and muscles       Infections       Infections         11       Fatigue       Pain at injection site       Pain at injection site       Infections       Infectility issue	8	Smell	Odourless		Dependent on drug		
10       Special requirement       None <ul> <li>Increasing dietary fibre intake improves effectiveness.</li> </ul> <ul> <li>Side effects</li> <li>Chills</li> <li>Localized blisters</li> <li>Constipation</li> <li>Coughing</li> <li>Coughing</li> <li>Loss of appetite</li> <li>Headache</li> <li>Infections</li> <li>Stiffening of joints and muscles</li> <li>Infections</li> <li>Stiffening of swallowing</li> <li>Sickliness</li> <li>Infections</li> <li>Infections</li></ul>	9	Taste	Tasteless		Dependent on drug		
<ul> <li>Faigle</li> <li>Consistence</li> <li>Localized blisters</li> <li>Constipation</li> <li>Loss of appetite</li> <li>Headache</li> <li>Icching</li> <li>Icching<!--</th--><th>10</th><th>Special requirement</th><th>None</th><th><ul> <li>Increasing dietary fibre intake improves effectiveness.</li> </ul></th><th>• Entique</th><th>• Diambooo</th><th>• Dooth</th></li></ul>	10	Special requirement	None	<ul> <li>Increasing dietary fibre intake improves effectiveness.</li> </ul>	• Entique	• Diambooo	• Dooth
Tuigue	11	Side effects		<ul> <li>Chills</li> <li>Localized blisters</li> <li>Constipation</li> <li>Coughing</li> <li>Loss of appetite</li> <li>Headache</li> <li>Itching</li> <li>Fever</li> <li>Diarrhoea</li> <li>Fatigue</li> <li>Pain at injection site</li> </ul>	<ul> <li>Failgue</li> <li>Feeling and being sick</li> <li>Loss of appetite</li> <li>Anaemia</li> <li>Hair loss</li> <li>Soreness of mouth</li> <li>Infections</li> <li>Bruising and bleeding</li> </ul>	<ul> <li>Diarmoea</li> <li>Loss of hair</li> <li>Soreness, dryness, reddening, and darkening of skin</li> <li>Stiffening of joints and muscles</li> <li>Difficulty in swallowing</li> <li>Sickliness</li> <li>Impaired sexual life</li> <li>Infertility issues</li> <li>Fatigue</li> </ul>	<ul> <li>Death</li> <li>Infertility</li> <li>Cataract</li> <li>New cancers</li> <li>Organ damage</li> <li>Graft-versus-host disease</li> <li>Infections</li> <li>Graft failure</li> </ul>

**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.

### **6.4 Positioning of Products**

# **6.4.1 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.

#### 6.4.2 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.



Downturn

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

# 6.4.3 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.





**6.4.4 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.

# 6.5 SWOT and Risk Analyses

Strengths	Weaknesses	Opportunities	Threat
<ul> <li>Prototypes</li> <li>Single dose, one-off treatment.</li> <li>Quick acting, results within 28 days (2 days for covid-19).</li> <li>Negligible, if any, side effects.</li> <li>Tasteless.</li> <li>Odourless.</li> <li>Easy to consume.</li> <li>Easy to store.</li> <li>Long shelf life.</li> <li>We are pioneers in this science.</li> <li>Potential customers like what we are doing and are eagerly waiting for the products.</li> </ul> Personnel <ul> <li>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<sup>6</sup>. 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.</li> <li>Technically gifted staff.</li> <li>Good understanding of the business environment.</li> <li>The co-founders are biological brothers.</li> <li>The co-founders and other key staff have known each other for at least 9 years.</li> </ul>	Drugs are yet to be clinically tried for approval. Lack own premises. Financially handicapped. Lack global representation.	<ul> <li>Currently there are no known cures for HIV, cancer, hepatitis B, and covid-19, thus no competitor in the market.</li> <li>Over 38.4 million HIV positive individuals worldwide, a ready market to tap.</li> <li>Over 19 million cancer patients worldwide, another ready market to tap.</li> <li>296 million hepatitis B positive individuals, a massive market to explore.</li> <li>Covid-19 is a threat to the entire world population, an immensely huge market to explore.</li> <li>New technologies will generate revenue through patent rights.</li> <li>Science can be adapted to generate solutions for other diseases, creating new markets.</li> </ul>	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?

### 6.6 PEST Analysis

### 6.6.1 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<sup>7</sup>. 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<sup>8</sup>. 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 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<sup>9</sup>. 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.
- 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.

### 6.6.2 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.

# 6.6.3 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.

# 6.6.4 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.

<b>6.7 VRIO</b>	Framework
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Parameter	Qualification	Competitive Stand	
Valuable	<ul> <li>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.</li> <li>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.</li> </ul>	• 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	
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.	and new products to life.	
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	<ul> <li>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.</li> <li>There is an excellent management plan to ensure acquisition and retention of all the resources necessary to bring these prototypes to life.</li> </ul>		

Activities	<b>Departments/ Functions</b>	Description		
	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.		
es	Operations	• The prototypes are custom-built in our laboratory. The main steps include genotyping, enzyme construction, efficacy testing, and tests for safety.		
ary activiti	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°C to ensure no value is lost because of changes in environmental temperatures during transportation or storage.		
Prim	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	<ul> <li>The products will be adapted to suit the needs of the customers.</li> <li>Customers will be trained on how to produce the products, correct production errors, and use it effectively.</li> </ul>		
	Procurement	• The right equipment and raw materials will be made available at the right time to ensure smooth flow of work.		
ivities	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.		
ort act	Human resource management	• There is an excellent plan to identify the best talents, recruit, train, motivate, and retain them.		
Suppo	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 <b>optimization</b> and <b>coordination</b> , which are prerequisites for increased margins/ profits of the company so that the investors are pleased and further investments are attracted		

### 6.8 Value Chain

# **6.9 Porter's Five Forces**

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

• 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.

7.0 Fundraising	ising	ndr	Fu	.0	7
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Stages, Reasons and Target Source					
<u>Idea</u>	Seed	Growth			
• The idea of developing therapeutics was	• Bringing our prototypes to life	• Once the publications are done, the			
conceived in late 2011 and by the middle	require conducting a clinical trial on	next stages will involve acquiring			
of 2012 several attempts were made to	each of them. The conditions for	necessary licenses for clinical trials.			
verify plausibility of the various	approval to conduct a clinical trial	This entails hiring the right talents in			
postulates. By December 2012	are strict and require massive	the fields of medical and			
experimentations begun, however, the	financial investment to meet them,	pharmaceutical practice; further			
work flow was not smooth because we	which we the founders can no longer	upgrading the manufacturing setting to			
lacked own laboratory to operate in and	raise on our own and for this reason	be compliant with industry regulations;			
as such relied on very good friends and	we are seeking investment.	insuring the trial subjects; and			
acquaintances who were generous	• Our first step in this direction is to	publicizing the work. All these require			
enough to let us use their laboratories	upgrade the present laboratory	additional financing, the exact amount			
(space, equipment and reagents). This,	infrastructure, and publish our	varying depending on the number of			
though kick-started our development	science. The significance of the	trial subjects and the country in which			
process, was very inconveniencing in	publications is that they will prove	the trial will be done. This will take us			
that we had to adjust to the schedules of	our concepts. For this stage, we are	to <b>Series A</b> .			
the various laboratories.	in need of seventy thousand	• This funding will also be used to			
• Because of the above reason, we paused	(70,000) US dollars.	register patents and trademarks.			
the project in 2014 and the co-founders	• Our ideal investor will be one that is	• In this stage we would wish to continue			
had to take on several jobs to raise funds	willing to walk with us in our	with the seed investor as the sole			
for the business. By the middle of 2017	journey to conquer the field of	funder. However, if not possible for the			
we had assembled all the necessary	medical therapeutics, helping in	same investor to fund this stage we			
equipment and re-started our project.	publicity and connecting us with the	shall opt for that investor with whom			
• We currently have four (4) prototypes:	key players in the industry.	the seed investor feels happy to deal			
BertoV1 for HIV; BertoCAN for cancer;	• We shall issue out shares in	with.			
BertoCOV for covid-19; and BertoHEP	exchange for the investment.	• Just as at the seed stage, shares will be			
for hepatitis B virus.		traded for the funds and subsequent			
• We are now looking forward to bringing		series will be raised depending on the			
these prototypes to life.		needs that arise.			

### 8.0 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 should they desire to leave at any given time.

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

### 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.

W Fo his re

Buying-back Shares	<b><u>10 Top Biotechnology Innovations in 2023</u></b> <sup>11</sup>
e intend to retain full ownership of the business and keep our brand.	The ranking factors used by IN-PART to uncover the top
llowing profitability, an investor that intends to leave the company will have	biotechnology innovations with the biggest impact on
s/ her/ their shares bought back at a mutually agreed market value so that we	science, medicine, engineering and agriculture are; 1) the
ain full control of the business.	number of requests from research and development
Brand Survival Strategy	professionals; 2) positive feedbacks from the reviewers; and
• As Biobert Research Group, our name embodies our key survival	3) total number of article readers.
attribute, research. With the changing climate, economic conditions, and	1. Naturally occurring biocompatible proteins for
psychosocial behaviour change among humans, new problems are	tunable proton conduction.
arising and these require tailored solutions to effectively deal with them.	2. Universal plant gene modification for more efficient
• Whether in the field of human medicine, veterinary medicine,	growth.
agriculture, environment, or industry, we are committed to developing	3. Genetically-modified fibre crops to make waterproof
new solutions, be therapeutics, vaccines or processes, that will meet the	materials.
poised challenges while impressing our investors by generating revenue	4. Recycling plastics with synthetic organisms.
so that all our stakeholders are made happy.	5. New methods for controlling gene expression in
• We shall nurture and attract top talents with the skills vital in our	agricultural biotechnology.
disciplines of practice and ensure that we are the destination of choice	6. Broad range biodegradable biosurfactants.
for every aspiring biological scientist in Uganda, for now, then later on	7. New strain of <i>E. coli</i> for the synthesis of superior
worldwide. The boldness with which we are pushing our prototypes is	PHA.
our first step in the creation of this attractiveness and is an	8. Reproductive hormone from cows, for cows.
announcement of our presence in the industry.	9. Cell-free protein production platform.
• By continually refining our technologies and studying the emerging	10. Genetically engineered plants to resist environmental
market trends, we shall tailor our products to match the new demands	stresses.
and diversify to offer a range of products for newer markets	
and a versal j to otter a range of produces for her er markets.	

#### 9.0 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	<ul> <li>Writing documents for investors (executive summary, business plan, pitch deck, and pro-forma statement).</li> <li>Creating a website for purposes of marketing.</li> <li>Pitching the business at an angel investment network.</li> </ul>	<ul> <li>Connecting to the national power grid.</li> <li>Connecting to the national water supply.</li> <li>Acquiring appropriate furniture and fittings.</li> <li>General brick masonry.</li> <li>Constructing incinerator.</li> <li>Fencing the premise.</li> </ul>	<ul> <li>Local registration of trademarks.</li> <li>Purchase of laboratory consumables.</li> <li>Repeating experiments where required.</li> <li>Submission of manuscripts for peer review.</li> </ul>	<ul> <li>Writing documents for investors (executive summary, business plan, pitch deck, and pro-forma statement).</li> <li>Updating the website for purposes of marketing.</li> <li>Pitching the business at an angel investment network.</li> </ul>	<ul> <li>Hiring talents with the necessary skills.</li> <li>Establishing a good manufacturing practice (GMP) compliant facility.</li> <li>Establishing partnerships with key players.</li> <li>Applying for clearance to conduct clinical trials.</li> <li>Recruiting clinical trial participants.</li> <li>Publishing results of clinical trials.</li> </ul>
Cost (USD)		25,000	45,000		
Time		6 weeks	12 weeks		

**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.

# 10.0 The Team

Current Management				
<b>Robert MIJUMBI</b>	Samuel BYENKYA			
• A graduate of bachelor of science technology	• He is our co-founder and			
(biology) - Kyambogo University - is our chief	director. He holds a post-			
executive officer, chief scientist, co-founder and	graduate diploma in			
director. His eleven years of laboratory practice	information systems			
has yielded expertise in proteomics, nucleic acid	management – Uganda			
techniques, and general research. Currently has	Management Institute,			
one hundred thirty-four manuscripts to publish	diploma in records keeping			
in biological science disciplines that cut across	and information			
biochemistry, bacteriology, virology,	management –			
histopathology and physiology, and chemistry.	Management Training and			
Designing enzymes for specific therapeutic	Advisory Centre, and			
purposes, with adaptations for various routes of	Bachelor of Library and			
administration, is a skill he prides in.	Information Science –			
• He has been in the education sector for a	Uganda Christian			
cumulative total of three years now and has	University.			
developed a lot of skill and experience in people	• His now thirteen years of			
training, evaluation and management;	experience in records			
organizational management; project design,	management makes him a			
implementation, monitoring, and evaluation.	valuable asset as an			
• He is fully acquainted with the regulatory	archivist, we trust him to			
frameworks, locally and internationally, that	handle all aspects of			
govern the development of biopharmaceutical	records generated in the			
products, right from performing laboratory	course of our work.			
experiments to conducting clinical trials on	• Also, because of the			
human subjects.	numerous administrative			
• He is a pragmatic leader that approaches	roles he has held in the			
situations with open-mindedness and calmness,	private sector, we shall			
which results in effective solutions raised for	benefit immensely from			
whatever problems arise; and a good reader of	this experience as we scale			
environmental trends, which leads to better	up our operations.			
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.				
Technical Bench				
• Top talents in the fields of laboratory, clinical	and pharmaceutical practices have			
already been identified and are ready to deploy o	once the appropriate time approaches			
where the business will have the finances to sust	ain 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.				

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