

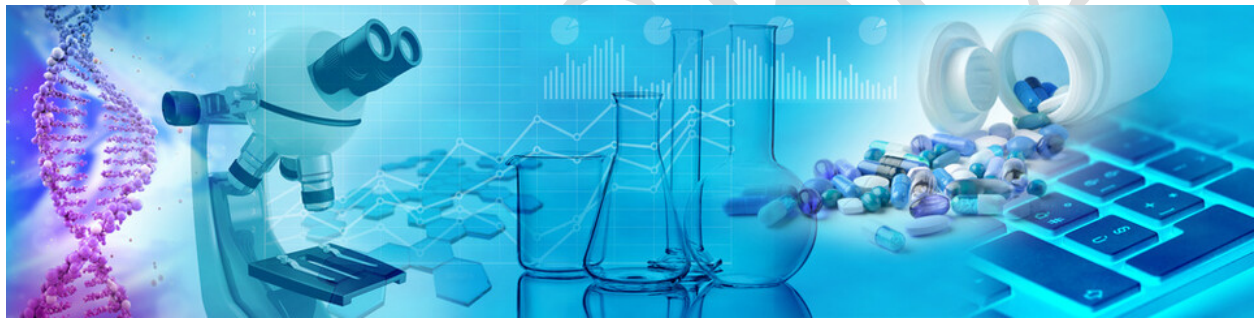


*Bio Pharm laboratories Ltd.*  
*Tanzania*

# Proposal to Set-Up a World Class Biopharmaceutical API Facility in Tanzania

Submitted To:

**The United Republic of Tanzania**



November 2023

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## Executive Summary

BactoChem is proposing to establish a one-of-a-kind bio-pharmaceutical factory in the United Republic of Tanzania (Tanzania) for the production of bovine and porcine biopharmaceutical Active Pharmaceutical Ingredient (APIs), initially focusing on the production of Chondroitin Sulfate, Heparin and Cholic acid derivatives. The factory will be designed as a modular plant, which will allow for scalability and flexibility in production capacity and range of products. This bio-pharmaceutical factory in Tanzania is part of BactoChem's strategic expansion plan to diversify its sources of raw materials, reduce dependence on a single source, improve access to essential medicines in low- and middle-income countries, generate employment and economic growth, and enhance healthcare quality in the region.

The project will promote technology transfer, capacity building and local production of life-saving essential medicines for Tanzania. The proposed factory will be established in collaboration with Export Processing Zones Authority (EPZA) Tanzania and will comply with all regulatory requirements for safety and efficacy.

### Objectives of the Project:

- To establish a mutually beneficial relationship for BactoChem and the people of Tanzania.
- To diversify sources of raw materials for the production of biopharmaceutical APIs.
- To improve access to essential medicines in Tanzania and the region.
- To generate employment and economic growth in the region.
- To enhance healthcare quality in the region.
- To promote technology transfer, capacity building and local production of life-saving essential medicines.

### Expected Outcomes and Benefits of the Project:

- Increased access to essential medicines in Tanzania and the region.
- Local production of life-saving essential medicines.
- Technology transfer and capacity building in the pharmaceutical industry in Tanzania.
- Employment and economic growth in the region.
- Improved healthcare quality in the region.
- Diversification of sources of raw materials for the production of biopharmaceutical APIs.
- Reduced dependence on a single source of raw materials.

Overall, the proposed bio-pharmaceutical factory in Tanzania represents a unique opportunity for BactoChem to expand its operations, while contributing to the growth and development of the pharmaceutical industry in Tanzania, improving access to essential medicines, and generating employment and economic growth in the region.

## Introduction

### About BactoChem Laboratories (BactoChem)

For over 45 years, Bactochem has been a leader in bio-pharmaceutical products and formulations. Incorporated in 1974 at Hyderabad, Telangana (India), the company started with the manufacturing of biological extracts like Peptones, Liver Extracts, Stomach Extracts, Ox Bile extracts etc., and has expanded its portfolio to include Heparin Sodium, Enoxaparin Sodium, Liver Injection Crude and Chondroitin Sulphate. Through use of ultra-modern technology in the production process BactoChem can produce bulk quantities of superior quality with less wastage of raw material.

Our **Vision** is to develop research-backed innovative and affordable biologicals to treat lifestyle disorders and provide life-saving critical care. Our **Mission** is to improve the health and wellness of people and animals globally through bio-pharmaceutical products that are manufactured to the highest standards of excellence, while continuously pushing for new cures and better ways of manufacturing known cures. Our **Values** guide everything, we do, and serve as the foundation of trust we have earned from our customers, colleagues and communities. We are:

- Passionate about improving the quality and longevity of human and animal life through the products we make.
- Committed to continuous learning and technical innovation to bring forth new cures and more affordable medicines.
- Vested in the highest quality and safety of our products.
- Responsible and practice earth-conscious sustainable manufacturing practices.
- Unwavering in our honesty, integrity, and fairness in all our transactions.

**Exhibit 1** presents our product portfolio with their intended use.

*Exhibit 1: BactoChem Product Portfolio*

Chondroitin Sulphate	Heparin Sodium	Enoxaparin Sodium
Commonly used as a dietary supplement to support joint health. It can also be used in the production of pharmaceutical products, such as topical creams and ointments for the treatment of osteoarthritis.	Widely used anticoagulant medication that is used to prevent and treat blood clots. As treatment of deep vein thrombosis, pulmonary embolism, and in the prevention of blood clots during surgery.	Enoxaparin Sodium is also an anticoagulant medication, similar to Heparin Sodium, that is used to prevent and treat blood clots.
Liver Injection Crude	Cholic Acid	Chenodeoxycholic Acid
Used as a dietary supplement to support liver health and in the production of pharmaceutical products, such as tablets or capsules, for the treatment of liver diseases.	Used in the production of bile acid sequestrants, which are used to treat high cholesterol levels and other lipid disorders.	Used in the production of gallstone-dissolving agents, which are used to dissolve gallstones in patients who are not suitable for surgical removal of the gallbladder.
Obeticholic Acid	Ursodeoxycholic Acid	7-ketolithocholic Acid
Used in the treatment of primary biliary cholangitis, a chronic liver disease that affects the bile ducts in the liver.	Used in the treatment of primary biliary cholangitis and other liver diseases.	Used in the production of bile acid sequestrants and other pharmaceutical products for the treatment of liver diseases.

## Quality

Our team is very conscious about the fact that the products we produce play a significant role in saving lives. A compromise on the quality impacts not just the patient but their family and friends. This is a responsibility our team takes very seriously. Therefore, at BactoChem there is no room for compromising on quality. We are committed to 'quality before profits'. We make products of the quality that we would treat our own families with. We ensure that the raw materials we use, the manufacturing equipment, our maintenance processes and the qualifications of the staff involved in the production are all aligned to ensure the safest, highest quality products leave our factory.

Since our raw material is of animal origin, we are diligent about ensuring traceability and quality control throughout the production process to minimize the possibility of any biological hazard. Therefore, our team is working to establish traceable supply chains that can pinpoint the animals from which the raw materials that we use are derived – ensuring a true “farm to pharma” traceability.

All BactoChem Products are manufactured in compliance with the World Health Organization (WHO) Current Good Manufacturing Practices (cGMP) under strict conditions in state-of-the-art facilities. This results in products that are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. Each of our products is manufactured in a dedicated block with no cross contamination. BactoChem is also an ISO 9001:2015, ISO 45001:2018, ISO 14001:2015 certified company.



## **Innovation**

BactoChem is a highly innovative and dynamic pharmaceutical company that is committed to developing new and innovative processes for the production of biopharmaceutical APIs and other synthetic APIs. With its strong team of highly qualified scientists and state-of-the-art research and development center, BactoChem is well-positioned to be a leader in the development and manufacture of biopharmaceutical and synthetic APIs for regulated markets.

BactoChem is actively investing in research and development to discover efficient and cost-effective methods of manufacturing of bio-chemical and other synthetic APIs to establish new process patents. BactoChem's facility in Balanagar, Hyderabad, includes a dedicated research and development center that is equipped with state-of-the-art process development and analytical equipment. The entire facility is made in clean rooms to ensure the highest standards of cleanliness and purity in the production of APIs.

BactoChem's R&D center is staffed by a team of 30 highly qualified scientists with doctorates and post-graduates in chemistry, who bring rich industry experience in product development and developing Drug Master Files (DMFs) for regulated markets. This team is focused on developing new and innovative processes for manufacturing biopharmaceutical and synthetic APIs, with the goal of improving efficiency, reducing costs, and improving the quality of the final product.

Our commitment to innovation is reflected in its success in filing six global patents within just 18 months of operations. The company also has a strong pipeline of 8-10 products in various stages of development, which are expected to be commercialized in the coming years. One of our key strengths is our ability to conduct up to six simultaneous product trials, which allows the company to rapidly develop and test new products and manufacturing processes. This helps to reduce development time and accelerate the commercialization of new products.

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## Project Description

### Purpose of Proposal

The proposed project entails the construction of a bio-pharmaceutical API factory in Tanzania, which will be designed to develop a variety of biopharmaceutical products derived from bovine and porcine sources. The purpose of this proposal is to seek approval and support for establishing an advanced and modern API manufacturing facility in Tanzania. *This facility will be the first of its kind on the African continent and will play a significant role in meeting the increasing demand for high-quality APIs in the region.* The proposed facility will be equipped with the latest technology and will adhere to international standards, making it a state-of-the-art manufacturing plant. Its establishment will not only meet the local demand for APIs but will also contribute to the growth of the pharmaceutical industry in Tanzania and the African continent. Through this proposal, we seek to create a world-class manufacturing facility that will not only benefit our company but will also create employment opportunities, transfer technology, and contribute to the economic development of Tanzania.

API stands for **Active Pharmaceutical Ingredient**, which is the main biologically active component in a pharmaceutical drug that produces a therapeutic effect in the body. API is the key ingredient in a medication that makes it work. The role of APIs is critical in the development and production of pharmaceutical drugs. The API is responsible for the therapeutic effect of the drug and determines the drug's specific mechanism of action. Without the API, the drug would be ineffective. During the drug development process, the API is carefully selected and tested for its efficacy, safety, and stability. The API is then formulated into a drug product, such as a tablet or capsule, along with other inactive ingredients that provide structure, stability, and ease of administration. Once the drug product is formulated, it undergoes rigorous testing to ensure its safety and efficacy. This includes testing for bioavailability, pharmacokinetics, and pharmacodynamics, as well as conducting clinical trials to evaluate the drug's safety and effectiveness in humans. The role of APIs extends beyond the drug development process. APIs also play a critical role in the manufacturing, packaging, and distribution of pharmaceutical drugs. The API must be manufactured under strict quality control measures to ensure its purity, potency, and consistency. The API is then packaged and labeled according to regulatory requirements before being distributed.

**Biopharmaceutical APIs** derived from bovine and porcine sources are essential products in the healthcare industry, as they are used to treat various medical conditions. Bovine-derived biopharmaceutical APIs are produced using materials sourced from cows, such as blood plasma, which contains proteins such as albumin, clotting factors, and immunoglobulins. These proteins are used to produce a variety of biopharmaceutical products, such as albumin, immunoglobulins, and clotting factors. For instance, albumin is used in the treatment of hypovolemia and hypoalbuminemia, while clotting factors are used in the treatment of bleeding disorders such as hemophilia. Porcine-derived biopharmaceutical APIs are produced using materials sourced from pigs, such as pancreases, which contain enzymes such as insulin. These enzymes are used to produce a variety of biopharmaceutical products, such as insulin, which is used in the treatment of diabetes.

The production of biopharmaceutical APIs derived from bovine and porcine sources involves a series of complex processes, such as extraction, purification, and formulation. These processes are carefully designed to ensure that the final product is of high quality, purity, and safety. For instance, heparin is a biopharmaceutical API derived from bovine and porcine sources that is used as an anticoagulant to prevent blood clots. The production of heparin involves a series of complex processes, including extraction, purification, and formulation. Heparin is sourced from porcine intestinal mucosa or bovine lung tissue, which

contains high concentrations of the heparin precursor, heparin sodium. Heparin sodium is extracted from the tissue using a combination of enzymes and chemical reagents as a crude extract. The crude extract is then subjected to a series of purification steps to isolate and purify the heparin. This involves a combination of ion exchange chromatography, gel filtration chromatography, and other specialized techniques. Once the heparin has been purified, it is formulated into a final product by mixing the heparin with other ingredients, such as buffers and stabilizers, to create a stable, injectable product. The final product is then subjected to a series of quality control tests to ensure that it meets regulatory requirements for safety, efficacy, and purity. These tests may include assays to measure the amount of active heparin, as well as tests for impurities and contaminants.

Overall, the manufacturing of biopharmaceutical APIs like heparin, chondroitin, cholic acid etc. is important to Tanzania for its potential to improve access to essential medicines, generate employment and economic growth, promote technology transfer and innovation, and enhance healthcare quality.

- **Meeting Local Demand:** Tanzania, like many African countries, relies heavily on imported pharmaceuticals to meet the healthcare needs of its population. By manufacturing biopharmaceutical APIs locally, Tanzania can reduce its reliance on imports and increase its self-sufficiency in the production of essential medicines.
- **Improving Access to Essential Medicines:** The local production of biopharmaceutical APIs can improve access to essential medicines, particularly in rural and underserved areas. It can also help to reduce the cost of medicines, making them more affordable and accessible to a larger segment of the population.
- **Generating Employment and Economic Growth:** The establishment of a bio-pharmaceutical factory in Tanzania will create jobs and stimulate economic growth in the country. The production of biopharmaceutical APIs requires highly skilled labor and advanced technology, which can contribute to the development of a skilled workforce and the growth of the pharmaceutical industry in Tanzania.
- **Promoting Technology Transfer and Innovation:** The establishment of a bio-pharmaceutical factory in Tanzania can promote technology transfer and innovation in the country. By partnering with international pharmaceutical companies, Tanzania can gain access to advanced technology and expertise, which can contribute to the development of a more robust pharmaceutical industry in the country.
- **Enhancing Healthcare Quality:** The local production of biopharmaceutical APIs can enhance healthcare quality by ensuring the availability of high-quality and safe medicines for the population. It can also contribute to the development of a more robust healthcare system in Tanzania, which can improve health outcomes and reduce the burden of disease.

## Tanzania API Factory: Our Proposed Plan

### Our Strategic Expansion Initiative

Our vision for expansion into Tanzania is to establish a mutually beneficial relationship for BactoChem and the people of Tanzania. BactoChem's expansion into Tanzania and subsequently into other parts of Africa is part of our imperative to diversify our footprint to tap into additional sources of raw materials and establish ourselves in high-growth markets. By establishing a presence in Tanzania, we can take advantage of the availability of bovine and porcine sources in the country and diversify our sources of raw materials for the production of biopharmaceutical APIs. Additionally, our expertise in the development and manufacturing of biopharmaceutical APIs can contribute to the development of a more robust pharmaceutical industry in

Tanzania, improving access to essential medicines and contributing to economic growth in the country. Overall, our expansion into Tanzania is a strategic move that will position us to meet the growing demand for essential APIs in regulated markets while reducing our dependence on a single source of raw materials.

***Additionally, we propose to expand to finished dosed form products as part of the value-chain forward integration, making affordable medication available from local sources.***

## **Our Plan**

As part of our proposed plan to establish a mutually beneficial relationship with Tanzania, BactoChem intends to set up a modular plant that can scale both in capacity and the range of products produced within the scope of bovine and porcine biopharmaceutical APIs. This modular plant will be designed to be flexible and adaptable, allowing us to respond quickly to changing market demands and opportunities.

One of the key advantages of a modular plant is that it can be easily scaled up or down depending on the volume of production required. This means that we can start with a smaller plant and gradually expand as demand for our products increases. We can also add new production lines and products as needed, enabling us to quickly respond to market opportunities and changing customer needs. Another advantage of a modular plant is that it can be customized to meet specific production requirements. We can design our plant to accommodate different sizes and types of bioreactors, filtration systems, and other process equipment. This will enable us to produce a wide range of biopharmaceutical APIs derived from bovine and porcine sources, including Heparin, Cholic Acid, Chondroitin Sulfate, and more. Furthermore, a modular plant is typically faster to construct than a traditional brick-and-mortar facility, allowing us to start production sooner.

The factory will initially focus on the production of Chondroitin Sulphate, Heparin and Cholic acid derivatives, with the capacity and expected output to be determined at a later stage based on the consistent availability of high-quality raw materials. The facility will be equipped with the latest technology and will adhere to international standards, making it a state-of-the-art manufacturing plant.

In addition to Chondroitin Sulphate, Heparin, and Cholic acid derivatives, the bio-pharmaceutical factory will also proposed to produce other essential biopharmaceutical products such as Liver Injection Crude, Aprotinin, Albumin, Insulin, and Gelatine based on access to appropriate raw materials of desired specifications. These products are widely used in the pharmaceutical industry for various medical applications, ranging from wound healing to blood clotting disorders.

In addition to producing biopharmaceutical APIs, BactoChem proposes to expand to finished dosed form products as part of our value-chain forward integration. By doing so, we aim to provide affordable medication to the local population from local sources. This will help to address the high cost of imported pharmaceuticals in Tanzania, which can be a barrier to access for many patients. Our proposed expansion into finished dosed form products will involve the formulation and packaging of biopharmaceutical APIs into dosage forms, such as tablets, capsules, and injections. These products will be manufactured to the same high standards of quality and safety as our APIs, ensuring their efficacy and effectiveness. By expanding into finished dosed form products, we will also create new employment opportunities and support the development of local manufacturing and supply chain infrastructure. This will contribute to the growth and development of the local economy and support Tanzania's broader goals of promoting local industry and self-sufficiency.

The factory will operate using advanced processes that will ensure the highest quality of the biopharmaceutical products. The processes will be designed to comply with international regulatory

standards, ensuring that the products meet the requirements of the local and international markets. The factory will also implement strict quality control measures to ensure that the products are safe and effective. This proposed bio-pharmaceutical factory will contribute significantly to the growth and development of the pharmaceutical industry in Tanzania and the African continent. By producing a range of biopharmaceutical products, the factory will play a crucial role in meeting the local demand for these products and reducing the reliance on imported products. Additionally, the establishment of the factory will create employment opportunities, transfer technology, and contribute to the economic development of Tanzania.

BactoChem

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## Market Analysis

Access to Essential medicines (EMs) remains a major global health challenge. The World Health Organization (WHO) estimates that 2 billion people are without access to EMs<sup>i</sup>. Local production of medicines is among several strategies to improve access to EMs in low- and middle-income countries (LMICs)<sup>ii</sup>. A 2011 WHO report identified the need for better alignment between industry and public health goals and proposed a framework based on national essential medicine lists (NEMs) to guide the support of local production in LMICs<sup>iii</sup> [5].

The WHO framework for local production is a set of guidelines and recommendations aimed at promoting the local production of essential medicines and improving access to quality and affordable medicines in LMICs. The framework *emphasizes the importance of building local capacity to produce essential medicines, promoting technology transfer, and establishing sustainable supply chains for which APIs are an essential component*. This includes ensuring a reliable supply of raw materials, establishing good manufacturing practices, and promoting the use of quality assurance systems. The framework also recommends that countries promote technology transfer and encourage partnerships between local manufacturers and international pharmaceutical companies to enhance local production capabilities.

In East Africa, national support for local production is reinforced at a regional level through The East African Community (EAC), an intergovernmental organization, established by a Treaty in 2000 to enhance cooperation among its six member states: Tanzania, Kenya, Rwanda, South Sudan, Burundi, and Uganda. The EAC agreement involves a customs union including free trade between member states and a common external tariff<sup>iv</sup>. In 2015, the EAC took a major step toward the integration of member state pharmaceutical industries by harmonizing the requirements for the registration of medicines<sup>v</sup>.

As part of the region's social and political integration, the EAC has developed its 2nd Regional Pharmaceutical Manufacturing Plan 2017–2027 which sets out four high-level targets over the 10-year period for increasing local production, and 19 implementation indicators. The plan states its commitment to EMs and aims to increase the proportion of EMs procured from EAC drug manufacturers to at least half of all EMs procured.

The Tanzania Medicines and Medical Devices Authority (TMDA) is mandated by the Medicines and Medical Devices Act (Cap 219) to regulate the manufacturing, importation, distribution and sale of medicines, medical devices and diagnostics<sup>vi</sup>. As the first African regulatory authority, TMDA was assessed by the WHO in 2018 as a well-functioning regulatory system for medicinal products<sup>vii</sup>. Tanzania established its first NEMs in 1991 and has had five updates, the latest is 2021. Medicines are supplied through the government's Medical Stores Department (MSD) and private organizations. The MSD is the main procurer of EMs in the country and provides medicines to the public sector and other organizations involved in healthcare provision. Tanzania's pharmaceutical market was worth an estimated \$400 million in 2015 and locally produced products constituted 12% of the overall market in 2014<sup>iii</sup>. Local manufacturers engage only in secondary and tertiary manufacturing<sup>viii</sup>, and like Kenya, raw materials are imported mainly from India<sup>ix</sup>. As is evident from Exhibit 2, **Tanzania is lagging its counterparts in addressing this national priority**.

*Exhibit 2: Number of local manufacturers, registered products and number and proportion of locally produced EMs in Kenya, Tanzania and Uganda, (%)*

	Kenya	Tanzania	Uganda
Local manufacturers of medicines	9	4	6
Locally produced Medicine products	946	97	181
NEML products	310 (33)	39 (40)	100 (56)
Medicines on NEML	430	510	526
Locally produced EMs	92 (21)	24 (5)	55 (10)

Exhibit 3 further highlights that *Tanzania has not kept pace with its EAC counterparts in local manufacturing and growing its indigenous manufacturing capacity.*

*Exhibit 3: Local manufacturers in Tanzania, Kenya and Uganda: number of registered products, number of registered EM products and as proportion (%) of all registered products, and number of individual EMs that products correspond to*

Manufacturer name	Registered products <i>n</i>	Registered EM products <i>n</i> (%)	Registered EMs <i>n</i>
<b>TANZANIA</b>			
Keko Pharmaceuticals	7	5 (71)	5
Prince Pharmaceuticals	17	6 (35)	6
Zenufa Laboratories	19	8 (42)	8
Shelys Limited	54	20 (37)	17
<b>Total</b>	<b>97</b>	<b>39 (40)</b>	<b>24</b>
<b>KENYA</b>			
GlaxoSmithKline Kenya	12	0	0
Medisel	2	0	0
Benmed	23	6 (26)	4
Regal Pharmaceuticals	94	26 (28)	16
Dawa Limited	133	37 (28)	28
Biodeal Limited	95	38 (40)	30
Universal Corp Limited	109	42 (38)	30
Lab and Allied	222	64 (29)	49
Cosmos Limited	256	97 (39)	66
<b>Total</b>	<b>946</b>	<b>310 (33)</b>	<b>92</b>
<b>UGANDA</b>			
Medipharm Industries	2	0	0
Kwality-Afro Asia Limited	1	1 (100)	1
Cipla Quality Chemicals	11	9 (82)	7
Abacus Parenteral	27	18 (66)	12
Kampala Pharmaceuticals	62	34 (55)	28
Rene Industries Limited	76	35 (46)	31
<b>Total</b>	<b>181</b>	<b>100 (54)</b>	<b>55</b>

The Tanzanian government has implemented several programs and initiatives aimed at improving the pharmaceutical manufacturing sector in the country, including:

- **National Pharmaceutical Sector Development Strategy (NPSDS)** which is a government-led initiative aimed at strengthening the pharmaceutical sector in Tanzania. The strategy focuses on improving the regulatory environment, increasing investment in the sector, and enhancing local production capacity.
- **Tanzania Investment Center (TIC)** a government agency that promotes investment in Tanzania. The agency provides a range of services to investors, including facilitation of investment approvals, land acquisition, and access to finance.
- **Tanzania Industrial Research and Development Organization (TIRDO)** a government research and development agency that works to support the development of local industries, including the pharmaceutical sector. The agency provides research and development services, technical support, and technology transfer services to local manufacturers.
- **The Tanzania Food and Drugs Authority (TFDA)** the government agency responsible for regulating the manufacture, importation, exportation, distribution, sale, and use of food, drugs, cosmetics, and medical devices has taken steps to streamline the registration process for pharmaceutical products by introducing an online registration system that allows pharmaceutical manufacturers and importers to submit their applications online, reducing the time and resources required for the registration process as well as a one-stop center for registration and inspection of pharmaceutical products, which has further streamlined the approval process.

*BactoChem is enthusiastic about the prospects to develop the pharmaceutical sector in Tanzania in collaboration with the Government if we can be assured of investment incentives, favorable regulatory environment for pharmaceutical manufacturing, streamlined approvals, consistent access to raw material, and security.*

## Target Customers

Target customers for the biopharmaceutical APIs manufactured by BactoChem in Tanzania include:

- **Local pharmaceutical manufacturers:** Tanzanian pharmaceutical companies that manufacture finished pharmaceutical products could be ideal target customers for the biopharmaceutical APIs produced in Tanzania. They could use the APIs as raw materials to produce a wide range of finished pharmaceutical products that would be supplied to local healthcare providers.
- **International pharmaceutical manufacturers:** International pharmaceutical companies that specialize in the production of finished pharmaceutical products could be ideal target customers for the biopharmaceutical APIs manufactured in Tanzania. These companies could purchase the APIs as raw materials to produce a wide range of pharmaceutical products that are used globally.
- **Contract manufacturing organizations (CMOs):** CMOs could also be target customers for the biopharmaceutical APIs manufactured in Tanzania. CMOs produce pharmaceutical products on behalf of other companies and could purchase the APIs as raw materials to produce finished pharmaceutical products for their clients.

## Market Potential for the Proposed Products

The market potential for the proposed products is significant, given the growing demand for biopharmaceutical products in Tanzania and the African continent as a whole. The proposed products, such as Heparin, Cholic acid, and derivatives, Chondroitin Sulphate, Liver Injection Crude, Aprotinin, Albumin,

Insulin, and Gelatine, are widely used in the healthcare industry for various applications. For instance, Heparin is used in the prevention of blood clots and is widely used in the treatment of cardiovascular diseases. Cholic acid and its derivatives are used in the treatment of liver diseases, while Chondroitin Sulphate is used in the treatment of osteoarthritis. Aprotinin is used in the prevention of bleeding during surgery, while albumin is used to treat hypovolemia and hypoalbuminemia. Insulin is used in the treatment of diabetes, and Gelatine is used in the production of capsules, tablets, and other pharmaceutical formulations.

Local and international markets for bio-pharmaceutical products present significant opportunities for the proposed bio-pharmaceutical factory in Tanzania. The factory's focus on high-quality, affordable, and accessible products will make it a reliable source of essential biopharmaceutical products for the healthcare industry. The factory will also contribute to the growth and development of the pharmaceutical industry in Tanzania and the African continent.

Here are some specific examples of companies that could be potential customers for the biopharmaceutical APIs produced by the proposed factory in Tanzania:

- **Heparin Sodium:** While Tanzania does not currently manufacture Heparin Sodium, there are several companies in Africa that manufacture finished dose formulations of Heparin or Heparin-based products. Some examples of companies that produce Heparin or Heparin-based products in Africa include Aspen Pharmacare (South Africa), Arab Pharmaceutical Manufacturing (Egypt), South African National Blood Service (South Africa), and Ibsina Pharma (Egypt). Heparin APIs can be exported to these and other manufacturers.

Additionally, currently, Tanzania relies heavily on imported Heparin, which is expensive and subject to supply chain disruptions, like during COVID-19. By establishing a biopharmaceutical factory in Tanzania to produce Heparin, BactoChem can help to reduce the country's dependence on imported Heparin and make it more affordable and accessible for the local population. Through our proposed project, we would like to utilize the local resources and expertise to manufacture indigenous finished dose Heparin, which will be made to the same high standards of quality and safety as imported Heparin. This will ensure that patients in Tanzania have access to a safe and effective alternative to imported Heparin, which can be subject to quality control issues and supply chain disruptions. Moreover, the production of indigenous Heparin will create employment opportunities and contribute to the development of local manufacturing and supply chain infrastructure. It will also help to promote self-sufficiency and support Tanzania's broader goals of developing a local pharmaceutical industry. By manufacturing indigenous Heparin in Tanzania, BactoChem can help to reduce the country's reliance on imported pharmaceuticals and contribute to the growth and development of the local economy.

- **Liver Injection Crude:** Potential target customers for the Liver Injection Crude API could include companies that produce pharmaceutical products for the treatment of liver diseases, such as Gilead Sciences, AbbVie, Bristol-Myers Squibb, and Merck.
- **Cholic Acid:** Potential target customers for the Cholic Acid API could include companies that produce bile acid sequestrants for the treatment of high cholesterol levels and other lipid disorders, such as Sanofi, Pfizer, and Novartis.
- **Chenodeoxycholic Acid:** Potential target customers for the Chenodeoxycholic Acid API could include companies that produce gallstone-dissolving agents for the treatment of gallstones, such as Genentech, GlaxoSmithKline, and Alfasigma.

- **Obeticholic Acid:** Potential target customers for the Obeticholic Acid API could include companies that produce medications for the treatment of primary biliary cholangitis, such as Intercept Pharmaceuticals, Gilead Sciences, and Dova Pharmaceuticals.
- **Ursodeoxycholic Acid:** Potential target customers for the Ursodeoxycholic Acid API could include companies that produce medications for the treatment of primary biliary cholangitis and other liver diseases, such as Intercept Pharmaceuticals, Gilead Sciences, and AbbVie.
- **7-ketolithocholic Acid:** Potential target customers for the 7-ketolithocholic Acid API could include companies that produce bile acid sequestrants and other pharmaceutical products for the treatment of liver diseases, such as Sanofi, Pfizer, and Novartis.
- **Aprotinin:** Potential target customers for the Aprotinin API could include companies that produce medications for the treatment of bleeding and coagulation disorders, such as CSL Behring, Pfizer, and Takeda.
- **Albumin:** Potential target customers for the Albumin API could include companies that produce medications for the treatment of blood disorders, such as CSL Behring, Grifols, and Octapharma.
- **Insulin:** Potential target customers for the Insulin API could include companies that produce medications for the treatment of diabetes, such as Novo Nordisk, Sanofi, and Eli Lilly.
- **Gelatine:** Potential target customers for the Gelatine API could include companies that produce pharmaceutical products, such as capsules, tablets, and coatings, as well as companies that produce medical devices, such as wound dressings, surgical sponges, and drug delivery systems.

It is important to note that the companies listed above are examples of potential target customers, and the specific target customers for the biopharmaceutical APIs produced by the proposed factory in Tanzania will depend on a range of factors, including the competitive landscape of the market, the specific product formulations and dosage forms, and the regulatory environment in different countries.

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## Investment

### Investment Highlights

BactoChem's investment in Tanzania is a unique opportunity for the government to ***attract foreign direct investment, promote economic growth, and create high-skilled job opportunities in the region using locally sourced raw materials.*** We are committed to working closely with the Tanzanian government to ensure that our investment contributes to the development and growth of the local economy, and we look forward to establishing a mutually beneficial partnership with the Tanzanian government. This entity will be established as a subsidiary of BactoChem or a new entity with the same management team's backing.

BactoChem's investment in Tanzania will have a significant positive impact on the local economy, both in the short and long term. The initial investment plan of 8 million to 10 million USD for the establishment of a modular bio-pharmaceutical factory in Tanzania will provide immediate employment opportunities to local people, as well as generate indirect employment opportunities in various related industries such as transportation, logistics, and services.

The estimated total capital investment of between 10 million to 14 million USD over the period of 8 years will not only contribute to the development of the pharmaceutical industry in Tanzania but will also promote technology transfer and capacity building in the region. This will enable local professionals to acquire new skills and knowledge, creating a pool of qualified workers who can contribute to the growth of the local industry. This investment will contribute to the creation of high-skilled jobs in the region, with the facility providing direct employment to 110 local people and indirect employment to an additional 200 to 300 people.

As part of our commitment to promoting sustainable and responsible business practices, BactoChem places a high priority on training and developing the local workforce. We believe that investing in the development of local talent is crucial for the long-term success of our business and for the growth and development of the local economy. To establish a skilled and knowledgeable workforce, we will provide extensive training programs for our local staff, both during the construction phase of the factory and during the ongoing operations. Our training programs will cover a range of areas, including technical skills, quality control, safety, and environmental management. Through our training programs, we aim to develop a skilled and knowledgeable workforce that can operate the factory to the highest standards of safety, quality, and efficiency. We believe that this investment in the local workforce will have significant long-term benefits for both BactoChem and the local community, including job creation, skills development, and economic growth. Specifically, we will train local staff on biopharmaceutical manufacturing processes such as the extraction, purification, and formulation processes involved in the production of APIs. They will also receive training on the use of state-of-the-art process development and analytical equipment. They will be trained on the quality control and assurance processes involved in the manufacture of pharmaceuticals, including testing for contaminants and pathogens, monitoring the production process for consistency and purity, and ensuring compliance with regulatory standards. They will also be trained on safety and environmental management practices, including the proper handling of hazardous materials, waste management, and emergency response procedures. Additionally, we will provide training for the management team on leadership skills, including planning, communication, problem-solving, and decision-making.

The establishment of a modular bio-pharmaceutical factory in Tanzania will also create opportunities for local businesses, as BactoChem will need to source raw materials and supplies from local suppliers. This will help to develop local supply chains and partnerships, thereby promoting the development of a strong and

sustainable pharmaceutical industry in Tanzania. Furthermore, the production of biopharmaceutical APIs in Tanzania will lay the foundation and contribute to the reduction of importation of essential medicines, which in turn will improve access to life-saving medicines for the people of Tanzania. This will not only improve the overall health of the population but will also contribute to the reduction of healthcare costs in the long term.

## Investment Details

### Cost of Project

S.No.	Particulars	Numbers	Total USD
<b>I</b>	<b>Land &amp; Buildings</b>		<b>3,858,879</b>
	Land	150 acres	45,115
	Manufacturing Sheds in 5 blocks	60000 sqft	1,443,696
	Cold Storage area	5000 sqft	300,770
	Sheds for storage	3000 sqft	72,185
	Clean rooms	2000 sq ft	72,185
	Construction of Q C and Micro Biology department	5000 sq ft	120,308
	Admin Block and Quarters		1,804,620
<b>II</b>	<b>Power Facility</b>		<b>505,294</b>
	Generator 300 kVA	1	24,062
	Solar power plant	500KVA	481,232
<b>III</b>	<b>Plant &amp; Machinery</b>		<b>3,146,655</b>
<b>IV</b>	<b>Lab &amp; Testing Equipment</b>		<b>269,189</b>
<b>V</b>	<b>Miscellaneous</b>		<b>1,103,224</b>
	<b>Grand Total</b>		<b>8,883,241</b>

## Projected Profit & Loss Statement

Particulars	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
1. Revenue from Operations	8,362,608	10,035,130	12,042,156	13,848,479	15,233,327	16,756,660	18,432,326	20,275,559
Sales in Africa 30%	2,508,782	3,010,539	3,612,647	4,154,544	4,569,998	5,026,998	5,529,698	6,082,668
Sales in other than africa 70%	5,853,826	7,024,591	8,429,509	9,693,936	10,663,329	11,729,662	12,902,628	14,192,891
2. Other Income	83,626	100,351	120,422	138,485	152,333	167,567	184,323	202,756
3. Closing Stock	343,669	412,403	494,883	569,116	626,027	688,630	757,493	833,242
<b>4. Total Revenue (A)</b>	<b>8,789,903</b>	<b>10,547,884</b>	<b>12,657,461</b>	<b>14,556,080</b>	<b>16,011,688</b>	<b>17,612,856</b>	<b>19,374,142</b>	<b>21,311,556</b>
5. Direct Expenses	-	-	-	-	-	-	-	-
i) Purchase of Stock in Trade	5,436,128	6,626,641	8,263,421	9,750,837	10,828,304	12,062,731	13,449,945	14,978,127
ii) Opening Stock - WIP	-	343,669	412,403	494,883	569,116	626,027	688,630	757,493
iii) Power and Fuel Expenses	125,439	150,527	180,632	207,727	228,500	251,350	276,485	304,133
iv) Wages to labour	151,588	166,747	183,422	201,764	221,940	244,134	268,548	295,402
v) Other Direct Expenses	125,439	150,527	234,822	270,045	297,050	360,268	396,295	435,925
<b>6. Gross Profit</b>	<b>2,951,308</b>	<b>3,109,774</b>	<b>3,382,761</b>	<b>3,630,824</b>	<b>3,866,778</b>	<b>4,068,346</b>	<b>4,294,240</b>	<b>4,540,476</b>
7. Indirect Expenses								
i) Employee Benefit Expenses	216,554	238,210	262,031	288,234	317,057	348,763	383,639	422,003
ii) Admin & Maintenance Expenses	376,317	496,739	650,276	747,818	875,916	963,508	1,059,859	1,165,845
iii) Conveyance & Travelling Exp	41,813	50,176	60,211	69,242	76,167	83,783	92,162	101,378
iv) Depreciation	888,324	799,492	719,543	647,588	582,829	524,547	472,092	424,883
v) Finance Cost	808,875	758,043	701,330	638,054	567,455	488,687	400,804	302,751
<b>8. Net Profit</b>	<b>619,425</b>	<b>767,114</b>	<b>989,371</b>	<b>1,239,888</b>	<b>1,447,353</b>	<b>1,659,059</b>	<b>1,885,684</b>	<b>2,123,616</b>

## Projected Balance Sheet

(Amount in USD \$)								
PARTICULARS	Projected	Projected	Projected	Projected	Projected	Projected	Projected	Projected
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
<b>I. CAPITAL A/C &amp; LIABILITIES</b>								
<b>1) Capital</b>								
(a) Opening Capital	-	1,691,753	2,290,102	2,834,256	3,478,997	4,173,727	4,970,075	5,875,204
(b) Reserves and Surplus	619,425	767,114	989,371	1,239,888	1,447,353	1,659,059	1,885,684	2,123,616
(c) Capital Introduction	1,332,486	-	-	-	-	-	-	-
(c) Drawings	(260,158)	(168,765)	(445,217)	(595,146)	(752,624)	(862,710)	(980,556)	(1,104,280)
<b>Closing Capital</b>	<b>1,691,753</b>	<b>2,290,102</b>	<b>2,834,256</b>	<b>3,478,997</b>	<b>4,173,727</b>	<b>4,970,075</b>	<b>5,875,204</b>	<b>6,894,539</b>
<b>2) Non Current Liabilities</b>								
(a) Long Term Borrowings	7,111,490	6,621,393	6,074,583	5,464,496	4,783,812	4,024,359	3,177,023	2,231,634
(b) Secured Loans	-	-	-	-	-	-	-	-
<b>3) Current Liabilities</b>								
(a) Short Term Borrowings	240,616	240,616	240,616	240,616	240,616	240,616	240,616	240,616
(b) Trade Payables	29,787	36,310	45,279	53,429	59,333	66,097	73,698	82,072
(c) Provisions	-	-	-	-	-	-	-	-
(d) Other Current Liabilities	10,546	11,601	12,761	14,037	15,440	16,984	18,683	20,551
<b>Total</b>	<b>9,084,191</b>	<b>9,200,022</b>	<b>9,207,494</b>	<b>9,251,576</b>	<b>9,272,928</b>	<b>9,318,131</b>	<b>9,385,224</b>	<b>9,469,413</b>
<b>II. ASSETS</b>								
<b>1) Non-Current Assets</b>								
(a) Property, Plant and Equipment								
(i) Tangible Assets	7,994,917	7,195,425	6,475,883	5,828,294	5,245,465	4,720,919	4,248,827	3,823,944
(i) Intangible Assets	-	-	-	-	-	-	-	-
(b) Other Non Current Assets	45,115	356,292	534,438	748,213	972,677	1,118,579	1,286,366	1,415,003
(c) Deposits and advances	29,578	239,437	335,212	469,296	563,156	647,629	744,773	819,251
<b>2) Current Assets</b>								
(a) Inventories	343,669	412,403	494,883	569,116	626,027	688,630	757,493	833,242
(b) Trade Receivables	572,781	687,338	923,782	1,062,349	1,168,584	1,285,442	1,413,987	1,666,484
(c) Cash and Cash Equivalents	26,558	89,732	125,624	138,187	152,006	167,206	183,927	202,319
(d) Deposits and advances	41,609	116,576	163,206	244,810	342,734	479,827	527,810	580,591
(e) Other Current Assets	29,965	102,819	154,466	191,310	202,280	209,899	222,042	128,579
<b>Total</b>	<b>9,084,191</b>	<b>9,200,022</b>	<b>9,207,494</b>	<b>9,251,576</b>	<b>9,272,928</b>	<b>9,318,131</b>	<b>9,385,224</b>	<b>9,469,413</b>

## Projected Cash Flow Statement:

Particulars	CASH FLOW STATEMENT							
	Amount in USD \$							
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
<b>Cash flows from operating activities</b>								
Net Income	6,19,425	7,67,114	9,89,371	12,39,888	14,47,353	16,59,059	18,85,684	21,23,616
Add: interest expense	8,08,875	7,58,043	7,01,330	6,38,054	5,67,455	4,88,687	4,00,804	3,02,751
Operating profit	14,28,299	15,25,158	16,90,701	18,77,941	20,14,808	21,47,746	22,86,489	24,26,367
Add: depreciation expense	8,88,324	7,99,492	7,19,543	6,47,588	5,82,829	5,24,547	4,72,092	4,24,883
Increase in inventory	(3,43,669)	(68,734)	(82,481)	(74,232)	(56,912)	(62,603)	(68,863)	(75,749)
Increase in trade receivables	(5,72,781)	(1,14,556)	(2,36,444)	(1,38,567)	(1,06,235)	(1,16,858)	(1,28,544)	(2,52,498)
Increase in Deposits and advances - Current	(41,609)	(74,968)	(46,630)	(81,603)	(97,924)	(1,37,093)	(47,983)	(52,781)
Increase in Other Current Assets -	(29,965)	(72,855)	(51,647)	(36,844)	(10,970)	(7,620)	(12,142)	93,463
Increase in Deposits and advances - Non Current	(29,578)	(2,09,859)	(95,775)	(1,34,085)	(93,859)	(84,473)	(97,144)	(74,477)
Increase in Other Non Current Assets	(45,115)	(3,11,177)	(1,78,146)	(2,13,775)	(2,24,464)	(1,45,902)	(1,67,787)	(1,28,637)
Increase in Trade Payables	29,787	6,523	8,969	8,150	5,904	6,764	7,601	8,374
Increase in Other Current Liabilities	10,546	1,055	1,160	1,276	1,404	1,544	1,698	1,868
<b>Cash flow from operations</b>	<b>12,94,240</b>	<b>14,80,079</b>	<b>17,29,249</b>	<b>18,55,848</b>	<b>20,14,582</b>	<b>21,26,051</b>	<b>22,45,416</b>	<b>23,70,813</b>
Dividends paid	-	-	-	-	-	-	-	-
Interest paid	(8,08,875)	(7,58,043)	(7,01,330)	(6,38,054)	(5,67,455)	(4,88,687)	(4,00,804)	(3,02,751)
Tax paid	-	-	-	-	-	-	-	-
<b>Net cash generated from operating activities</b>	<b>4,85,365</b>	<b>7,22,036</b>	<b>10,27,920</b>	<b>12,17,795</b>	<b>14,47,127</b>	<b>16,37,364</b>	<b>18,44,612</b>	<b>20,68,062</b>
<b>Cash flows from investing activities</b>								
Payments to purchase equipment	(88,83,241)	-	-	-	-	-	-	-
Proceeds from disposals of equipment	-	-	-	-	-	-	-	-
Intangible Assets	-	-	-	-	-	-	-	-
<b>Net cash used in investing activities</b>	<b>(88,83,241)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Cash flows from financing activities</b>								
Issues of share capital	13,32,486	-	-	-	-	-	-	-
Term loan Amount received	75,50,755	-	-	-	-	-	-	-
Short Term Borrowings- Working Capital	2,40,616	-	-	-	-	-	-	-
Dividend/Drawings	(2,60,158)	(1,68,765)	(4,45,217)	(5,95,146)	(7,52,624)	(8,62,710)	(9,80,556)	(11,04,280)
Principle payment of the Loan	(4,39,265)	(4,90,097)	(5,46,810)	(6,10,086)	(6,80,685)	(7,59,453)	(8,47,336)	(9,45,389)
<b>Net cash used in financing activities</b>	<b>84,24,433</b>	<b>(6,58,862)</b>	<b>(9,92,027)</b>	<b>(12,05,232)</b>	<b>(14,33,309)</b>	<b>(16,22,163)</b>	<b>(18,27,892)</b>	<b>(20,49,669)</b>
<b>Net cash flow for the period</b>	<b>26,558</b>	<b>63,174</b>	<b>35,893</b>	<b>12,562</b>	<b>13,819</b>	<b>15,201</b>	<b>16,721</b>	<b>18,393</b>
Cash and cash equivalents at the beginning of the period	-	26,558	89,732	1,25,624	1,38,187	1,52,006	1,67,206	1,83,927
Cash and cash equivalents at the end of the period	26,558	89,732	1,25,624	1,38,187	1,52,006	1,67,206	1,83,927	2,02,319
<b>Net increase/decrease in cash</b>	<b>26,558</b>	<b>63,174</b>	<b>35,893</b>	<b>12,562</b>	<b>13,819</b>	<b>15,201</b>	<b>16,721</b>	<b>18,393</b>

## Investment Considerations

BactoChem recognizes that investing in Tanzania requires careful consideration of several factors. As such, we are seeking guidance and support from the Tanzanian government and its agencies in the following areas:

- Land Allotment:** We require a suitable and adequate land allotment of 150 acres, preferably near Dar es Salaam, with good groundwater resources and clearance from Environment departments. The land must also be declared as a Special Economic Zone (SEZ) by the Export Processing Zones Authority (EPZA), as most of our produce will be exported. The land must be red soil, suitable for our operations. We request the land to be allotted to us rent-free lease as an incentive. We understand that land is a valuable resource, and we are committed to utilizing it to its fullest potential to promote economic growth and development in the region. As part of our commitment to sustainable and responsible business practices, BactoChem will maintain adequate green spaces to offset the carbon footprint of our operations. We recognize the importance of minimizing our environmental impact and promoting sustainable development, and we are committed to ensuring that our factory operates in an environmentally responsible manner.
- Approval Process:** We request an expedited one-stop approval process from all regulatory bodies, including the Ministry of Health and Commerce Office, to obtain all necessary permits, licenses, and visas for establishing and operating our bio-pharmaceutical factory in Tanzania.

- **Electricity Supply:** We require a reliable electricity supply capable of supporting a load of 500 to 600 HP for our operations.
- **Water Supply:** We may require a reliable daily supply of up to 100,000 liters of water for our operations through tube wells.
- **Immigration Clearance and Business Visas:** We require assistance with Immigration Clearance and other necessary Business Visas for our staff and factory. We request expedited visa and immigration approval for our staff and factory to ensure a smooth transition and quick establishment of our operations in Tanzania.
- **Exclusivity Contracts for Raw Material:** We require exclusivity contracts to be signed with all slaughterhouses for the supply of Trachea, Bile Liquid, and small intestinal Mucosa to our factory. Currently, these raw materials are being discarded as waste. Our proposal will utilize these materials and reduce the environmental impact. This will ensure a steady supply of raw materials for our operations and assure the value of this strategic investment for both parties. *A minimum 200 tons* of raw material of each of the following is required for economic viability:
  - Small Intestinal Mucosa
  - Trachea
  - Bile
  - Liver
  - Blood
  - Fat

Duty-free import of these raw materials will be permitted to match factory capacity expansion.

**NOTE:** *It is critical that these raw materials are procured from animals certified free of foot-and-mouth disease.*

- **Import and Export Tax Incentives:** We require information on the available import and export tax incentives that we can avail to ensure the competitiveness of our products in the international market.
- **Security for Investments:** We require assurance and sovereign guarantees from the Tanzanian government on the security of our investments in Tanzania.

BactoChem is committed to establishing a mutually beneficial partnership with the Tanzanian government and its agencies, with a view to promoting economic growth and development in the region, creating high-skilled job opportunities, and improving access to essential medicines. We look forward to working with the Tanzanian government to address the above considerations and establish a successful world-class bio-pharmaceutical factory in Tanzania.

## Conclusion

In conclusion, BactoChem is committed to establishing a modular bio-pharmaceutical factory in Tanzania, which will be the first of its kind on the African continent. Our proposed project is centered around the production of bovine and porcine derived biopharmaceutical APIs, starting with Chondroitin Sulphate, Heparin and Cholic acid derivatives *using locally sourced raw materials that are currently being discarded as waste*. We have identified Tanzania as a strategic location for our investment, given its progressive and supportive government, favorable regulatory environment, and abundance of raw materials.

Our proposal highlights the various aspects of our project, including the production process, market analysis, and investment plan. We have also outlined the key considerations that will determine our investment decision, including the approval process, land allotment, visa, and immigration approval, required raw material quantity and quality guarantees, and security for our investments.

We believe that our investment in Tanzania will have significant potential benefits for both BactoChem and the Tanzanian people, including the creation of direct and indirect employment opportunities, technology transfer, capacity building, and improved access to life-saving medicines.

We respectfully request the Tanzanian government's approval and support for our proposed project. We are committed to working closely with the government to ensure that our investment contributes to the growth and development of the local economy, and we look forward to establishing a mutually beneficial partnership.

Thank You.

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