



AFRICA IN THE GLOBAL VACCINE MANUFACTURING LANDSCAPE: ADVANCEMENTS



BIOMEDICALABS LLC

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Company Overview

Key Mission and Objectives of Biomedicallabs LLC

- To improve overall health service delivery across the African Continent by developing the manufacturing capacity to produce vaccines in Africa, designed to suit Africa's specific circumstances, conditions and standards.
- To introduce biopharmaceuticals as an alternative treatment option for Malaria, Tuberculosis and HIV/AIDS.
- To expand the product range and establish R & D capacity both for vaccines and for biosimilars.

Company Overview Cont.

- Africa is the only region of the world which does not have adequate **vaccine manufacturing capacity**. The continent therefore imports 99.7% of its vaccine requirements to fulfill its **Expanded Program on Immunization (EPI)** mandate funded by donor agencies and administered by **UNICEF (United Nations Children's Fund)**.
- In the very near future it is envisaged African Governments will have to take over funding of vaccine purchases.
- Independently we had identified vaccine manufacturing as a **business idea** whose time has come.



Setting up a Vaccine Company: The approach)

- Currently a Limited Liability Company (LLC) registered in the United States of America, we envision setting up a special purpose vehicle where we team up with the Government of the African country where our project will be located and form a public private partnership. Two other African Governments will also be co-opted into taking a minority stake in the re-organized project.
- It is envisaged this will create a vehicle that Governments, UN Agencies, International Donors and organizations like AVMI can work with.
- Phase One of our combined **vaccine/biosimilar** manufacturing plant will be completed, test-run, licensed and handed over to **Biomedicallabs** in **twenty-four to thirty (24-30) months** enabling us start production of both vaccines and biosimilars.

The Approach Cont.

- Using this timeframe, our products will be on the market in a little under **three years** from breaking ground.
- The technology to be used called **Modular Aseptic Solutions (MAS)**, offers a complete package including the manufacturing equipment, building specifications, standards and plans as determined by **International Society for Pharmaceutical Engineering (ISPE)**.
- MAS also includes assistance with personnel, construction, identifying complementary technical partners, sourcing funding, sourcing raw materials, advice and consultancy and tailoring the technical package to suit the client's particular requirements.

The Business Model

- We project that Phase One of vaccine manufacturing will cost **US\$35 million** and an additional **US\$27 million** is projected for the inclusion of biosimilar manufacturing totaling **US\$62 million**.
- We currently propose that private investors will raise the bulk of the investment funds and will be responsible for day to day business operations.
- The public sector investors will take up only nominal shareholding whilst concentrating on facilitating cooperation and collaboration and facilitating the marketing of our products in Eastern and Southern Africa.

- By enhancing vaccine manufacturing capacity in Africa.
- Increased competition which will lead to a reduction in the cost.
- Better utilization of African Human Resources.
- Recognition of African conditions, circumstances and standards in the development of vaccines and medicines.
- Increasing investment in the health sector in Africa.
- Getting ready for when Africa weans itself from donor dependency.

Challenges and Lessons Learnt

- Raising investment capital; inadequate support for start-up businesses
- A difficult business climate in most African countries
- A failure by some Governments to appreciate the need to invest in the health care business
- Reliance on outsiders to do what we can, and should, do ourselves
- The fact that public private partnerships in vaccine manufacturing is the only logical way to go

Future Plans

- Increasingly, Governments, organizations and individuals in and outside of Africa are carrying out all manner of initiatives to bring Africa to where it should (or could) be in vaccine manufacturing and Biomedicallabs is a beneficiary of this positive trend.
- Support from AVMI gives Biomedicallabs more clout with other potential partners.
- Support from AVMI will also give us more credibility with potential investors.
- AVMI, by virtue of their on hand experience can benefit our efforts as we are a green field operation.
- AVMI can assist by reviewing our business plan and providing suggestions/input.
- AVMI can help us gain access to international interested parties e.g. the United Nations and other development agencies.

African Vaccine Manufacturing Initiative



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