BUSINESS PLAN FOR STANDARDIZATION, MARKETING AUTHORIZATION, AND COMMERCIALIZATION OF AISHAMIN, AN ANTIDIABETIC PHYTODRUG

Executive Summary

Business Name: National Institute for Pharmaceutical Research and Development (NIPRD).

Business Type: Government Research Institute into Pharmaceutical Research, Development, and Commercialization

Project Title: Development, Standardization, and Commercialization of a NAFDAC-Approved Antidiabetic Phytodrug.

Location: Abuja, Nigeria

Ownership: Federal Government of Nigeria

Partners: National Agency for Science and Engineering Infrastructure (NASENI), Pharmaceutical Manufacturer Group of Manufacturers Association of Nigeria, Federal Ministry of Health, Teaching Hospitals, and NAFDAC.

1. Project Overview

This project aims to develop, standardize, clinically validate, and commercialize a safe and effective antidiabetic phytodrug derived from Nigerian medicinal plants traditionally used in diabetes management. The product will undergo phytochemical standardization, preclinical and clinical evaluation, and regulatory approval (NAFDAC Marketing Authorization) before commercial launch as a capsule or tablet formulation.

2. Market Analysis

2.1 Industry Overview

- Nigeria has over 11 million people living with diabetes (IDF, 2024), with the number projected to rise by 40% by 2030.
- Annual spending on imported antidiabetic drugs exceeds ₦80 billion, primarily on oral hypoglycemics and insulin.
- The herbal and nutraceutical market is growing at 7–10% CAGR, driven by cost, side-effect concerns, and cultural acceptance.

2.2 Market Gap

- High cost of imported drugs.
- Lack of standardized, clinically validated herbal alternatives.
- Growing awareness of preventive and complementary medicine.

2.3 Target Market

- Primary: Diabetic patients in hospitals, pharmacies, and clinics.
- Secondary: Herbal medicine users, wellness centers, and e-commerce consumers.
- Tertiary: Regional export to ECOWAS under AMA-regulated herbal categories.

3. Product Description

3.1 Product Concept

Product Name (Proposed): *AISHAMIN*®

Formulations:

- *AISHAMIN Capsule or Tablet* (500 mg standardized extract)
- *AISHAMIN Herbal Tea*
- *AISHAMIN Syrup* (for mild diabetic and pre-diabetic patients)

3.2 Mechanism of Action

Multi-target glucose-lowering activity through:

- Insulin sensitization
- α-glucosidase inhibition
- Pancreatic β-cell protection
- Antioxidant enhancement

3.3 Scientific Basis

Phytochemical markers to be developed and validated via HPLC/LC-MS profiling.

3.4 Competitive Advantage

- Scientifically standardized and clinically validated.
- 40–60% cheaper than imported oral antidiabetics.
- Locally sourced, supporting national raw materials development.

- Minimal side effects and improved glycemic control from polyherbal synergy.

4. Regulatory and Quality Plan

4.1 Regulatory Pathway (NAFDAC)

- **Step 1:** Product Dossier Preparation (Common Technical Document – CTD Format)
    - **Module 1:** Administrative and Product Information
    - **Module 2:** Quality Overall Summary (QOS)
    - **Module 3:** Quality (Pharmaceutical Data – Raw Material, Manufacturing, QC)
    - **Module 4:** Non-Clinical (Toxicology, Pharmacology)
    - **Module 5:** Clinical Data (Pilot & Confirmatory Studies)
- **Step 2:** NAFDAC Herbal and Complementary Medicine Directorate evaluation.
- **Step 3:** GMP inspection of manufacturing facility.
- **Step 4:** Marketing Authorization (5-year renewable).

4.2 Quality Control

- Standardization using **HPLC/UV–Vis fingerprinting**.
- Marker compound quantification and batch reproducibility.
- Stability testing under ICH conditions.
- Pharmacovigilance and post-marketing monitoring.

5. Research & Development Strategy

Stage	Activities	Partners	Duration
Pre-Formulation	Plant selection, authentication, extraction, phytochemical screening	University of Lagos, NIPRD	3 months
Preclinical Studies	Toxicity, efficacy in alloxan-induced diabetic rats	NIMR	6 months
Formulation Development	Standardized dosage forms, SOPs	In-house R&D team	3 months
Clinical Trials (Phase I–II)	Safety and efficacy	Teaching Hospital partners	12–18 months

Regulatory Submission & Approval	NAFDAC CTD dossier submission	Regulatory Affairs Consultant	6 months

6. Operations and Production Plan

6.1 Facility

- GMP-compliant phytopharmaceutical plant with:
  - Extraction and drying units
  - Encapsulation and packaging lines
  - In-house QC laboratory (HPLC, UV-Vis, TLC, micro lab)

6.2 Supply Chain

- **Backward integration** with local herbal farmers (contract farming).
- Training on Good Agricultural and Collection Practices (GACP).
- Quality traceability through barcode and digital documentation.

6.3 Production Scale

- Initial capacity: 100,000 capsules/month (expandable to 500,000/month).
- Export-ready facility by Year 3.

7. Marketing and Commercialization Strategy

7.1 Market Positioning

Positioned as a clinically proven herbal alternative for Type 2 Diabetes.

7.2 Branding & Promotion

- Medical detailing to physicians and pharmacists.
- Endorsement via Nigerian Diabetes Association.
- Digital campaigns emphasizing safety and local innovation.
- Scientific conference presentations and media engagement.

7.3 Distribution Channels

- Hospitals, pharmacies, and herbal outlets.
- Distributors across Nigeria’s six geopolitical zones.
- E-commerce and online health stores.
- ECOWAS export (via GMP and NAFDAC recognition).

8. Financial Plan

8.1 Start-Up Cost Estimate (₦ Million)

Item	Cost (₦M)
R&D (Extraction, Toxicology, Clinical)	70
Regulatory Documentation & Trials	30
Equipment & GMP Facility Setup	120
Raw Material Procurement & Contract Farming	25
Marketing & Branding	25
Working Capital	30
Total Investment Required	**300 million**

8.2 Revenue Projections

Year	Sales (₦M)	Operating Cost (₦M)	Net Profit (₦M)
1	180	150	30
2	350	210	140
3	600	300	300
ROI (3 years)	—	—	**~65% cumulative**

8.3 Funding Sources

- NASENI Research Commercialization Grant
- Equity and private investment.
- Bank of Industry (BOI) Pharma/Health Fund.
- NAFDAC–NIPRD herbal medicine grant.
- TETFund or African Development Bank innovation financing.

9. Risk Management

Risk	Mitigation Strategy
Variability in plant raw material	Contract farming + GACP certification
Regulatory delay	Engage early with NAFDAC/NIPRD technical units

Market skepticism	Publish clinical data + doctor outreach
Counterfeiting	Tamper-proof packaging and serialization
Capital constraints	Staged funding; R&D partnerships with universities

10. Implementation Timeline

Phase	**Key Milestones**	**Duration**
Phase 1	R&D and standardization	6–9 months
Phase 2	Preclinical and clinical trials	12–18 months
Phase 3	NAFDAC submission and approval	6–9 months
Phase 4	Commercial launch	3 months
Total Duration:	**~3 years**	

11. Sustainability and Socioeconomic Impact

- Promotes local content and import substitution in the antidiabetic drug market.
- Enhances healthcare access and affordability.
- Generates employment for farmers, researchers, and production workers.
- Contributes to SDGs 3, 8, and 9, i.e. health, economic growth, and innovation.

12. Conclusion

This project presents a transformative opportunity to commercialize a potential scientifically validated, NAFDAC-approved antidiabetic phytodrug that leverages Nigeria's biodiversity for national health and industrial development. By combining traditional knowledge, modern science, and regulatory compliance, NIPRD is pioneering a sustainable and profitable model for phytopharmaceutical innovation for the management of diabetes mellitus in Africa.