



U.S. MARKET COMMERCIALIZATION PLAN CHECKLIST

Issues That Life Science Companies Must Consider
When Preparing for the American Market





BioPortUSA's comprehensive Commercialization Plan is aimed at successfully bringing your company's product to market while maximizing its adoption, profitability and value creation.

Although it is recognized that your company may have a number of these items planned, in-process, or completed, this initial process is structured and timed to utilize a small subset of a broader plan to minimize spending while providing a timeline, critical deliverables and clarity.

Specifically, this commercialization plan is structured to address key components including current situational assessment, objectives, organizational gaps and competencies underlying those objectives.

It clarifies the economic value proposition and develops a pro forma P&L to assist in fund raising. By leveraging strategic insights and detailed financial projections, this plan ensures choosing an optimal path to commercialization and sustainable growth.



COMMERCIALIZATION PLAN OUTLINE

Overview

- Aspiration
- Disease State
- Market Size & Opportunity
- Competitive Analysis / Target Market Share Lifecycle
- SWOT Analysis / 5-Forces
- Financials Including 5-Year P&L
- Key Milestones

Product

- Product Description
- Regulatory Pathway
- Product Development Schedule and Lifecycle
- Main Parameters of Value and Unique Differentiators
- Economic Value Propositions
- Evidence-Based Medicine (EBM) Supported Benefits
- Buyer Profiles
- Branding

Clinical & Regulatory

- Regulatory Pathway, Timing, and Claims
- Pivotal Trial Description and Timing
- Ergonomics

Service & Warranty

Customer Segmentaion

- Classification
- Segmentation & Value Drivers for Each
- Medical Affairs



Pricing

- Economic Overview
- Region Floor Pricing
- Volumes
- Market Access and Reimbursement

Distribution

- US Sales Force / Channel Structure
- International Distribution
- Incentive Plan
- Sales Training Plan
- HCP Training / MedAffairs

Promotion

- Positioning Development
- Messaging Development
- Creative Development

Pre-Launch & Post-Launch Activities

Commercial Projections

- Revenue Projections as % of Market
- Pro-Forma P&L Projections Based on Specific Funding/Capital Levels
- Commercialization Schedule
- Regulatory Approval & Launch Dates

Budgets

- Global & Regional
- Demonstration Units



PHASE 1: ENGAGEMENT PROCESS

Introductory Meeting Agenda

1. Situational Assessment:

What is the current status of the product realization process?

- Organization
- Proof of concept
- Clinical Trials
- Market Assessment and EVP

2. Objective Review

- Short-term
- Interim
- Long-term

3. Organization Strengths & Weaknesses

- Clarify competencies and gaps to meeting commercial objectives and maximizing ROI

Deliverables

1. Validation Market

Assessment and approach for the US market and the World.

2. Economic Value Proposition

Pricing, TAM, Share estimates, etc.

3. Pro Forma P&L

3-5 years for directional guidance and fundraising

4. High Level Work Breakdown Structure and Timeline



U.S. MARKET COMMERCIALIZATION PLAN

As outlined in the BioPortUSA U.S. Market Commercialization Plan, these 13 business factors are critical areas that your company must address when considering U.S. Market entry:

- Tax Incentives and Physical Location
- Corporate Structure
- Financing Structure
- Entity Governance
- Statutory Legal Considerations for Companies Doing Business in the United States
- Labor and Employment Tax
- Intellectual Property (IP)
- FDA Regulatory
- Pricing and Reimbursement
- Marketing & Communications
- Preparing for Collaboration or M&A Transaction
- Litigation Avoidance Strategy

BioPortUSA offers access to industry experts and a menu of coordinated services all under one roof, addressing each of these business factors. We facilitate thoughtful, strategic and cost-effective guidance to help your company navigate the complex process for U.S. Market entry. Contact us to get started.

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