



U.S. MARKET LAUNCHPAD

READINESS ASSESSMENT

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



BIOPORTUSA.COM



Foreign Life Science companies that decide to expand operations into the United States face many challenges. Completing regulatory requirements, choosing a location and hiring employees are all subjects that will command your immediate attention.

The Market Launchpad addresses some of the issues and considerations that need to be made by a foreign company when preparing for market entry into the United States. BioPortUSA can help you navigate these complex processes.

Preliminary Considerations

When entering the United States, you have to decide on the states in which your company will be physically located and where your entity is registered. They could be the same, but usually they are not, due to tax and operational considerations.

- A. Identifying domestic legal and tax consequences for U.S. Market entry
- B. Location for office in the United States
 - 1.State incentives (e.g. tax breaks)
 - 2.State law (corporate, securities, insurance)
 - 3.Proximity to desired employee pool

Corporate Structure

Wholly-owned subsidiary? Affiliate? Joint Venture? Knowing how you want to operate is just one factor in deciding what form your entity will take.

- A. Formation of a U.S. subsidiary
 - 1. Corporation
 - 2. Partnership
 - 3. Limited Liability Company



Corporate Structure *continued*

- B. Acquisition of an existing U.S. company for U.S. Market entry
- C. Contractual arrangements with existing U.S. companies (e.g. outsourcing ancillary service, co-development arrangements, distribution arrangements)

Financing Structure

It is imperative to have a solid financial strategy to ensure successful U.S. Market entry. Capital can come in many forms including grants, loans and investment from the private sector. Avenues to consider include:

- A. State Economic Development Authorities (EDAs) and grant programs
- B. U.S. entity debt financing
- C. Asset-based or project debt financing
- D. Venture Capital / Private Investment firms
- E. Issuance of securities on U.S. public market: “foreign private issuers” requirements of the Securities Act and the Exchange Act
 - 1. Register foreign company securities as ADRs
 - 2. Register securities in the U.S. subsidiary
 - 3. SEC requirements
 - a. SEC rules and regulations
 - b. Registration requirements
 - c. Disclosure requirements
 - d. Ongoing reporting requirements
- F. Exceptions to the registration requirements for certain private placements
- G. Additional requirements posed by state securities law (known as “Blue Sky” laws)



Entity Governance

After you have decided on a specific corporate structure, your entity must comply with Federal and State laws and regulations. Failure to do so can delay market entry, increase operational costs and risk losing an investor's contributions.

A. Make up of U.S. Board of Directors

1. Parent representatives
2. Management representatives
3. Outside investor representatives
4. Independent direction

B. Protective Provisions

1. Parent
2. Outside investors

Statutory Legal Considerations

Federal legislation over the past decade has increasingly focused on foreign companies operating in the United States. Knowing what the law says may not be enough to avoid trouble. Awareness of how the law is being enforced, what industries are 'under the microscope' and what impact local and national politics will have on your operations is essential.

- A. Compliance with the International Investment and Trade in Service Survey Act
- B. Compliance with the Foreign Agents Registration Act
- C. Compliance with the Currency and Foreign Transactions Reporting Act
- D. Foreign-owned entities face special rules and industry-specific limitations when seeking contracts from U.S. governmental entities, such as the Buy American Act.



Statutory Legal Considerations continued

- E. Real estate ownership restrictions
 - 1. Primarily State law which pose restrictions on ownership by a foreign company
 - 2. Federal law
 - a. Compliance with the Trading with the Enemy Act
 - b. Compliance with the International Emergency Economic Powers Act
 - c. Compliance with the Foreign Investment in Real Property Tax Act

Labor And Employment

Federal laws and regulations are just the beginning. Each state also has its own rules for how to manage the relationship between employer and employee. Although there are union-free areas throughout the country, unions do exist in every state and in almost every industry. Not all unions are created equal however, as each state's laws will control how much power they wield.

- A. Taxation for foreign employees working in the United States
- B. Executive compensation for U.S. management
- C. Compliance with U.S. Federal, State and Municipal employment laws and labor standards
- D. Employee benefit plan compliance with the U.S. Employee Retirement Income Security Act
- E. Compliance with the Occupational Safety and Health Act
- F. Workers Compensation
- G. Advance notice requirement prior to termination
(e.g. Worker Adjustment and Retraining Notification Act)
- H. Compliance with immigration law



Tax

When conducting business in the United States, there are tax implications that you need to be aware of outside of the existing obligations to your home country. Also, if you are going to receive investment dollars from the U.S., you will need to take the corresponding tax responsibilities into consideration as well. Below are the areas that we will help you review and prepare for:

- A. Taxation of foreign companies doing business in the United States depends on many factors:
 1. Tax treaties
 2. U.S. entity structure
 3. Federal tax law
 4. State tax law
 5. Domestic tax law
- B. Transfer pricing will also be a factor:
 1. What does the home country parent entity pay the US entity for finished goods?
 2. What does the parent entity charge the affiliate for raw material, marketing support, general and administrative overhead?
 3. Are licenses and royalties for patents or trademarks (IP) involved?



Intellectual Property (IP)

Before entering the U.S. Market, it is critical that a company understands the positioning of their IP in relationship to what might already exist in the United States. In many cases, a Patent Landscape can be conducted to see which IP has been registered and whether or not yours will infringe upon it. If it does, we need to address this before you do anything else, otherwise a competitor will pursue legal action against you to stop your product from entering the United States. As a result, we recommend undertaking the following steps:

- A. Identification of IP that needs to be protected in the United States by performing an IP audit. Select appropriate IP protection (Patent, TM, TS, Copyright).
- B. If there will be some kind of partnership arrangement, a careful identification, valuation and ownership will be evaluated under U.S. law.
- C. Terms of contribution (all equity vs. royalty – consider both tax and economic implications).
- D. Are there any patentable inventions not yet registered in the United States?
If so, patent applications must be prepared and filed with the U.S. Patent and Trademark Office before encountering a bar date on each invention.
- E. Confirmation of Freedom to Operate
- F. Trade & Service Marks
 1. Conduct a mark search to identify preexisting marks/potential conflicts.
 2. An application for Federal registration of a mark may be filed with the PTO on the intent to use alone; however, it will not mature into a registration prior to actual use of the mark in the United States.
- G. Copyright: Unlike most other jurisdictions, the United State provides for the registration of copyrights with the U.S. Copyright Office. Such registration is not mandatory for copyright protection; it may, however, lend importation advantages and benefits in potential copyright infringement suits.



Intellectual Property *continued*

- H. Identification of trade secrets protection laws that are in effect in the target state. These laws may overlap with available patent protection.
- I. Identification of any license agreements in effect in the United States that grant someone else exclusive rights to use your IP (or parts of it).

FDA Regulatory

There are many regulatory hurdles that an international life science company needs to be aware of that cannot be taken lightly. Understanding what pathways to take and fulfilling FDA requirements is critical. Our team is expert in how to navigate complex FDA processes and can guide you accordingly:

- A. Develop a clear regulatory pathway strategy for the FDA regulated product (i.e. medical device, drug, biologic, or a combination product).
- B. Is your product a “new drug” / “new medical device” / “new biologic” / or “new combination product” as defined by the Federal Food, Drug and Cosmetic Act (FFDCA)?
 - 1. If so, you need to file either a new drug application (NDA) or an abbreviated new drug application (ANDA) for a drug / 510(k) or PMA for a medical device / BLA for a biologic / or a filing for a combination product based on its primary mode of action prior to marketing it in the United States.
- C. Under certain conditions, the U.S. Food and Drug Administration (FDA) will accept foreign clinical trials in support for regulatory filings. Do clinical trials so far conducted by your company meet those requirements?
- D. Strict regulations apply to labeling, promotion, and advertisements. Prior to disclosing any information about your product, verify that you are not violating the FFDCA or and FDA regulations or FTC regulations.
- E. Filing requirement: Certain agreements between pioneer drug companies and ANDA applications are subject to antitrust review by the Federal Trade Commission and Department of Justice.



Pricing And Reimbursement

Unlike most of the world where Universal Healthcare with a Single Payer System exists, the United States has a very complex system with multiple payers. As a result, developing a pricing strategy that will allow a foreign life science company to remain competitive, along with creating an economic healthcare pathway for reimbursement is critical to your success.

- A. Private and government insurance reimbursement strategy – Understand the different business models based on site of care, mode of administration and FDA pathway.
- B. Medicare/Medicaid coding and reimbursement – Understand federal timeliness for coverage, coding and payment and impact on revenues generation and patient access.

Marketing & Communications

Marketing & Communications for the U.S. Market has a very distinctive voice, look and feel. Your efforts need to be tailor-made for this environment, with the proper mix of components to successfully build maximum visibility for your brand. You need to develop a U.S. strategy for your:

- A. Advertising
- B. Branding
- C. Investor Communications
- D. Print
- E. Web/Digital
- F. Promotion/labeling/sampling



Preparing For Collaboration Or M&A Transaction

Many International Life Science companies leave too much money on the table when they engage in a strategic partnering arrangement. This is in part due to being risk averse. There are a number of considerations that a company should be prepared to review with a US partner before committing to a long-term contract. At BioPortUSA, our senior consultants will advise you on best practices to assure positive growth outcomes.

- A. Joint development
- B. Co-promotion and co-marketing
- C. License agreement restrictions
- D. Manufacturing and supply arrangements
- E. Contractual restrictions on assignment of any key contracts

Litigation Avoidance Strategy

When doing business in the United States, it is of the utmost importance to protect your company from any possible lawsuits. The USA has a perception of being a very litigious society, and at BioPortUSA, we want to make sure that you are protected against any legal action. Even if you private label your technology to a US strategic sales partner, you are held liable if something goes wrong. In order to help protect you, we want to make sure that you have the following in place:

- A. Corporate conduct policy
- B. Record keeping policy
- C. Recall Strategy
- D. Manufacturing Process Review

Market Launchpad

As outlined in the Readiness Assessment above, 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.



United States

Mark Lesselroth
President & CEO

mark@bioportusa.com

+1 315-569-0642

Europe

Dr. Manfred Kauer
Senior Consultant

manfred@bioportusa.com

+49 176 53066289