Strategies for life sciences companies expanding to the U.S.
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With you today

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About SelectUSA

SelectUSA is the U.S. federal-level program dedicated to facilitating and promoting high impact business investment into the United States.

SelectUSA has assisted thousands of clients, including international companies, U.S. firms, and economic development organizations (EDOs), facilitating more than $64 billion in client-verified investment, supporting more than 86,000 jobs across the United States.
SelectUSA services

**Market research**

**ACTIONABLE INFORMATION** on business investment in the United States and developing an expansion strategy.

**Events & services**

**PLATFORM FOR CONNECTIONS** that will provide in-depth, on-the-ground expertise and guidance at a local level.

**Ombudsman**

**NAVIGATING THE FEDERAL SYSTEM** to help with questions or concerns about U.S. federal rules and regulations.

For more information, visit [https://www.selectusa.gov/](https://www.selectusa.gov/) or contact SelectUSA@trade.gov.
In 2017, FDI directly supported **291,800 U.S. life science jobs** in the life sciences industry.

### Life Sciences: Employees of Majority Foreign-Owned U.S. Affiliates, by Industry, 2017

- Pharmaceuticals and medicines: **211,200**
- Medical equipment and supplies: **80,600**

### Pharmaceuticals and Medicines: Employees of Majority Foreign-Owned U.S. Affiliates, by Country of UBO, 2017

- United Kingdom: **52,700**
- Germany: **25,800**
- Japan: **13,600**
- Netherlands: **4,600**
- Other Europe: **87,100**
- Other Asia: **10,200**

*UBO = Ultimate Beneficial Owner
Source for all data: U.S. Bureau of Economic Analysis (data accessed June 2, 2020)

Employee ranges are given for countries and regions with suppressed data: Canada (5,000 – 9,999), France (10,000 – 24,999), Switzerland (25,000 – 49,999), Other World (10,000 – 24,999).
Majority foreign-owned firms operating in the life sciences industry contributed **$23.0 billion** to U.S. goods exports in 2017.

Foreign-owned firms operating in the life sciences industry contributed **$22.9 billion** to U.S. research and development (R&D) in 2017.

### Exports and R&D Expenditures of Majority Foreign-Owned U.S. Affiliates, by Industry, 2017

- **Pharmaceuticals and Medicines**:
  - Exports: $19.1 billion
  - R&D: $21.7 billion

- **Medical Equipment and Supplies**:
  - Exports: $3.8 billion
  - R&D: $1.2 billion
OUR AGENDA
Today’s agenda

- Life sciences industry outlook
- U.S. expansion strategy considerations
• What sector of life sciences is your business most closely aligned?
A. Biotechnology
B. Pharmaceutical
C. Medical Device
D. Contract Research Organization
E. Contract Manufacturing Organization
F. Consulting to the life science industry
LIFE SCIENCE OUTLOOK
The U.S. life science ecosystem is highly intertwined with the world’s largest healthcare system, well-funded capital markets, and the most productive research pipeline. That environment is supported by a highly-skilled talent pool coming out of major centers of higher education, as well as the brightest minds from across the globe.
Top life science markets in the U.S.

**Total U.S. life science employment**

- 3-4% growth YoY as compared to the total U.S. labor market of 1.7%
- Trends in labor are reflected in increased capital activity

**Employment by life science sector**

- BioTech is the fastest growth sector in terms of labor and capital raised
- Growth is driven by genetics, immuno-oncology, and advanced data science

Source: CBRE
Top life science markets in the U.S.

**Top leading life sciences markets**

1. Boston-Cambridge
2. San Francisco Bay Area
3. San Diego
4. New Jersey
5. Raleigh-Durham
7. New York City (and surrounding areas)
8. Philadelphia
9. Los Angeles
10. Chicago

**Top emerging life sciences markets**

1. Seattle
2. Houston
3. Austin
4. Minneapolis
5. Denver
6. St. Louis
7. Dallas/Ft. Worth
8. Atlanta
9. Pittsburgh

Ranked by size of laboratory inventory, size and long term growth in life science employment, number and concentration of key scientists, and the size of funding sources.

Ranked on the basis of recent life science employment growth, number and concentration of key scientists, NIH funding, quality and quantity of educational institutions focused on life sciences, research and health services, number of high tech workers.

*Source: CBRE*
Major themes

• Global recovery from economic disruption
• Life science is the hope for an end to the pandemic
• COVID-19 therapies have dominated 2020
• US clinical pipelines more robust than global counterparts
• Private investment remains strong
• IPO’s have slowed, but life science represents a greater share
• Major drug pricing legislation unlikely in 2020
• Global trend to protect supply chains
Hoping for a “V”

RSM US MIDDLE MARKET BUSINESS INDEX

Source: RSM US LLP
Snapshot of COVID related interventional trials

1527
Total Trials
1527 Interventional Trials

987
Sponsors
785 Collaborators

338
Drugs
984 Targets, 2 Biomarkers

2043
Investigators
10 Participating Countries

373
New Trials Past Month
1072 Open Trials

Trials By Phase

Source: Trial Insights & scientist.com
Clinical trial enrollment: March 2020 vs 2019

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<thead>
<tr>
<th>Country</th>
<th>Change</th>
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<tr>
<td>China</td>
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<tr>
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<td>Germany</td>
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<tr>
<td>Spain</td>
<td>-68%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>-80%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>-65%</strong></td>
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</tbody>
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Source: Medidata
Global clinical trial starts: All starts vs % focused on COVID

Source: Trial Insights
U.S. companies had a less pronounced impact on non-COVID clinical trial starts compared to WHO registries.
Life science IPOs represent a disproportionate piece of the market

Between January 2018 and May 2020:
- Life science IPOs represent 26% of all capital raised and 43% of all IPOs
- Technology/media/telecom made up 35% of capital and 20% IPOs

Life science IPOs over the last two years have also had an offer to date return of approximately 45%.

Source: Bloomberg
Active private capital drives innovation and employment

VC & PE Activity - ($1M - $10B)

Investment Capital % of Capital Deals % of Deals Average Round
More than $100M $13,129 58% 40 5% 6
$100M - $10M $8,178 36% 245 29% 5
$3M - $10M $1,076 5% 553 22% 5
Less than $3M $363 2% 368 44% 4

Source: PitchBook

2020 Life Science VC and PE Deals by Sector

- Biotechnology: 32%
- Drug Discovery: 18%
- Diagnostic Equipment: 11%
- Therapeutic Devices: 10%
- Surgical Devices: 8%
- Pharmaceuticals: 6%
- Monitoring Equipment: 5%
- Other Healthcare Technology Systems: 4%
- Drug Delivery: 3%
- Other Devices and Supplies: 3%
Positive perception may postpone major drug pricing reform

- Increasing public sentiment for Life Sciences and strong support for innovation and development
- Funding decision for “extenders” was pushed from May 22 to Nov. 30, past the election cycle
- Consideration of an International Pricing Index (IPI) for Medicare Part B is absent from current drafts of bipartisan drug pricing legislation
- Generics and biosimilars poised to benefit as lawmakers favor competition over outright price controls

Source: Quid
Biologics, orphan and generics are supporting drug portfolios

- U.S. accounts for the largest number of drug approvals annually
- While generics are the fastest growing segment the market, the continued development of novel and orphan drugs supports record profits
- Major drug companies acquire, not develop the majority of their pipeline

New Drug Approvals - Abbreviated vs Novel (by Quarter)

Source: Bloomberg, FDA
U.S. EXPANSION STRATEGY CONSIDERATIONS
What stage of expansion is your business at?

- We are already in the U.S.
- We have expanded to other countries but not the U.S.
- We are still considering our expansion strategy
- We are not considering expanding over the next 12-18 months
Defining your organization’s U.S. expansion vision

What is your **strategy?**
Spend the time required to do your diligence before entering the U.S. The temptation for many businesses is to execute first, then plan later. Stay focused but open minded and flex when the situation dictates.

What are your **goals?**
Leading practices of successful U.S. market entrants demand that you begin by defining your business goals and aspirations. Putting down brief, specific measurable goals to these areas is key.

Where will you **focus?**
Which markets represent the greatest opportunity? Where will you segment by customer, geography, product or channel? Define this with specificity, do your research and put realistic figures to it, and then allocate the vast majority of your resources to the top tier of opportunities.

How will your product or service **succeed?**
Taking your product or service to a new market undeniably requires you to be an open minded skeptic about its prospects in a new country. What is your target business model and should it differ or be localized in some way to succeed?

How will you **configure** to meet your goals?
Evaluate the capabilities your new business must have to meet the goals that your steering team developed.

What is your **plan?**
Identify key work streams, decompose them into tasks, set start and end dates, and assign owners and do research to identify the budget needed. Make a business case that shows initial cost, payback period, return on investment and cash flow over time.
Expansion planning

- Business and expansion strategic plan
- Select advisors
  - Tax/accounting, legal, visa, real estate, insurance, banking
- Analyze tariffs
- Conduct tax analysis
- Develop implementation plan
Expansion strategy development

• Market and customer analysis

• Location and labor analysis
  - Access to workforce is critical

• Tax credits and incentives
  - Secured prior to expansion
  - Highly variable by location

• Operational analysis
Tax and entity planning

• Determine domicile
• Determine entity type and structure
• Entity formation
  - FEIN and state id
  - SOS registration
• Employment tax and withholdings
• International tax planning
• State and local tax planning
Human resource planning

• Social Security and employment taxes
  - Filing requirements

• Affordable Care Act and workers comp
  - Filing and compliance requirements

• Visa planning

• Compensation and benefits planning
  - FMLA and other requirements
  - Compensation benchmarking
Accounting and financial reporting

- Select accounting software/provider
  - Scalable virtual service
- Determine accounting and reporting procedures
- Determine financial audit requirements
  - U.S. audit generally not needed for private companies
Facility considerations

• Secure real estate
  - Analyze temp space vs. lease vs. purchase

• Obtain required permits / licenses
  - Local businesses licenses

• Technology / IT needs
  - Varying IT security requirements by industry
Developing your U.S. expansion roadmap

1. Expansion planning
2. Strategy development
3. Tax and entity planning
4. Human resources planning
5. Accounting & financial reporting
6. Facility considerations
THANK YOU FOR YOUR TIME AND ATTENTION