



SNAP RECAP

European Biotech Leader Roundtable #1: Summary of Follow-Up Sessions

Establishing a Global Mindset and Commitment to Europe, Aligning Priorities, and Setting Up the Right Partnering and Distribution Models



What is the European Biotech Leader Roundtable?

For biopharmaceutical companies seeking to enter Europe—or that already have a presence there—Europe presents an interesting combination of opportunity and complexity. The markets that comprise Europe can be very attractive, but the pathway to sustained success is not always easy to discern.

To dissect the complexity, identify best practices, and formulate guiding principles, Blue Matter has assembled a panel of biopharma executives and other experts with proven track records of success in Europe. These leaders have agreed to share their knowledge and “lessons learned” through a series of Roundtable meetings and follow-up sessions.

Roundtable #1 was a virtual meeting held on March 26, 2020. During the session ([Co-Designing the Ideal Biotech Journey to Success from the US to Europe](#)), our panel identified critical questions, best practices, and top pain points for biopharma companies entering Europe.

What are Follow-Up Sessions?

Following Roundtable #1, several members of our panel convened virtually to explore some aspects of European market entry in more detail, with a focus on US-based biopharma companies. Those follow-up sessions were conducted on April 30 and May 28, 2020.



Session Participants

	April 30, 2020	May 28, 2020
Topic	Establishing a Global Mindset, Expertise, and Commitment to Europe	Establishing Globally Aligned Partnering and Distribution Models that Meet European/Regional Needs and Leverage Local Capabilities
Panelists	<ol style="list-style-type: none"> 1. Theresa Heggie, CEO, Freeline 2. Daan Kranenburg, General Manager, Expansion Markets, bluebird bio 3. Alexey Kutahov, General Manager, Europe, Sarepta Therapeutics 4. Sebastian Stachowiak SVP and Head of Europe, Global Blood Therapeutics 	
Blue Matter Moderators	<ol style="list-style-type: none"> 1. Zeren Kocak, Senior Consultant 2. Dirk Moritz, Senior Adviser 3. George Schmidt, Managing Partner 	<ol style="list-style-type: none"> 1. Zeren Kocak 2. Theo Manolikas, Principal 3. Dirk Moritz 4. George Schmidt

This document provides a concise and integrated summary of both sessions.



Establishing a Global Mindset, Expertise, and Commitment to Europe

Key Success Factors / Potential Pain Points:

1. Ensuring that the US teams make “head space”, build the required expertise and shift their mindset when the organization decides to expand beyond the US.
2. Avoiding a US-centric “command and control” structure and enabling European / regional decision-making once the team is brought on board.
3. Fully accounting for region-specific regulatory and market requirements and different competitive landscapes when determining a global product positioning.

Potential Solutions / Considerations

1. Leadership should **make investment decisions based on the long-term** (e.g., three-to-five-year plan), taking into consideration the resources required, the expected regional contributions, and the desired outcomes of the company (e.g., revenues, breadth of patient access).
2. All teams should “own the overall business” and consider themselves part of a **global team with regional accountability** as opposed to viewing themselves as siloed regional teams.
3. **A smaller global leadership** team should be set up, and connections across teams should be enabled through effective governance.
4. The **global leadership team** should be seen as an **enabling function** rather than a top-down, hierarchical entity.
5. The overall mindset should be inclusive of all teams, encouraging **joint accountability**.
6. **Global brand teams** should be established that include **regional representatives** in key areas (e.g., marketing, access, etc.).
7. **To account for specific local needs, regions** should be involved in **strategy and implementation decisions** as early as possible.
8. Global leadership should **trust the regions** and give them autonomy to implement their adapted regional strategy.
9. Teams should **be hired with a global mindset from the beginning**, as opposed to shifting the mindset and the decision-making processes to be more decentralized after the organization expands beyond the US.
10. The company may need to **rethink the role of Global Marketing**, holding it accountable for helping to get the strategy right in each individual market.



Establishing Globally Aligned Partnering and Distribution Models that Meet European / Regional Needs and Leverage Local Capabilities

Primary Issues:

1. How to determine the right decision parameters for guiding key decisions such as timing of market entry and whether to “go it alone” vs. partnering?
2. How best to manage distributor markets (central vs. regional / local)?

Key Success Factors / Potential Pain Points:

1. Ensuring that the European expansion strategy is embedded within a broader global partnering / distribution strategy that avoids duplication of separate and potentially competing organizations for Europe and the rest of the world.
2. Aligning the US-based organization on an agreed set of decision parameters that will be used to make key decisions (e.g. timing and sequence of geographic entry, as well as partnering) in an integrated way.
3. Properly defining the management of distributor markets (i.e. deciding what is led by the global function vs. regional or local functions).
4. Ensuring proper company focus and investing sufficiently in the bandwidth of functions that will support decision-making, manage distributors, etc.

Potential Solutions / Considerations (regarding decision-making on market entry timing and partnering):

1. Typically, **early-stage** US-based organizations will initially focus on **commercial viability**, sustaining their **financial position**, and developing a **revenue stream**. Later, focus expands to **broader access** and a larger geographic scope including also humanitarian or philanthropy programs.
2. For key decisions, both **external** and **internal parameters** should be considered.



3. Key **external parameters** include:
 - a. Size of the commercial opportunity and patient population
 - b. Likelihood of reimbursement and (early) patient access
 - c. Achievable price and expected revenues
 - d. Regulatory effort and chances of success
 - e. Drug supply requirements
 - f. Ease of doing business
 - g. Corruption and political risk
 - h. Others
4. Key **internal parameters** include the company's:
 - a. Willingness & commitment to provide access to patients (also level of access)
 - b. Financial situation and capability
 - c. Risk tolerance and global experience
 - d. Likelihood of development success
 - e. Pipeline situation
 - f. Product costs
 - g. Supply chain complexity & infrastructure needs
5. There is **no magic formula** for defining the right set of **decision criteria**. Each company will define its own criteria based on its specific situation and culture.
6. Decision criteria largely depend on the **type, value, and the complexity of the product(s)**. For example, a company providing a therapy as a pill will typically have a much higher risk tolerance than a company providing a high cost / high value gene therapy with a complex supply chain.
7. The **commercial opportunity** should be attractive both for the company as well as for any potential partner or distributor.
8. **Distributors** might have the right capability, market knowledge, and critical relationships to quickly unlock significant value in markets that may initially be perceived as less attractive.
9. **High complexity** of getting product to patients, challenging supply issues, and/or highly concentrated expertise (e.g. in rare diseases) may require **partners** with sophisticated capabilities.
10. **Key criteria** for assessing partner / distributor options are:
 - a. Speed to market & revenues
 - b. Investment required
 - c. Level of control
 - d. Complexity of product supply
 - e. Risk
 - f. Relationship and level of trust



Potential Solutions / Considerations (regarding management of distributor markets):

1. Key variables that should be considered include the following:
 - a. Level of company expertise on regional partnering markets
 - b. Governance
 - c. Roles & responsibilities
 - d. Timing of decisions
 - e. Choosing the right partner
 - f. Deciding where IP resides
 - g. Long-term & pipeline considerations
 - h. Time zones
 - i. Risk
2. The global partner / distributor model and structure varies by company and depends on its philosophy, existing expertise, and mindset.
3. Setting up & defining the right **governance and decision-making process** is critical for success
 - a. Ideally, the strategy for country prioritization, geographic expansion and alone vs. partnering should be defined globally, e.g. by the **company board or a “business board”**. This body also should make key business decisions based on pre-defined criteria such as opportunity, risk, etc.
 - b. An **operational team** should assess capability and resource needs and allocation. At this level, the inclusion of potential partners is highly desirable.
 - c. The **regional / local organization** should be responsible, accountable, and be empowered to allocate resources and lead strategy implementation at the regional / local level.
4. As a general principle, future **distribution partners** should be treated as **true partners**, be part of the team, and ideally, be involved as early as possible in the decision-making process to best leverage their capabilities, market knowledge, and previous experience with other models and companies.

Practical Tips for Heads of Europe:

1. Develop close personal relationships with the CEO and CCO and gain their buy-in that they need to champion such collaboration across the organization.
2. Identify best practice examples and showcase to company leadership.
3. Leverage individuals in the global leadership team that have international / EU experience.
4. Bring the CEO to Europe to meet the key customers in focus countries and highlight key issues.



5. Develop longer term (3+ year) plans to provide more context to Global leadership for EU investments.
6. The definition and alignment on key decision criteria is a critical first step for deciding on market prioritization, entry sequence, and alone vs. partnering options.
7. The set of decision criteria will vary significantly by company and depends on the specific company situation, nature of the product, culture & mindset, (financial) objectives, success definitions, and appetite for risk. Deeply understanding the above will be critical for success.
8. A good governance and decision-making process is critical. There is no off-the-shelf solution.

To see new materials as they become available, please visit Blue Matter's [blog](#) and our [Resources Page](#) on European market entry.

