SNAP RECAP

European Biotech Leader Roundtable: Follow-Up Session

How to Build an EU Organization for an Effective Launch—Guiding Principles for Optimal Resource Investments and the Ideal Sequencing

European Biotech Leader Roundtable

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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 can be challenging and 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.

Our panel held its first Roundtable meeting (virtual) 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 the European Biotech Leader Roundtable meeting, several members of our panel convened again virtually to explore some aspects of European market entry in more detail, with a focus on US-based biopharma companies. This document summarizes Follow-Up Session #3, which was held on June 18, 2020. It is presented in a simple outline format and is only intended to capture the main ideas from the discussion. A combined summary of follow-up sessions 1 and 2 can be accessed here.

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Session Participants

	June 18, 2020
Topic	How to Build an EU Organization for an Effective Launch – Guiding Principles for Optimal Resource Investments and the Ideal Sequencing
Panelists	1. Neil Hughes, General Manager and Head, EMEA, Insmed, Inc. 2. Alexey Kutahov, General Manager, Europe, Sarepta Therapeutics 3. Michelle Lock, Former Sr. Vice President and Head of Europe, Sage Therapeutics
Blue Matter Moderators	1. Theo Manolikas, Principal 2. Nafees Masri, Consultant 3. Dirk Moritz, Senior Adviser 4. George Schmidt, Partner

How to Build an EU Organization for an Effective Launch

Guiding Principles for Optimal Resource Investments and the Ideal Sequencing

Problem Statements Discussed During the Session:

1. What are the guiding principles for building an EU organization?
2. What are the most relevant decisions for building out an EU organization?
3. What is the ideal sequence and timing of these decisions relative to launch?

Key Assumptions for the Discussion:

1. US-based biotech start-up that has decided to "go-it-alone" in Europe
2. Focus is on a speciality product or in a rare / orphan disease
3. Single product launch with potential future product launches through pipeline or BD activities
4. Key functions in place in the US but no fully established European footprint
5. EU market authorization is up to 3 years away
6. Launch focus is on major European markets first with potential for further geographic sequencing
7. European General Manager (GM) has been hired and started work

Problem Statement 1: What are the guiding principles for building an EU organization?

The panel identified four key guiding principles. For each principle, the panel listed several important questions and / or details that relate to it. They are summarized below.

1. **Establish first WHY the company wants to go to Europe.**
    a. Key questions
        i. What is the defining purpose and vision for entering Europe?
        ii. What are the company's primary objectives for entering Europe?
    b. Related Considerations

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i. With larger immediate returns on investment expected from the US market, European investment should directly serve a purpose within—and align with—the global company vision. It is critical to understand the key drivers of European investment, e.g.:
   1. Does the Board want to optimize revenues to achieve break-even as soon as possible or serve as many patients as possible, which might include limited or no reimbursement and delay profitability?
   2. Is "collateral value" a driver? (European presence provides indirect global company value with key reference pricing being used for subsequent pricing decisions in other markets, such as Japan).

ii. To capture the European opportunity, significant early investment must be made. For example, consider the long-term infrastructure needs for Europe as some key investments may be needed early (such as an early screening or genetic testing infrastructure).

iii. Investment decisions should be linked to key milestones or trigger points.

2. **Clarify exactly WHAT the company wants to achieve in Europe.**
   a. Key questions
      i. What are the key strategic priorities?
      ii. What key decisions need to be made?
      iii. What are the prioritized target markets and the associated launch / commercialization sequence?
      iv. What is the commercial strategy (where to play and how to win)?
      v. What is the European business model, which may be different from the US model (e.g., do it alone vs. partnering / distributors, supply solution, etc.)?
   b. Related Considerations
      i. The European market entry should align with the global vision and ambitions. This should be reflected on whether the company decides to go-it alone vs. partner with distributors.
      ii. Who owns the strategy in Europe? Decision makers with accountability for the European strategy should likely be based in Europe, as this could help provide a more cohesive and scalable European organization.
      iii. It's important to remember that the initial priority markets do not necessarily need to be the EU5 (Germany, France, UK, Italy, and Spain). For example, both Spain and France can be slow to gain access, while in the UK, reimbursement and the lack of clarity around Brexit can be challenging. There may be compelling reasons for a company to prioritize other markets first.

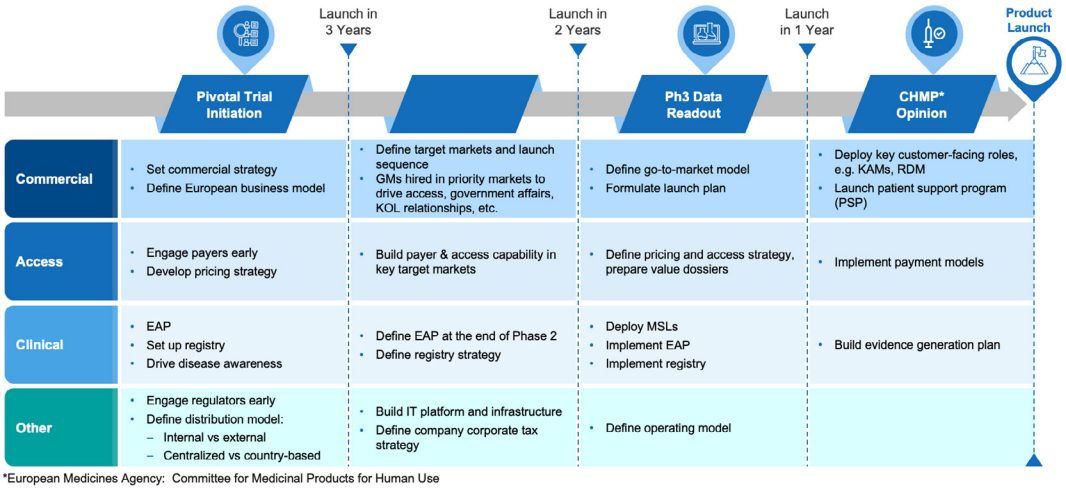
iv. Factors which may influence the prioritization of markets include speed to market, pricing, KOL placement, access, and the size of the addressable patient population.
v. Educate both US and European stakeholders as needed to shift entrenched views on which markets truly align with the corporate strategy.
vi. It is important to drive and define the US HQ's expectations with early input from local expertise and knowledge.
vii. Ensure that the development program fits the EU's specific needs and reflects the regional reality, e.g. with regards to treatment paradigms and standard of care. Identify and address approval bottlenecks.
viii. Company global resource bandwidth will be finite and therefore it is important to be selective on where to focus within Europe.

3. **Define and align on HOW the company will make key decisions.**
   a. Key questions
      i. What are the decision-making and governance processes (e.g. centralized vs. decentralized)?
      ii. What parameters will be utilized to decide on the attractiveness of potential markets (market size, time to reimbursement, achievable price, etc.)?
   b. Related Considerations
      i. Ensure alignment with the US HQ over where decision making authority lies and determine which decisions will be made from the US HQ vs. the EU HQ.
      ii. Empower European leadership to make local decisions to help ensure alignment to both local needs and corporate strategy.
      iii. Decision-making authority must be clearly delineated across the global, regional, and local levels.
4. **Map out key decisions and define WHEN they will be made and WHEN implementation should be done.**
   a. Key questions
      i. When will key decisions be made (what are the trigger points, gates, etc.)?
      ii. When do implementation efforts need to start?
      iii. When do key capabilities need to be in place?
   b. Related Considerations
      i. Developing a long-term hiring plan is essential (and different from the US). It should be defined as part of a wider building strategy. Recruiting begins at least 24-30 months prior to expected approval.
      ii. Executive-level recruitment in European markets is a long process and requires significant lead time as regional laws require comparatively long notice periods.

iii. Establishing a European GM during Phase 2 provides the company with an opportunity to ensure generated data meets necessary requirements for approval.
iv. Securing market access is critical and efforts need to be mapped out in alignment with the company's geographic focus and country pricing and reimbursement negotiations.
v. Leveraging vendors over FTEs for early functional requirements will bring specialized expertise while reducing risk. Vendor use can be gradually phased out as FTEs are hired.

Problem Statement 2: What are the most relevant decisions (investment and others) for building out an EU organization? And what is the ideal sequence and timing of these decisions relative to launch?

The panelists' thoughts are summarized in Figure 1, below.



*European Medicines Agency: Committee for Medicinal Products for Human Use

Problem Statement 3: What is the ideal sequence and timing of these decisions relative to launch?

1. **Commercial**
   a. Hiring a Europe General Manager (GM) should ideally occur 3 years before launch. Early on, GMs will need to be "jacks of all trades" including a broad set of skills and experiences covering government relations, market access, and an understanding of the market and the KOL landscape. In addition, GMs should have the capability to inform infrastructure plans and have an understanding of the necessary licenses and certifications.
   b. A successful launch outcome is crucial, as both the positives and negatives of a launch will be felt throughout the product

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lifecycle. Ensure field force excellence through investing in KAM/RDM at least 6 months prior to launch.

c. Support services such as patient support programs (PSP) should not be overlooked and should be executed 3 months before launch.

2. **Market Access**
   a. Ensure consideration of both payer & regulatory perspectives early, as this will allow the company to adapt clinical trial data sets to meet the requirements.
   b. Early conversations with payers will also help expedite additional conversations closer to launch.
   c. Tailor the pricing strategy to meet the company's strategic objectives (e.g. quick uptake, etc.)
   d. Internal discussions on reference pricing will be important:
      i. Is the strategy focused around getting higher prices?
      ii. Will the company need to control pricing across markets due to reference pricing?
   e. The pricing strategy should inform phase 3 trial design as key data points will be required to achieve pricing strategy objectives.
   f. Specialized vendors can conduct data assessments to fully understand trade-off considerations and the associated outcomes for pricing, access, and approval.
   g. Avoid opportunistic launches as they will directly impact reference pricing.
3. **Medical**
   a. Hiring a small number of medical science liaisons (MSLs) 2 years prior to launch will allow the organisation to engage with stakeholders within the disease space and build relationships with KOLs.
   b. Infrastructure for early access programs (EAP) should be considered as early as the end of Phase 2:
      i. EAPs may represent an attractive opportunity to provide early clinical experience.
      ii. EAPs can be costly, so it's important to define how they will be run and from where funding will be sourced.
   c. Disease registries can be helpful.
      i. Evaluate if the company needs its own registry or if it can be driven by societies.
      ii. Ensure the registry is recognized by societies and viewed as patient centric.
4. **Other Capabilities / Infrastructure**
   a. The company must decide if it will adapt or adopt the information technology, human resources, finance, and other systems and processes. It is important to leverage existing capabilities when possible, but also stay open to option of building what's needed.

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i. It is important that European function leads build relationships with global leads.
ii. European functions should feed directly to the global functions.
iii. The European functional leaders should have a seat at the global function meetings as this will allow them to inform global decisions and help align global personnel with the European organization.

b. Define the corporate tax strategy. This will have significant implications regarding where structures and operations are placed across Europe, and where specific event and meetings will need to be held.