SNAP RECAP

European Biotech Leader Roundtable #1

Co-Designing the Ideal Biotech Journey to Success from the US to Europe

Summary of Key Points from a Virtual Roundtable Conducted on March 26, 2020

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 is not always easy to discern. To help, Blue Matter has assembled a panel of biopharma executives and other experts that have proven track records of success in Europe. These leaders have agreed to share their knowledge and "lessons learned," beginning with this virtual roundtable and ideally via a series of virtual and live events. Over time, Blue Matter will share their insights to help other companies maximize their success in Europe.

Roundtable Participants:

- **Alexey Kutahov**, General Manager, Europe, Sarepta Therapeutics
- **Beat Bachmann**, Head of Economic Promotion, Canton of Zug
- **Daan Kranenburg**, General Manager, Expansion Markets, bluebird bio
- **Michelle Lock**, Former SVP and Head of Europe, Sage Therapeutics
- **Neil Hughes**, General Manager and Head, EMEA, Insmed
- **Theresa Heggie**, Former SVP and Head of CEMEA, Alnylam Pharmaceuticals, Incoming CEO at Freeline
- **Thomas Lackner**, SVP and Head of Europe, Apellis Pharmaceuticals

Blue Matter Moderators & Participants:

- **Dirk Moritz**, Principal
- **George Schmidt**, Managing Partner
- **Nafees Masri**, Associate Consultant
- **Theofanis Manolikas**, Principal
- **Thomas Quirk**, Partner
- **Zeren Kocak**, Senior Consultant

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The Purpose of This Roundtable

In this first, virtual roundtable event, the group was asked to consider a biopharma company's journey to Europe in three stages:

1. Evaluating European Market Entry
2. Deciding to Enter the European Market
3. Entering Europe

Within **each stage**, the group was asked to share three things from their **own experiences**:

1. Critical Questions – What are the most important questions by stage?
2. Best Practices – What did success look like and what would you consider best practice?
3. Pain Points – What special challenges did you face, or what would you do differently if given the chance?

This summary document captures the group's collective input in a simple outline format. In future virtual and live gatherings, the team will explore the most important questions and keys in more detail.

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1 Stage 1: Evaluating Market Entry

Critical Questions

The questions below are not a comprehensive list of all questions a biopharma company must answer when evaluating a European market entry. Rather, the list focuses on those questions that were considered most strategically relevant for the group. The same is true for the Critical Questions listed for stages two and three.

1. **How important is Europe for the company?**
    a. Why are we going to Europe and how does it fit within our global commitment?
    b. What is our commitment to patients and how do we deliver on that commitment in financially sustainable way?
    c. What trade-offs would be required relative to other markets around the world?
    d. What are product and portfolio considerations?
    e. How do we decide whether to launch in Europe (what is the process and what information do we need)?

2. **What will be required to succeed?**
    a. Do we have the appropriate clinical data needed for regulatory success (FDA vs EMA attitudes and data requirements)?
    b. What is our level of commitment for gathering additional clinical data (e.g. post-approval commitments)?
    c. What will be required to secure reimbursement, as well as early and broad patient access in key markets?
    d. What is the best way for our drug to reach the patient (supply model)?

3. **How would we enter Europe?**
    a. What should our commercial / business model be?
    b. What is the opportunity and what is the cost?
    c. Should we go it alone, partner, or out-license?
    d. What is the priority and sequence of markets?
    e. What kind of organization do we need to build (e.g. might some global functions be best placed in Europe)?

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Best Practices

The list below is not intended to be comprehensive. It highlights those things that were "top of mind" for what success looked like in this stage for the group, based on their personal experiences. The same is true for stages two and three.

1. Achieving global alignment on how success should be defined based on the company's priorities and values (e.g. profitability & patient numbers vs broad level of access, etc.)
2. Aligning the global and European views to boost overall support for the strategy
3. A clear understanding of the regulatory pathway(s) and planning for the most likely scenarios
4. Getting early EMA input (definitely before phase 3 of clinical development, and preferably before phase 2)
5. Conducting an early Health Technology Assessment (HTA) to identify key value components and gaps
6. Engaging early with payers to fully understand their needs and perspectives
7. Pricing and reimbursement scenario planning at an early stage (as more and better data can result in better pricing)
8. A clear understanding of where Europe fits into the company's global strategy
9. A well-defined plan for EU launch focus and sequencing, focusing first on the most strategically important markets to drive key investment decisions
10. Adopting a holistic approach to the design of the European organization, with proper attention paid to all functions beyond Marketing and Medical Affairs
11. Diligent investment planning, including for headcount to prepare markets

Pain Points

The list below is not intended to be comprehensive. It highlights those pain points that were "top of mind" for the group, based on some of their personal experiences. The same is true for the Pain Points listed for stages two and three.

1. Inadequate assessment of clinical trial data in light of EMA requirements
2. Late engagement with the EMA regarding study design and failure to gather the earliest possible advice
3. Late generation of important additional clinical data
4. Gaining late input regarding the Health Technology Assessment
5. Unknown future impact of the UK (Brexit) / NICE on the EU launch sequence

2 Stage 2: Deciding to Enter the European Market

Critical Questions

1. **What does success look like?**
    a. What is the life cycle management plan for the company and how does Europe fit into it?
    b. How do we best co-create our global strategy and European market entry strategy? (This is most relevant for clinical-stage biotechs, as more mature companies may have more of the strategic framework in place.)
        i. What is our company vision and ambition?
        ii. What are our success metrics?
        iii. What are our governance processes? How do we best align and work effectively across the global and European teams?

2. **Where do we play and when?**
    a. What is our product and portfolio strategy / prioritization?
    b. What is our market, patient, and physician segment prioritization?
    c. What is our cross-market regulatory strategy?
    d. What are our market access and medical strategies?
    e. How big do we want to enter and which markets do we go into first (few countries, quick to markets/smaller opportunities versus stepwise/bigger opportunities)?
    f. What's the sequence of market launches and what is the gating for adding resources?

3. **How do we enter Europe?**
    a. What resources, capabilities, and infrastructure do we need to win?
    b. What are the risks and opportunities?

Best Practices

1. A purposeful focus on core markets to avoid dilution of attention
2. A well-defined culture to avoid any disconnects between the European organization and the "mother ship"
3. A systematic approach to deciding when to hire key team members and put resources in place (This must balance the benefits of hiring early with the risks that the asset may not launch and those people and resources will never be needed)
    a. A willingness to hire key team members earlier rather than later, even in the face of uncertainty (Medical Affairs and Market Access personnel, for example, should almost always be hired very early)

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   b. In some cases, being willing to hire Market Access and Medical Affairs in some countries before the GM, accepting the risk of "fit" issues between the GM and those functions
   c. A well-defined blueprint and plan for hiring that looks out for at least two years (complete with the timing of hires) and a corporate commitment to adhere to it and to resource it
4. Alignment of market access planning with life cycle management of the portfolio
5. Early KOL engagement
6. Strong relationships between clinical operations and clinical trial sites

Pain Points

1. Dealing with uncertainty (With the benefit of hindsight, a company will almost always say it built its organization "too late." Unfortunately, no one has hindsight early in the process. Generally, a company needs a systematic approach for weighing the benefits of building a European organization early vs. the risks associated with a product failure. However, early action is generally best, if possible.)
2. Hiring certain team members too late. (Definitely focus on getting Medical Affairs, Market Access, and the General Manager on board as early as possible).
3. Readiness to launch at the country level prior to financial plans being ready (driven by Finance adhering to "industry norms" when the teams "on the ground" were able to be far more agile)

3 Stage 3: Entering European Markets

Critical Questions

1. How do we organize ourselves to most effectively execute our strategy?
    a. How do we execute the integrated plan by function?
    b. How can we communicate effectively between Europe and the headquarters?
    c. How should we gain alignment on key roles, responsibilities, and decision-making processes (and have these evolve as needed over time)?
    d. What Human Resources policies need to be set beforehand to ensure that we can move quickly?
    e. Do we need to relocate any global functions based on where the talent or infrastructure situations are more favorable?

2. How do we rapidly learn and adjust?
    a. How do we adjust local plans and resources to account for roadblocks or other realities "on the ground" to ensure that we continue to deliver on our strategy?
    b. How do we capture the right learnings from the US and other market launches, then apply them appropriately to European markets?
    c. For an organization that is launching products simultaneously on both sides of the Atlantic, what processes should be built ahead of time to ensure that key learnings are shared in both directions?

3. How do we build for sustained success?
    a. What future opportunities and challenges do we see?
    b. How do we position ourselves as a company to support our aspirations over time?
    c. What novel capabilities might we need in the future?

Best Practices

1. Excellent initial hires for the European leadership team, as they will be responsible for building up teams beneath them
2. Team members with the right mindset: Positive outlook; "We" as opposed to "Us versus Them"
3. Appropriate use of FTEs vs contractors and/or contractors that can transition to FTEs when the asset(s) become de-risked (The company must strategically build its team early while also minimizing risk. The company must invest intelligently into "high-probability" revenues.)
4. A dedicated, cross-functional launch excellence team that covers all elements of the strategy and communicates regularly with the home office

5. Clear understanding of roles, responsibilities, and decision-making processes
6. Strong relationships and open communications between the US / headquarters and European teams
7. The right amount of time in the headquarters office for European leadership team members (but not too much)
8. Named Patient Programs (NPPs) to help secure early access (if appropriate)
9. Awareness, Trial, and Usage (ATU) to understand market dynamics and facilitate product uptake

Pain Points

1. Country teams that are deployed with inadequate resources
2. Medical Science Liaisons (MSLs) that are deployed too slowly or late
3. Late deployment of disease state education or market conditioning efforts
4. Sub-optimal communications between the European team and the headquarters office
5. Lack of clarity on decision-making processes and authorities, forcing all decisions back up to the top
6. "Over-siloed" mindsets (functional, regional, etc.)
7. Too much time in the US headquarters office for European leadership team members

Future Sessions

In a future session, the European Biotech Leader Roundtable will build on this foundation to co-create the ideal path to Europe. Over time, additional participants may lend input regarding various aspects of succeeding in Europe. Throughout the process, Blue Matter will capture this input in the form of summary documents like this one, blog articles, white papers, contributed articles in biopharma industry journals, and other formats.

To see new materials as they become available, please visit Blue Matter's blog and our Resources Page on success in European markets.

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