GREATER ZURICH AREA

# Unlocking European markets

**Strategic pathways for U.S. BioPharma expansion**

# About the whitepaper

The Greater Zurich Area Ltd (GZA) hosted a virtual roundtable for a select group of BioPharma leaders interested in expanding their operations into Europe in February 2025.

This white paper consolidates the key messages and insights from the roundtable shared by leading industry experts on successful strategies for entering and scaling in European BioPharma markets.

## The speakers offer three unique perspectives:

1. **International BioPharma companies**
   represented by
   Margarida Duarte, Executive VP, CCO, Deciphera Pharmaceuticals
   and
   Stephen Mitchener, Chief Business Officer, Alpha-9 Oncology

2. **Accelerator**
   represented by
   Pierre-Henri Belin, Co-Founder & CEO, xcube.bio

3. **Government**
   represented by
   Thomas Fuchs, Deputy Head of Economic Promotion, Canton of Zug (part of the Greater Zurich Area)

This summary of the roundtable is presented in a simple outline format. It is intended to capture the key points made by the speakers and has been edited for brevity.

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# The European market landscape

Expanding into European markets presents both opportunities and challenges for BioPharma companies. The European market offers access to over 500 million people but comes with complexities such as fragmented regulations, varied pricing models, and different market access pathways.

Europe represents 160% of the U.S. patient potential but only about 40% of the U.S. market's value. Pricing and reimbursement processes are decentralized, leading to heterogeneous market dynamics across countries.

While the European Medicines Agency (EMA) provides centralized drug approval, individual countries manage their own pricing and reimbursement negotiations.

**It is key to prepare commercialization with the following features in mind:**

**Fragmented market entry processes**
If regulatory pathways are largely centralized, patient access, pricing, and reimbursement remain national processes. It is key to understand priorities and to progress step by step.

**Price levels**
In Europe, prices are generally lower than in the U.S., averaging 36%[1] of the U.S. list price for standard drugs and 69%[2] for orphan drugs.

[1] Rand corporation, 2024
[2] Chambers J, Clifford K, Enright D, Neumann P. Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act. Health Policy 2023

**Added value criteria**
National reimbursement authorities in Europe look at the added value to the standard of care – true clinical differentiation that drives reductions in downstream sequelae, and/or eliminates or avoids future health care expenditures are minimum entry requirements.
It is possible to get above-average pricing with clinical data demonstrating added-value to the right comparator.

**Extended timelines**
Commercial access can take up to several years post-approval for later countries due to intricate pricing and reimbursement processes. There are opportunities to generate early revenue and carefully phasing investment is essential to preserve optionality.

## Strategic market entry approaches

### Going solo

Building an in-house European presence allows full control over commercialization but comes with higher financial and operational risks.

**Companies that succeed often:**

- Start with lean, flexible infrastructures
- Focus on markets with the highest revenue potential due to large populations and relatively better performing economies (think, Germany and France)
- Build scalable operations that can eventually support multiple products within the fixed cost structure

A winning entry strategy requires a differentiated product and launching first in a large market where early uptake generates substantial revenue and pricing negotiation to achieve (at minimum) floor pricing targets. Some markets may even be attractive as reimbursement can sometimes be gained prior to negotiations with health authorities.

Going solo requires starting with a lean, flexible infrastructure, potentially deploying early access programs (EAP), and prioritizing high-probability markets to increase the probability of profitability from year one.

### Partnering strategies

Partnering with established European firms can reduce market entry risks. It requires compromise on control of the asset and willingness to give away a significant share of value. Therefore, the selected partner must have the right capability to optimize the asset value.

**Key considerations for selecting partners include:**

- Portfolio synergies (e.g. insights and know-how in the same disease area)
- Market access expertise (e.g. track record in optimizing prices under short timelines)
- Strong local networks of field-based personnel who have already established relationships with key prescribers)

**Case insight:**
A U.S. BioTech partnered with a European specialist to commercialize an oncology asset. Key to the partnership's success was early preparation of value dossiers, understanding local payer dynamics, and ensuring the partner had the necessary infrastructure and focus.

### Hybrid approaches

Some companies adopt a hybrid model, combining direct presence with support of one or several local partners. This tailored and adaptive approach balances risk and control, allowing companies to leverage local expertise and execution while maintaining strategic oversight.

**Best practice:**
Hybrid approaches often involve setting up regional hubs, such as in Switzerland. From this owned or co-owned operating entity, deployment across European countries is executed through various partnering strategies.

# Success factors for European expansion

### Sequenced market access and pricing strategy

- Prioritize early revenue markets like Germany and France.
- Carefully plan pricing strategies to avoid downward pressure that result from reference pricing systems.
- Start hiring early to account for longer lead times in the EU compared to the U.S., and focus on building a team with strong expertise in the European market. Utilize early access programs (EAP) to generate hands-on experience and potential advocacy ahead of reimbursement.

Example: In Germany, companies can launch products while simultaneously negotiating prices, offering an opportunity for early revenue.

### Lean infrastructure and high-quality talent

- Build lean and agile infrastructures with the flexibility to scale.
- Hire high-caliber talent with deep market knowledge.
- Establish strong medical affairs and market access teams early.

Profitability from the first year of launch is possible by focusing on high-probability success markets and efficient operations.

### Relevant clinical data and active regulatory engagement

- Design clinical trials with European market needs in mind, focusing on endpoints valued by EU payers.
- Seek scientific advice from key HTA bodies early in the development process.

Tip: Engaging with HTA bodies like Germany's G-BA during clinical trial design can help align study endpoints with market expectations.

### Cultural and organizational alignment

- Foster strong communication between U.S. and European teams.
- Ensure organizational structures support cross-regional collaboration.

Tip: Focus on cultural alignment and clear governance structures to bridge differences between U.S. and European operations.

**Successful European expansion**

# Switzerland's Life Sciences hub in numbers

**The Greater Zurich Area is one of the leading Life Sciences centers in Europe with its unique combination of academic excellence, highly skilled talent, and a business-friendly economy.**

Greater Zurich is home to some of the industry's biggest names and new pioneering firms, turning the Swiss region into a true global Life Sciences hub: Amgen, Biogen, MSD, Novartis, Roche Diagnostics, Novo Nordisk, Astra Zeneca, Johnson & Johnson, Zimmer Biomet, Alnylam, Benchling, Vir Biotechnology, Crinetics, Mirum Pharmaceuticals, Peptone, Blueprint Medicines, Cytokinetics, Apellis, Absci, Blueprint Medicines, Takeda, Octapharma, GlaxoSmithKline Pharmaceuticals, and many more.

**350+**
companies in BioTech & Pharma

**1,400**
companies in MedTech

**7.3+**
billion CHF annual revenue BioTech

**23.4+**
billion CHF annual revenue MedTech

Sources:
Swiss Biotech Association (Report 2024),
Swiss MedTech (sector study 2024)

**2.0+**
billion CHF annual investments in BioTech companies

**2.4+**
billion CHF in annual BioTech R&D investments

**19,000+**
people working in BioTech

people working in MedTech
**71,000+**

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## The Swiss advantage

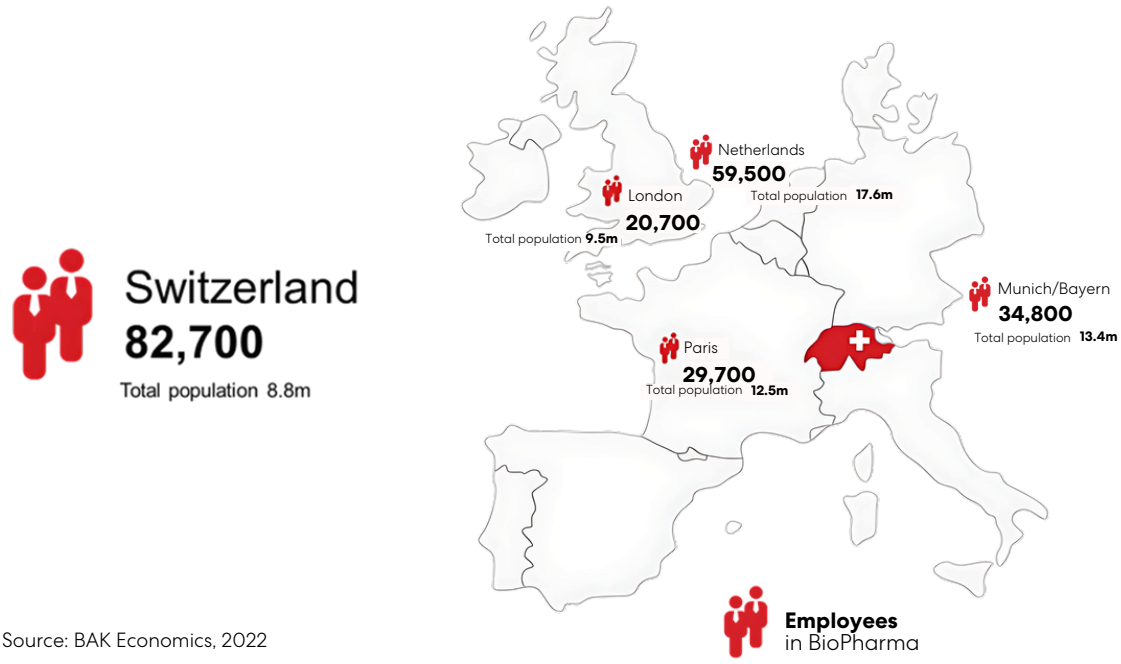
Switzerland stands out as a premier hub for European BioPharma operations. Its unique blend of economic, scientific, and infrastructural strengths makes it an ideal location for U.S. BioPharma companies aiming to expand into Europe.

**1**

**Highly skilled talent pool**
Switzerland consistently ranks among the top countries for talent competitiveness. Its Life Sciences sector benefits from a deep pool of highly qualified professionals, including market access experts, clinical researchers, and regulatory specialists.
Many professionals possess multilingual capabilities, enabling smooth interactions across Europe's diverse markets.

**2**

**Strong innovation ecosystem**
Switzerland boasts a vibrant Life Sciences ecosystem, supported by world-class research institutions like University of Basel, EPFL Lausanne, University of Zurich, or ETH Zurich. Switzerland hosts numerous BioTech and Pharma companies, fostering collaboration and innovation. The presence of leading global companies and a dynamic startup scene further strengthens Switzerland's position as a Life Sciences hub.




Source: BAK Economics, 2022


**3**

**Business-friendly environment**
Swiss authorities actively support foreign direct investment and provide comprehensive economic promotion services. This includes assistance with company setup, networking opportunities, and connections to local service providers.

**4**

**Favorable tax environment**
Switzerland offers one of the most attractive corporate tax rates in Europe, with some cantons offering effective rates as low as 12% or even lower, when potential rebates are negotiated. This tax efficiency, coupled with a stable legal framework, makes it financially advantageous for BioPharma companies to establish their European operations.

**5**

**Central location with excellent connectivity**
Situated in the heart of Europe, Switzerland offers exceptional connectivity to major European markets thanks to Zurich Airport, Geneva Airport as well as the airport in Basel, providing daily flights to key cities across the globe, ensuring seamless logistics and easy access to customers, partners, and regulatory bodies.

# Contact information & services

Expanding into Europe requires careful planning, strategic execution, and adaptability. Companies that succeed in European markets are those that balance risk with opportunity, build lean and scalable infrastructures, and develop market-specific strategies. Leveraging local hubs like Switzerland and adopting flexible market entry models can significantly enhance the chances of a successful European expansion.

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Introductions to key contacts in industry, academia, and government agencies

Facilitating contact to potential research partners at universities and research institutes.

Support in location evaluation, introduction to service providers, and advice on regulations.

**Contact us today!**
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