Avoiding Pitfalls of U.S. Biotech Companies Coming to Europe

Whitepaper based on a virtual roundtable held on January 27, 2021
On Wednesday, January 27, 2021, Heidrick & Struggles and Greater Zurich Area Ltd (GZA) co-hosted a virtual roundtable for a select group of leaders from biopharmaceutical companies interested in expanding their operations to Europe. The one-hour panel addressed some of the key decisions in hiring and finding talent, tax and IP considerations as well as accessibility and attractiveness of a location.

The speakers of the event offered four unique perspectives:

1. **Head of Europe**
   represented by Michelle Lock,
   Head of Europe/International, Acceleron Pharmaceutical

2. **Government**
   represented by Beat Bachmann,
   Head of Economic Promotion,
   Canton of Zug
   (part of the Greater Zurich Area)

3. **Talent & People**
   represented by Oliver Schiltz,
   Managing Partner Switzerland,
   Global Co-Lead Biotechnology,
   Heidrick & Struggles

4. **Tax & IP**
   represented by Samuel Bussmann,
   Partner, MME Legal Tax Compliance,
   Co-Founder BioXpansion GmbH

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.
Europe represents the second largest market in the world for pharmaceuticals. Therefore, it is highly attractive to companies with products that offer a compelling and differentiated value proposition. However, expanding to Europe can be daunting due to Europe’s multiple geographies and languages, different regulatory needs, as well as multiple EU payer requirements and reference pricing systems.

Some of the critical questions when expanding to Europe are

<table>
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<tr>
<th>Go alone or not?</th>
<th>Can the product succeed in Europe/internationally?</th>
<th>Can the organization empower ex-U.S. decision making?</th>
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<tbody>
<tr>
<td>Maintain control over commercialization in major markets</td>
<td>Regulatory, pricing, and commercial model</td>
<td>Enable appropriate local decision making and flexibility</td>
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Guiding principles for successful international builds

<table>
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<tr>
<th>Build early</th>
<th>Invest for success</th>
<th>Calibrate &amp; pulse build-out</th>
<th>Over-invest in talent</th>
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<tbody>
<tr>
<td>- International build to commence 2-3 yrs pre-launch</td>
<td>- Invest early to avoid under-resourcing and potential slow uptake</td>
<td>- Recruit in ‘gated’ waves; 1st wave based on opportunity and pricing</td>
<td>- Invest early, prioritize experience and mindset</td>
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<td>- Clarify global/ regional/local</td>
<td>- Build with efficient, effective infrastructure</td>
<td>- Sequence country launches and define market specific strategies</td>
<td>- Empower hiring decisions and provide autonomy to make decisions</td>
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Timing & clarity are important

The EU general manager (GM) role is a critical position and should be the first hire (24-30 months pre-approval). The sequencing of hiring is important as mistakes can be costly and time consuming. Roles to be appointed 18-24 months pre-approval include: Market Access, Medical Affairs, Regulatory and Commercial (MMRC) leadership. Allow ample time for recruitment as EU has significantly longer onboarding times than the U.S. Clarity should be built early for each leadership team member’s line function and leadership team accountabilities and communicated transparently. Align early on what decisions will be made from corporate HQ then empower EU leadership team to successfully run Europe.

First hire: months pre-approval
(selected companies in the Greater Zurich Area)

Insights provided June 2020 by
Paul Beresford - Blueprint Medicines
Michelle Lock - Sage Therapeutics
Oliver Schiltz - Heidrick & Struggles
Orlando Oliveira - Agios
Theresa Heggie - Alnylam
Thomas Lackner - Apellis and Prothena
Mark Altmeyer - Arvelle
## Key milestones

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<th>- 30 Month</th>
<th>- 24 Month</th>
<th>- 18 Month</th>
<th>- 12 Month</th>
<th>- 9 Month</th>
<th>- 6 Month</th>
<th>Launch</th>
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<td>- Secure corporate legal strategy</td>
<td>- EU HQ site location</td>
<td>- Country launch sequencing</td>
<td>- Legal/compliance strategy</td>
<td>- Finalize distribution model</td>
<td>- Commercial launch readiness</td>
<td>- Product launch</td>
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<td>- Hire of General Manager and Office Manager</td>
<td>- Recruit Heads of Medical, Market Access, Regulatory &amp; Commercial</td>
<td>- Site selection and country builds</td>
<td>- Access and commercial execution</td>
<td>- Build ‘Wave II’ countries</td>
<td>- Build ‘Wave II’ countries</td>
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<td>- Market access and pricing and reimbursement study</td>
<td>- Build of European operating model</td>
<td>- Access &amp; commercial plans built</td>
<td>- Onboard sales organization</td>
<td>- General Managers of ‘Wave I’ countries</td>
<td>- Head of Finance, HR and distribution</td>
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<td></td>
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<td>- Tax strategy</td>
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<td></td>
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<td>- Legal, Compliance and General Manager</td>
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### Infrastructure build is the engine of the company

Build infrastructure in a scaled manner and according to the purpose. Infrastructure is needed for a variety of business processes:

- Manufacturing
- Distribution to Europe
- Warehousing in Europe
- Analytical testing & packaging
- Distribution through wholesalers
- Product to patients

The set-up and maintenance of the infrastructure of different business units including finance & tax, commercial, legal & compliance, regulatory & quality, information systems, and supply chain.
More than 300 companies focus on pharma, biotech or medtech. The canton is home to a mix of small to large companies with a high influx of job growth of U.S. biotech companies in the last 20 years. Companies in the canton include: J&J (1,000+ employees), Biogen (500+ employees), Amgen (300 employees), Astra (200 employees), BMS (200 employees), Bluebird Bio (60 employees), Seagen (60 employees), Alnylam (40 employees).

New European headquarters from U.S. based biopharma companies include (2019/2020)

- Apellis
- Arvelle Therapeutics
- Deciphera
- Global Blood Therapeutics
- Kiniksa Pharmaceuticals
- Reata Pharmaceuticals
- Stemline
- Viela Bio

Beat Bachmann
Head of Economic Promotion, Canton of Zug

The Greater Zurich Area and the canton of Zug have evolved into a dynamically expanding life sciences hotspot. Academic excellence, business-friendly regulations, IP protection, a large international talent pool and R&D collaborations between universities and start-ups as well as large multinational corporations (like Roche, Johnson & Johnson, Biogen or Stryker) serve as an engine motor for innovation.

The canton of Zug is the preferred HQ location in the Greater Zurich Area and in all of Switzerland. The canton of Zug has ranked #1 for over 20 years in location attractiveness across all Swiss cantons. It’s the preferred headquarters location in Europe with a presence of several hundred of European and international headquarters.

Life sciences companies are of critical importance to Zug and vice versa. 8% of all jobs (or 9,000 jobs) are in life sciences in the canton of Zug.

Oliver Schiltz
Managing Partner Switzerland, Global Co-Lead Biotechnology, Heidrick & Struggles

Branding matters

Biotech companies headquartered in U.S. life sciences hubs (i.e., Greater Boston area, San Francisco, San Diego, New York/Tri-State area), may have a strong brand awareness in the local market. However, they are relatively unknown in Europe. Increasing overseas publicity prior to and during recruitment is a necessary yet often underestimated effort by U.S. companies undergoing expansion and seeking to source the best talent from established biotech or big pharma companies in Europe.

You need a strong brand ambassador in Europe

This starts with partnering with a well-researched, well-networked, credentialed search firm team to attract the best talent. You need a partner as your brand ambassador, differentiating you from other competitors in the market. This brand leadership during the European build-out continues with a strong Head of Europe/International in place and with the EU leadership team.
You need unique selling points as a biotech beyond being ‘innovative’
It is not enough nowadays to stand behind a very innovative product pipeline. There are approximately 30+ U.S. biotech companies building a European hub during any given financial year, each competing with similar tag lines about innovation and focus. Further differentiation is key to attract the top leaders, especially as it relates to the culture of your organization.

Hiring process: key takeaways

**Levelling of the positions**
Appropriate and competitive levelling of the critical hires during a European build-out will allow your biotech to attract top talent in a competitive European market. For example, it is ideal if the Head of Europe/Head of International is hired at SVP level in order to recruit functional talent at VP level.

**Advantage of an experienced and diverse team**
As many U.S. biotech companies phase their European build-out (waves of hiring), it is important that first hires are agile and experienced enough to take on multiple responsibilities initially in an entrepreneurial environment. U.S. biotech companies that hire experienced talent at the more senior level often see quicker results.

**Duration of recruitment process**
U.S. biotech companies may allocate an average of six months from entering an engagement with an executive search firm to officially onboard a new candidate. Extenuating circumstances (e.g., unpredictable market dynamics, or a long notice period of the chosen candidate) might result in a longer duration (e.g., ~9 months to 1 year) from search start date to candidate start date.

**Onboarding**
A proper onboarding process that includes sending European hires for 2-3 weeks to visit the U.S. HQ and integrate with colleagues will dramatically enhance the future cross-cultural relations and intercontinental alignment.

Why expand to Europe?

**Strengthen your U.S. HQ**
U.S. biotech companies that build a hub outside of the U.S. can differentiate themselves from competitors since they are now an international versus a national company.

**Build a diverse culture**
Some U.S. biotech companies hesitate to build in Europe as they feel that their unique entrepreneurial culture could be compromised as the organization grows larger and takes on an international cultural element. In discussions with several U.S. biotechs such as Alnylam, Seattle Genetics, and Tesaro, several leaders attested to the contrary: that the international footprint only enriched the company culture.

**Become an attractive target for acquisition**
When you build and launch successfully in Europe, you build a multi-product, multi-national company and your international business can become an attractive target for acquisition at a premium.
U.S. biotech companies with international business acquired at a premium

Key considerations: legal structures & tax set-up in Switzerland

- AG vs. GmbH (consider U.S. tax implications)
- Regional holding company (double tax treaty network)
- Repatriation of funds to the U.S.
- Employee participation schemes
- IP planning: can be costly if done too late (exit charges, reputational issues etc.)
- Principal company vs. limited risk operations
- Funding of operations (how are funds being repatriated to the U.S.?)

Living and working in Switzerland

- Work and residence permit
  → EU/EFTA Citizen vs. non-EU/EFTA
- Housing
  → Rent vs. purchase (deemed rental income)
- Social security
  → Three pillars
- Health insurance (mandatory, up to the employees)
- Taxes
  → Income tax: federal, cantonal/communal (+ church)
  → Wealth tax: cantonal/communal (+ church)
  → Resident vs. non-resident taxpayers (taxation at source)
  → Expatriate status

Samuel Bussmann
Partner, MME Legal Tax Compliance, Co-Founder, BioXpansion GmbH
World-class technology in Europe’s most stable environment

As a global leader in innovation and talent attraction and with Switzerland’s business-friendly, stable and reliable environment, the Greater Zurich Area offers international companies real added value and peace of mind for their strategic expansion. Greater Zurich has evolved into one of the leading locations for biotechnology and pharmaceutical companies in Europe, thanks to the region’s academic excellence, Switzerland’s business-friendly regulations, IP protection, large international talent pool and R&D collaborations between universities and start-ups, as well as large multinational corporations.

Connect to tomorrow
Would you like to join this thriving ecosystem and start your own success story? Why not start by talking to one of our experts about your strategic expansion in/into Europe?

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Greater Zurich Area Ltd (GZA) is a reliable Swiss business concierge for companies looking to grow internationally. We help you create a convincing business case for setting up a strategic location in Switzerland. Moreover, we guide you through the business and technology ecosystems and network you with the relevant companies, universities and research institutes, investors and incubators, authorities and service providers.

GZA is the official investment promotion agency of 9 cantons (states) in German- and Italian-speaking Switzerland. The public-private partnership is supported by 30+ partners from business and science.

greaterzuricharea.com/biotech

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Oliver Schiltz is Managing Partner, Switzerland and Global Co-Lead Biotechnology at Heidrick & Struggles, an international executive search and leadership advisory firm.

Oliver and his team have a multiple track-record in helping biotech companies to build their leadership teams at HQ and Affiliate level.

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