### GREATER ZURICH AREA

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

Whitepaper based on a virtual roundtable



# About the virtual roundtable

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. Chief Operating Officer & Chief Commercial Officer represented by Michelle Lock, COO & CCO, Covis Pharma

### 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, Global Co-Lead Biotechnology, Korn Ferry

### 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.



### **Michelle Lock** Chief Operating Officer & Chief Commercial Officer, Covis Pharma

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

### Go alone or not?

Maintain control over commercialization in mayor markets Can the product succeed in Europe/ internationally?

Regulatory, pricing, and commercial model

Can the organization empower ex-U.S. decision making?

Enable appropriate local decision making and flexibility

# Guiding principles for successful international builds

### Build early

- International build to commence 2-3 yrs pre-launch
- Clarify global/ regional/local

### Invest for success

- Invest early to avoid under-resourcing and potential slow uptake
- Build with efficient, effective infrastructure

## Calibrate & pulse build-out

- Recruit in 'gated' waves; 1<sup>st</sup> wave based on opportunity and pricing
- Sequence country launches and define market specific strategies
- Engage payers early

### Over-invest in talent

- Invest early, prioritize experience and mindset
- Empower hiring decisions and provide autonomy to make decisions

### **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.





### **Key milestones**

- 30 Month	- 24 Month	- 18 Month	- 12 Month	- 9 Month	- 6 Month	Launch
<ul> <li>Secure corporate legal strategy</li> <li>Hire of General Manager and Office Manager</li> <li>Market access and pricing and reimbursement study</li> </ul>	<ul> <li>EU HQ site location</li> <li>Recruit Heads of Medical, Market Access, Regulatory &amp; Commercial</li> <li>Build of Euro- pean opera- ting model</li> </ul>	<ul> <li>Country launch sequencing</li> <li>Site selection and country builds</li> <li>Access &amp; com- mercial plans built</li> <li>Tax strategy</li> <li>Legal, Compli- ance and Ge- neral Manager</li> </ul>	<ul> <li>Legal/compliance strategy</li> <li>Access and commercial execution</li> <li>Onboard sales organization</li> <li>General Managers of 'Wave I' countries</li> <li>Head of Finance, HR and distribution</li> </ul>	<ul> <li>Finalize distribution model</li> <li>Build 'Wave II' countries</li> <li>General Managers 'Wave II' countries</li> </ul>	<ul> <li>Commer- cial launch readiness</li> <li>Build 'Wave II' countries</li> <li>Head of IT</li> </ul>	– Product launch

Strategy build	and	Execution

### 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.

### **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, businessfriendly 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, 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. 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

### **Oliver Schiltz** Managing Partner, Korn Ferry

### **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.



### Samuel Bussmann

Partner, MME Legal Tax Compliance, Co-Founder, BioXpansion GmbH



## 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  $\rightarrow$  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
  - $\rightarrow$  Income tax: federal, cantonal/communal (+ church)
  - $\rightarrow$  Wealth tax: cantonal/communal (+ church)
  - → Resident vs. non-resident taxpayers (taxation at source)
  - $\rightarrow$  Expatriate status

# 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 businessfriendly 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 you own success story? Why not start by talking to one of our experts about your strategic expansion in/into Europe?

#### Lukas Sieber

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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

#### **Oliver Schiltz**

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Oliver Schiltz is a Managing Partner of Korn Ferry. He is based in Zurich, Switzerland, and a member of the Global Life Sciences and CEO & Board Practices.

Mr. Schiltz has over 17 years' experience in executive search and has worked extensively on senior level searches across the C-suite and business critical positions (CEO, CCO, Head of Europe, etc.).

Oliver Schiltz, Managing Partner at Korn Ferry, was employed by another advisory firm when the virtual roundtable took place on January 27<sup>th</sup> 2021 and when the whitepaper was published later that year by the Greater Zurich area.

#### kornferry.com