GREATER ZURICH AREA

U.S. Biopharma Expansions to Europe: Ensuring Successful Build-Out & Market Access

Whitepaper based on a virtual roundtable

KORN FERRY

About the whitepaper

The Greater Zurich Area Ltd (GZA), Apellis, and Korn Ferry co-hosted a virtual round-table for a select group of bio-pharma leaders interested in expanding their operations into Europe. The panel brought together European launch specialists, talent experts, and Swiss government officials to cover critical questions and guiding principles necessary for a successful European launch, as well as insider knowledge of how to best navigate the regulatory environment.

The speakers of the event offer three unique perspectives:

1. **International biopharma company**
   represented by
   Thomas Lackner, SVP & Head of International, Apellis Pharmaceuticals
   and Andrea Bracco, VP International Values, Access & Policy & Ad-interim GM Italy/ Greece, Apellis Pharmaceuticals

2. **Talent & people**
   represented by
   Oliver Schiltz, Managing Partner, Global Co-Lead Biotechnology, Korn Ferry

3. **Government**
   represented by
   Beat Bachmann, Head 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.

Imprint
Editor: Greater Zurich Area Ltd (GZA)

Thomas Lackner

Senior Vice President & Head of International, Apellis Pharmaceuticals

Apellis

Europe represents the second largest market globally for biopharma companies. Therefore, it is highly attractive to companies with products that offer a compelling and differentiated value proposition. However, companies expanding to Europe must navigate the differing languages, geographies, and healthcare systems of Europe, regulatory needs that are not always in sync with those of the FDA, and varying payer requirements and archetypes.

Read Apellis' success story!

Critical questions surrounding expansion to Europe

1. **Are companies usually expanding alone or with a partner?**
   Companies choose to maintain control over commercialization in larger markets and work with partners for smaller markets.

2. **Can the product succeed in Europe?**
   Product success is determined by prevalence (population or genotype-based), scientific expertise in the disease, and the regulatory, pricing, and commercial models.

3. **Which pre-launch action items increase the probability of success?**
   Companies should plan on engaging with key stakeholders before launch and anticipate EU regulatory and payer needs in the trial design.

Guiding principles for a successful European launch

1. **Build early**
   a. Build-up the European organization 2-3 years before launch
   b. Have a realistic view of the regulatory pathway
   c. Clarify the regional and functional governance model

2. **Invest for success**
   a. Invest early to avoid under-resourcing and potential slow uptake
   b. Engage payers early and broadly
   c. Generate RWE

3. **Calibrate and pulse build-out**
   a. Scale with efficient, effective infrastructure
   b. Recruit in "gated" waves based on opportunity and time-to-reimbursement
   c. Sequence country launches and define market-specific strategies

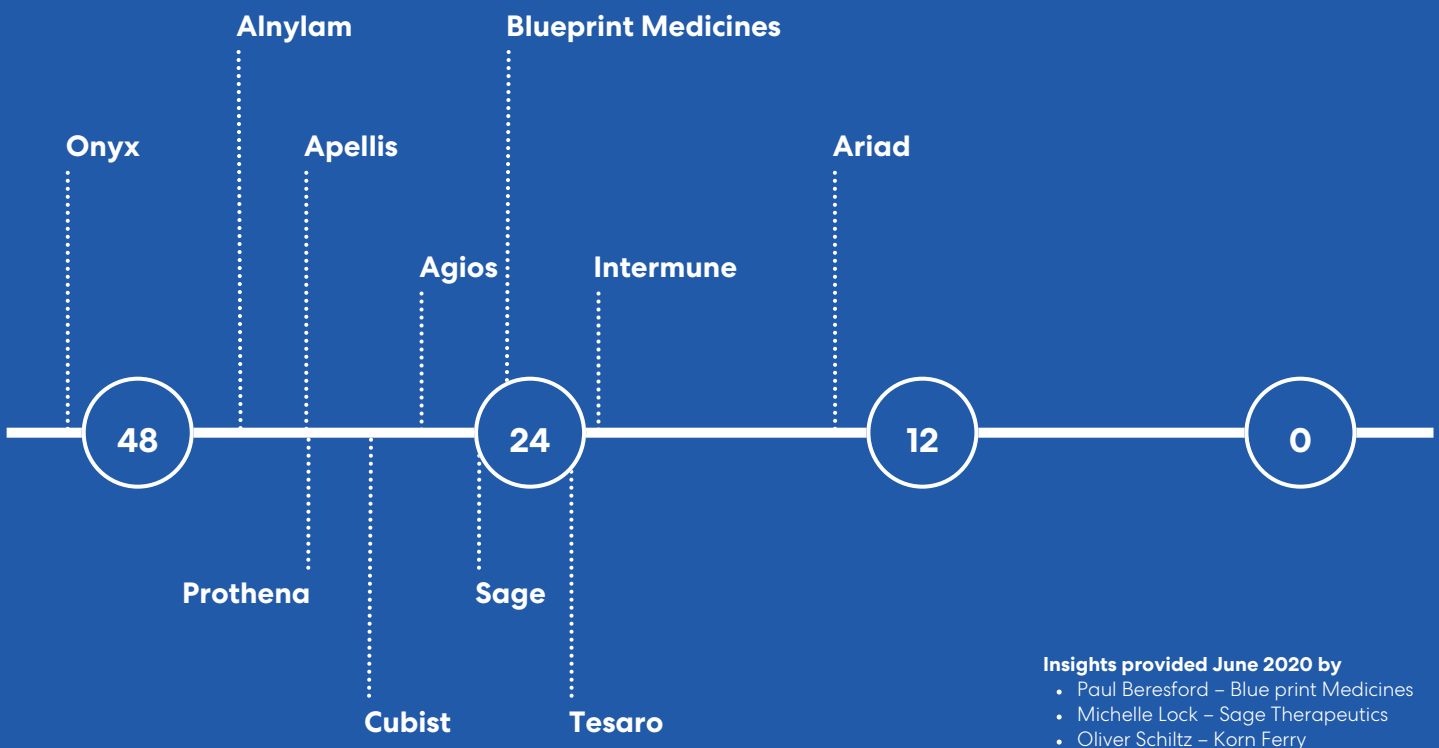
4. **Over-invest in talent**
   a. Culture-fit and experience in launching products into Europe are key
   b. Focus on leaders with reputation and large network
   c. Attract good talent with competitive leveling
   d. A more challenging value proposition requires more experienced talent

Timing and clarity of roles are critical

The European General Manager is a critical position and should be the first hire, at least 24 months pre-approval.
The sequencing of hiring is important as mistakes can be costly and time-consuming in the European talent landscape.

European Function Lead roles to be appointed 18-24 months pre-approval include: Market-Access, Medical Affairs, Regulatory, Commercial, Legal/Compliance, Finance, Supply Chain, and QPPV. Allow ample time for recruitment (4–6 months) as the EU has significantly longer onboarding times than the U.S.
Clarify the roles and responsibilities of the European leadership team and align early on the global/regional/local governance model. Expectations must be set early and transparently to retain top-tier talent.

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



Insights provided June 2020 by

- Paul Beresford – Blue print Medicines
- Michelle Lock – Sage Therapeutics
- Oliver Schiltz – Korn Ferry
- Orlando Oliveira – Agios
- Theresa Heggie – Alnylam
- Tomas Lackner – Apellis and Prothena
- Mark Altmeyer – Arvelle

Andrea Bracco

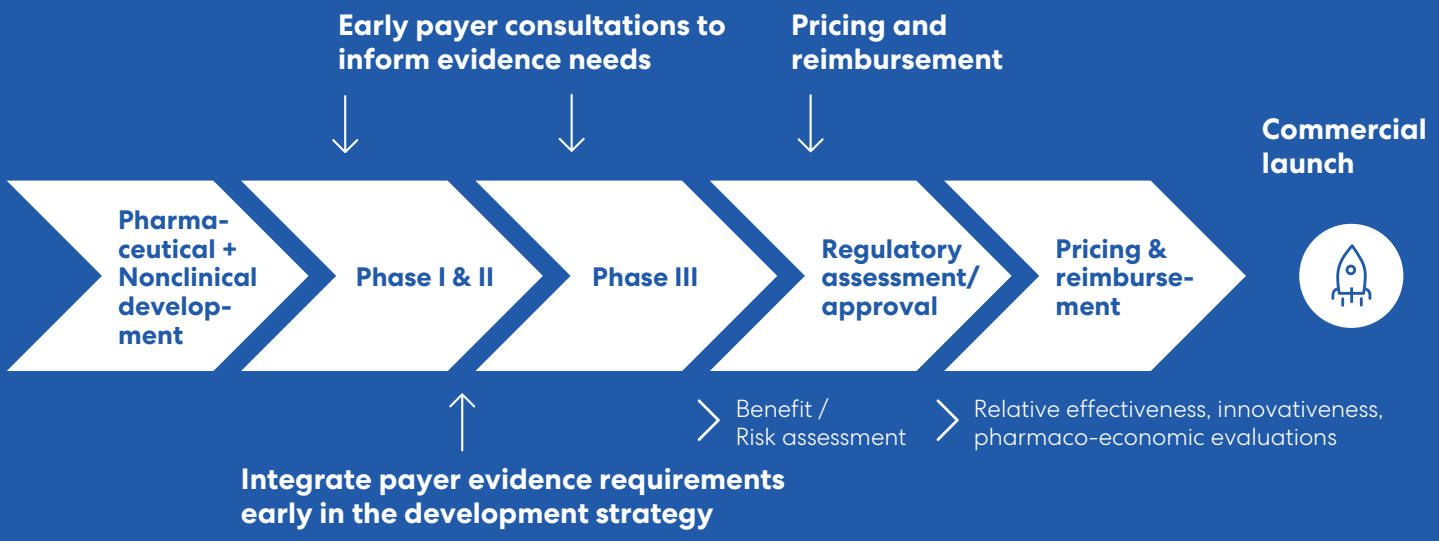
VP International Value, Access & Policy &
Ad-interim GM Italy/Greece, Apellis Pharmaceuticals

Apellis

Understanding the disease and broader commercial landscape is key to developing a European business opportunity.
Highlighting the unmet medical need should be supported by epidemiological data and brought into context by involving payers, key opinion leaders, and patients. This evidence determines the pricing strategy and influences both economic models and launch sequence.

With supporting evidence, European payers make an effort to minimize time to market. Before submitting the reimbursement dossier, the models must be adapted to the national markets and should also explore opportunities for early access programs.

A successful launch in Europe requires early inputs from the access team



Critical regulatory considerations

Value-based pricing is the standard in Europe
Pricing is measured wholistically, by the impact of the technology on the patients, caregivers, the healthcare system, and society. Value propositions need to be supported by compelling evidence and suitable risk-share arrangements.

27 states – 27 pharma systems
Every country in Europe has different payers which in turn have different requirements. It is critical to engage with these stakeholders early to understand the varying requirements and begin procuring the necessary evidence well in advance of launch.

Consultations help to increase the probability of commercial success
Multi-stakeholder engagements, such as parallel consultations of regulations and health technology assessments, are instrumental in reaching agreements on different aspects of clinical development and overcoming divergences on evidence requirements.

Future European-level HTA

The proposed EU Regulation for Health-Technology-Assessment (HTA), if successful, will go into effect in 2025, and intends to centralize the review process after approval by the European Medicines Agency (EMA), which will remove regulatory redundancy and speed up market-access for innovative products.
The proposal will require the **submission of a single dossier for health technology assessment at the EU level,** as well as Joint HTA scientific consultations in parallel with EMA and engagement with a stakeholder network.

It will be extended to orphan drugs after three years and all EMA authorized products by 2029. Although this will streamline the pan-European regulatory approval process, pricing and reimbursement decisions will still be determined by the Member States.

Regultory takeaways for companies looking at Europe

- Engage in the European HTA-initiative to understand the positions of different countries and to anticipate potential challenges Expanding alone or with a partner?
- Create partnerships and collaborate early with payers
- Build a strong talent base in Europe with a focus on experience and capability with pricing negotiations
- Innovation is rewarded when supported by sufficient evidence
- Keep an eye on the proposed HTA EU Regulation, which will harmonize evidence requirements across states and potentially reduce time to market

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.

Why expand to Europe?

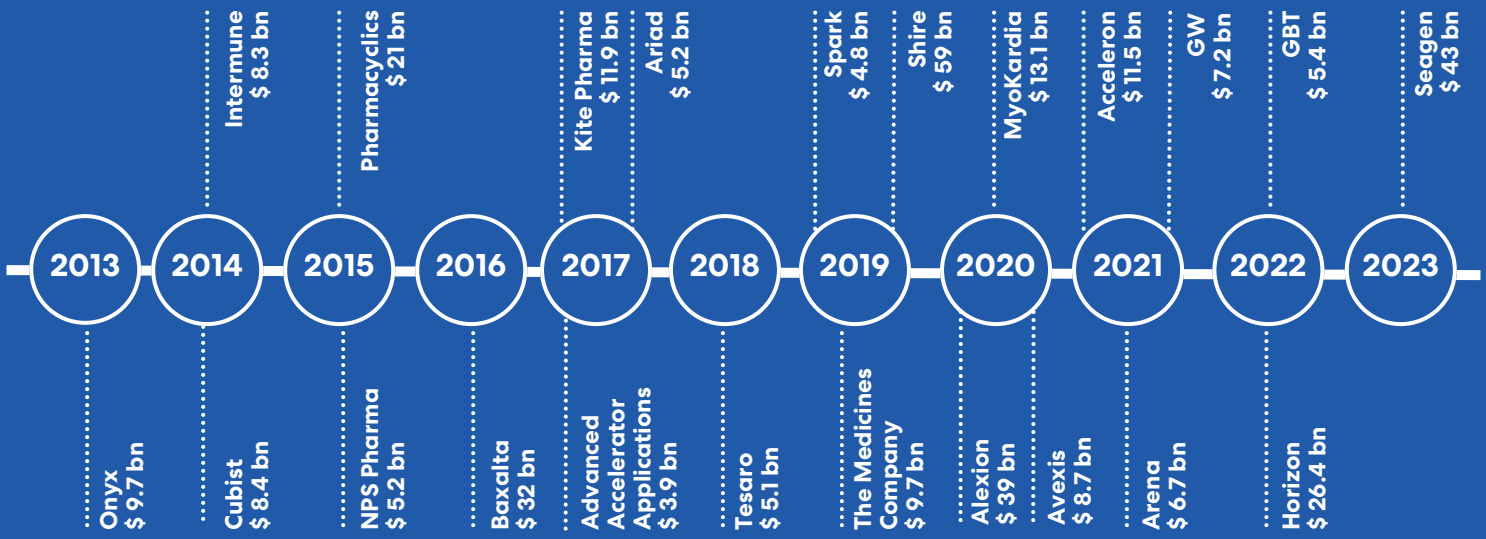
Strengthen your U.S. HQ
U.S. biotech companies that build a hub outside of the U.S. can differentiate themselves from competitors since they are now an international versus a national company.

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

Companies with a presence in the Greater Zurich Area; year & acquisition amount



Beat Bachmann
Head of Economic Promotion, Canton of Zug

Kanton 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 a leading 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), Seagen (60 employees), Alnylam (40 employees).

Recent 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

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.

Want access to key ecosystem contacts?

Reach out to our team for free support!

Greater Zurich Area Ltd offers free-of-charge services for forward-looking companies:

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

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

Building the business case, introduction to service providers, and advice on regulations.

Get in touch!

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Greater Zurich Area Ltd (GZA) is the 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.

Bio-Technopark Schlieren, Zurich