



A partnership between Nautilus Life Science (USA) and HEMAP AG (Switzerland)



Bridging commercial-stage US Biotech to Europe

*from
Strategic Options
to
profitable Market Entry*



Nautilus
Life Science

<https://bridgeforgrowth.com>



Bridging US to Europe

"Europe – shall we do it – and how?"



"We think it's best, if you out-license your product to us"

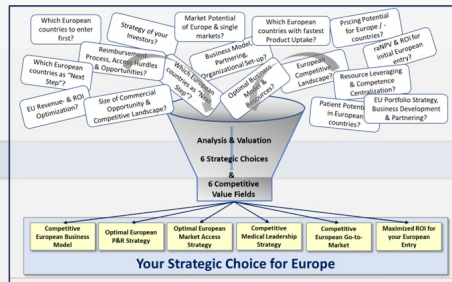
"Don't worry, you can outsource everything to us – we do 'It' for you"

"Co-Marketing with us is best for you, we know the market"

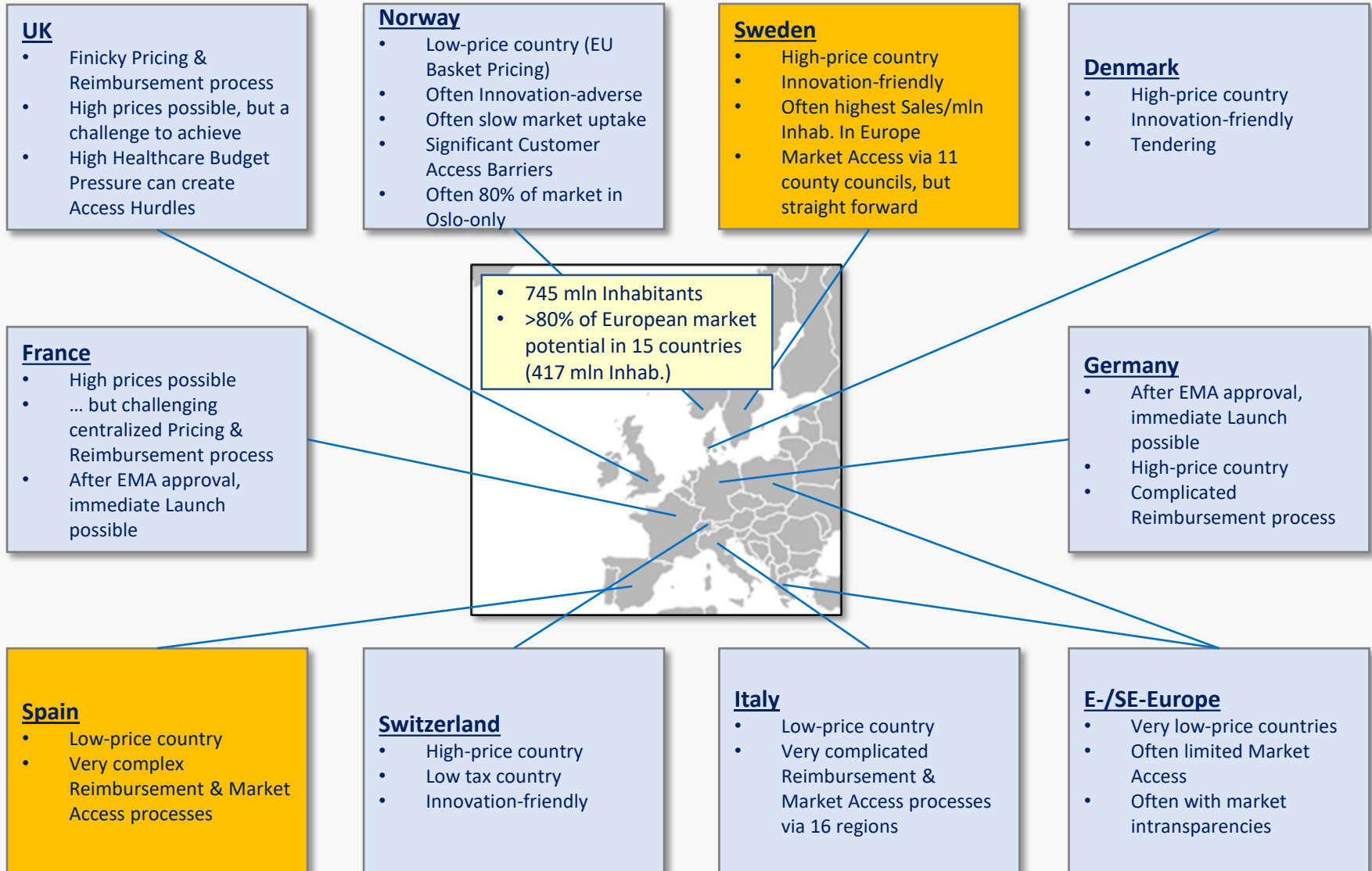
3rd Party- & Vendor-Offerings



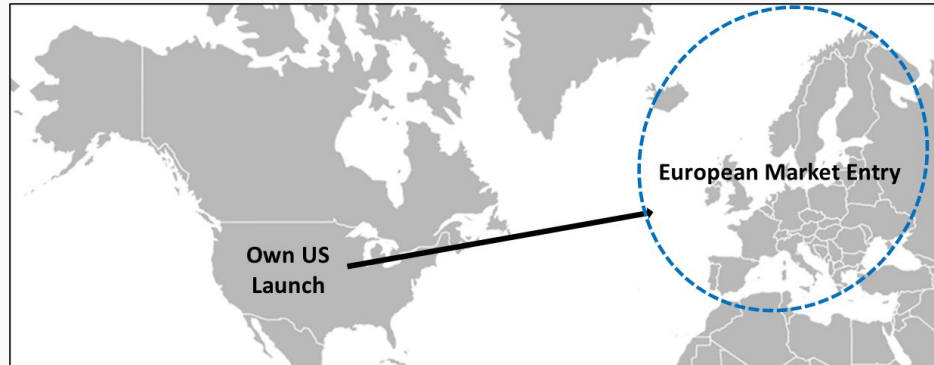
We come in before you make the Decision



The complexity of Europe: Pharmaceutical Market Dynamics *(a small selection)*



Bridging US to Europe: Challenges & Opportunities



Top 5 Opportunities:

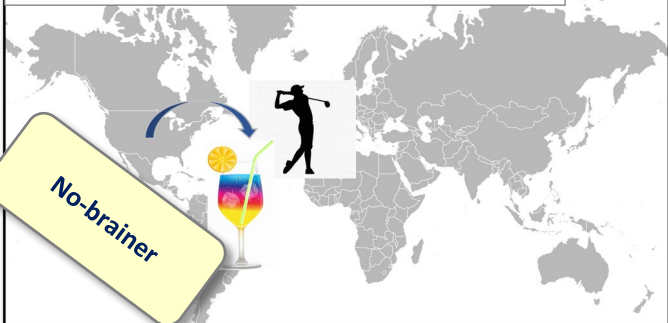
- European business opportunity nearly as big as for the US, expansion to Europe maintains business growth
- Harmonization of laws & regulations within Europe
- Sequenced Reimbursement approach for optimal Pricing & Reimbursement
- Right Strategy re. sequenced Market-entry for rapid Market Penetration and high Return-on-Investment (esp. in high-price countries)
- European business helps Risk-mitigation of US-business (e.g. increasing P&R restrictions in US)

Top 5 Challenges:

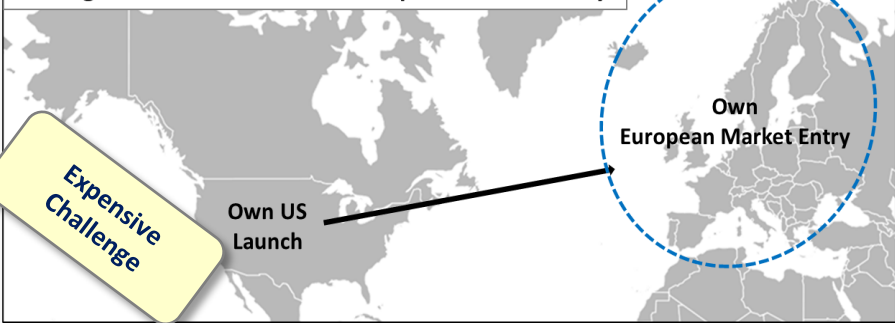
- Rare Diseases: US market rapidly saturated
- Local differences of Market Access requires country-specific Market Access Programs
- Wide range of country-specific laws & regulations (e.g. employees, taxes, etc..)
- UK and Switzerland as non-EU countries require specific workstreams & resources (supply chain, regulatory)
- Local & regional Offices required

6 Strategic Choices for entering the European Market

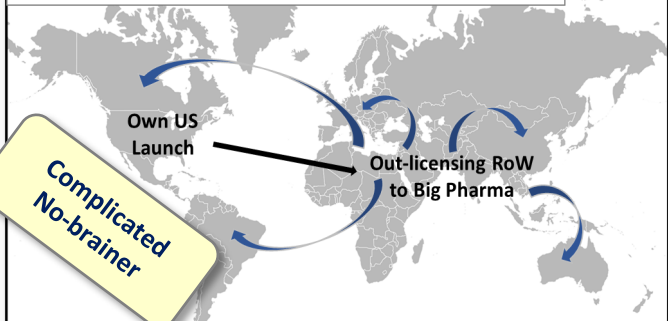
Strategic Choice 1: Exit



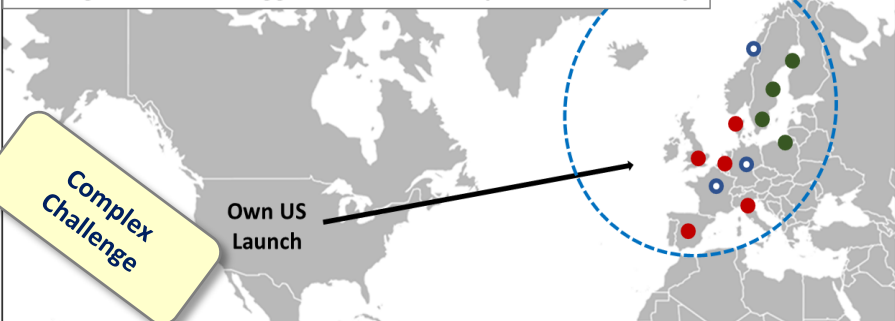
Strategic Choice 4: 100% own European Market Entry



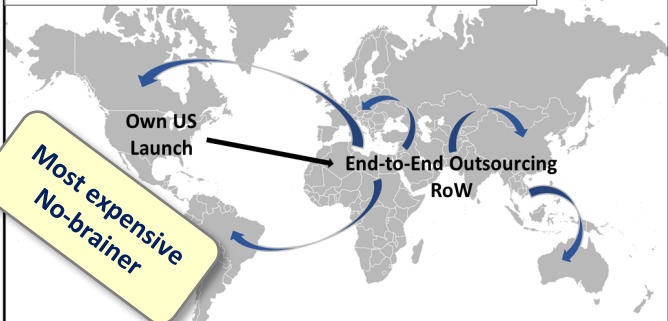
Strategic Choice 2: Out-licensing to Big Pharma



Strategic Choice 5: Staggered-flexible European Market Entry



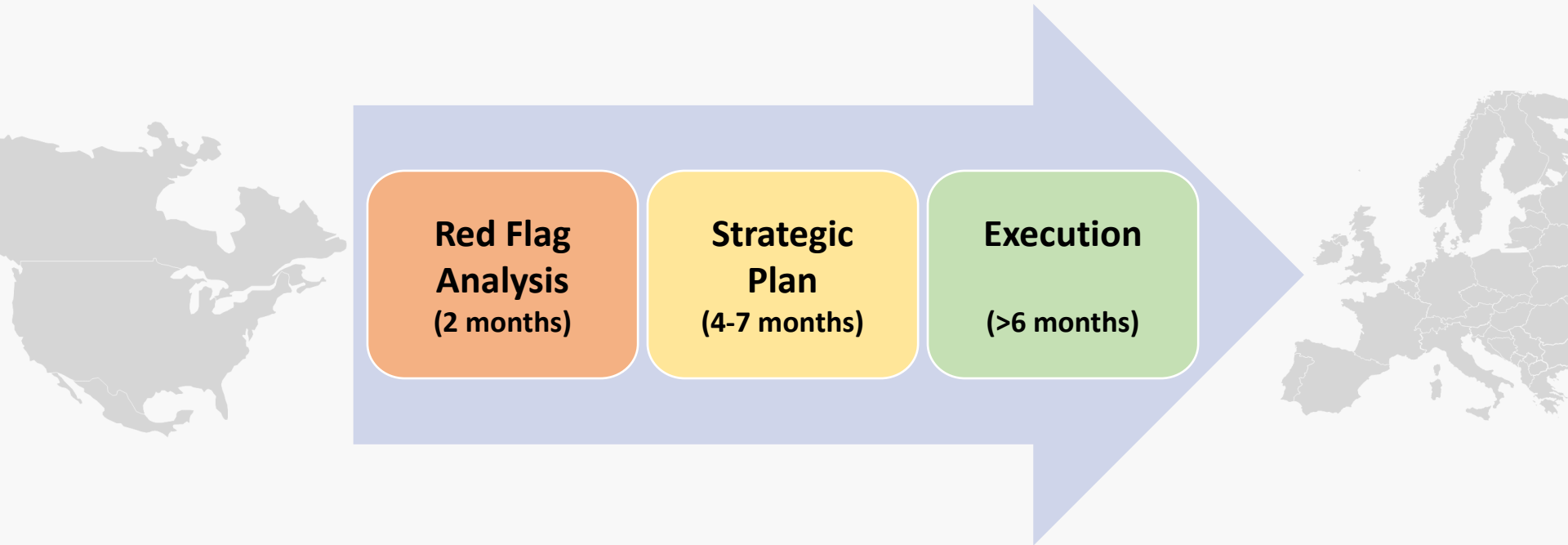
Strategic Choice 3: End-to-End Outsourcing



Strategic Choice 6: No European Market Entry at all

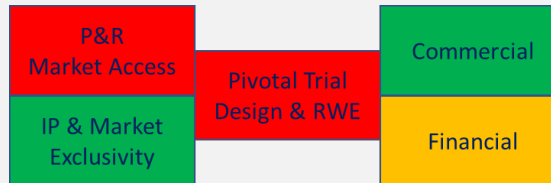


The Bridge to Europe



Red Flag Analysis for G5 countries

**Red Flag
Analysis
(2 months)**



Key-Indicators G5 (UK/DE/IT/ES/FR):

- Pricing, Reimbursement and Market Access
- Pivotal Trail Design and Real World Evidence
- IP & Market Exclusivity
- Commercial-Indicators
- Financial-Indicators

1 → Risk Mitigation Recommendations

2 → Decision to Proceed

Strategic Plan for G5+ countries

**Strategic
Plan
(4-7 months)**



Optimal European P&R Strategy	Competitive European Business Model	Competitive Medical Leadership Strategy
Optimal European Market Access Strategy	Competitive European Go-to-Market	Maximized ROI for your European Entry

Deep-Dive into G5+, among others:

- How to achieve competitive Pricing & Reimbursement
- How to engage with different Payers & Access Stakeholders
- How to engage KOLs & Key Stakeholders
- How to choose right form of Organizational set-up
- How to identify & implement Segmentation & Targeting
- How to optimally allocate Resources across Portfolio of Countries

1 → **P&L European Expansion**

2 → **Strategic Plan for European market entry**

3 → **Go/no-Go Decision**



Execution

Execution

(>6 months)



Our Engagement does not stop with a plan:

- Combined 60 years of experience in the pharmaceutical industry
- Worked for multiple companies in
- Several European Countries for
- Multiple Therapeutic Areas

1 → **Operation Plans and Dashboard**

2 → **RWE and Market Access Data Generation**

3 → **Project Management and Execution**

4 → **Due Diligence PMO** (if in-/out-licensing)

First Step Requirements



**Red Flag
Analysis
(2 months)**

Customer:

- Overview Clinical Data
- Status RWE Data
- IP-Status
- Epidemiology
- Key Competitor Insights

The Bridge®:

- Tools and Processes to analyse G5 Key-Indicators
- Pricing, Reimbursement and Market Access
- Pivotal Trial Design and Real World Evidence
- IP & Market Exclusivity
- Commercial-Indicators
- Financial-Indicators

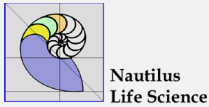
1

Risk Mitigation Recommendations

2

Decision to Proceed

Short Bios: Tom & Bjoern



Thomas Berthold, PhD

*Owner & Principal at
Nautilus Life Science, USA*

23 years international & global career with Janssen Pharma / Biotech (Johnson & Johnson) and Desitin Pharmaceuticals, from Sales Rep to Management Board member; in Sales, Marketing, Business Analytics & Asset Valuation, R&D, Portfolio Management and Finance.

Entrepreneurial Business Consultant in Life Science (Marketing, Medical, Launch Readiness, Epidemiology, Portfolio Management, L&A, M&A) since 2011.

Many years of international and cross-cultural experience from positions and projects in several European countries and the USA. Author of several scientific publications in Biology.

PhD in Biology, University of Hamburg, Germany; Post doc Researcher with German Research Foundation; Research Associate, British Museum of Natural History (UK), Danish Bilharziasis Laboratory (Denmark), Royal Museum of Central Africa (Belgium)



Bjoern Grob, MSc

Partner at HEMAP AG, Switzerland

20 years successful international career with Janssen Pharma / Biotech (Johnson & Johnson) and Pharmacia & Upjohn, from Sales Rep to Business Unit Head with full P&L responsibility to Management Board member; in Sales, Marketing, Life Cycle Management, Market Access, Business Development and Change Management.

Entrepreneurial Business Consultant for Health Economics and Market Access since 2019.

Broad international and cross-cultural experience from numerous positions and assignments in several European countries and operating companies. Author of several scientific publications in Biology and Health Economics.

*MSc in Anthropology and Molecular Biology, University of Zuerich, (Switzerland);
Research Associate, University of Wisconsin (USA) & Cambridge University (UK); Diploma in Health Economics, European School of Health Economics*