

# The Pros & Cons of Product Launches in Europe vs the US

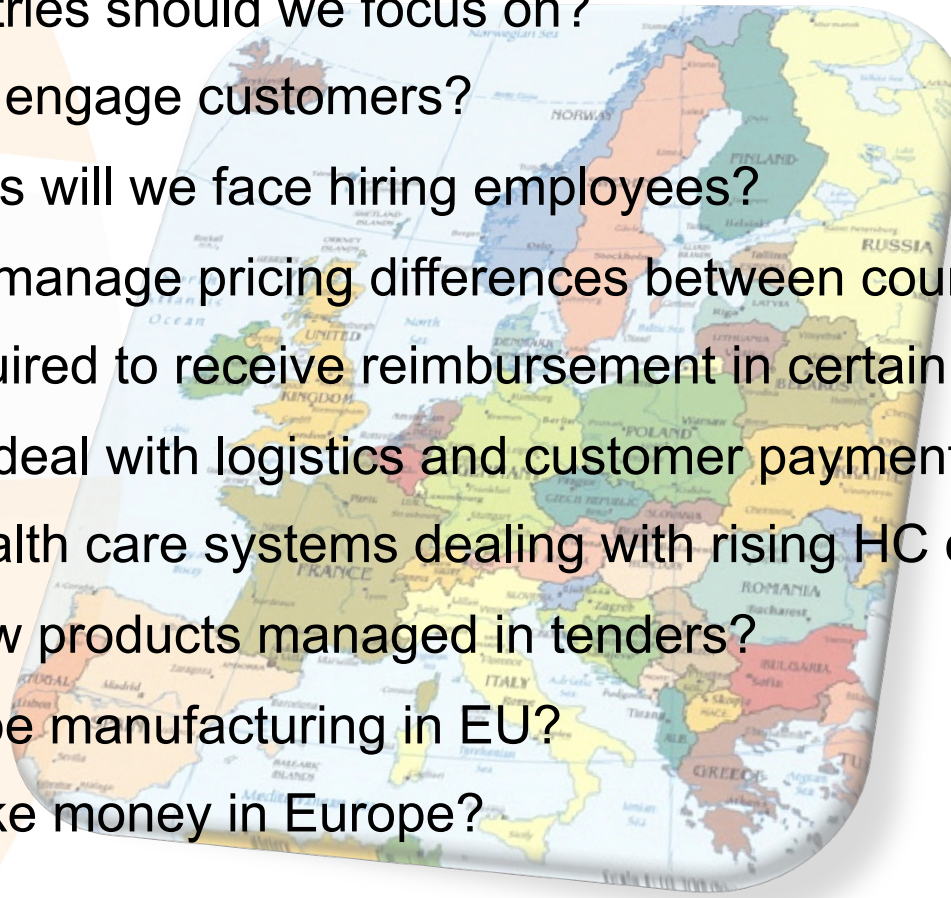
Panel Chairman:  
Robert Keefer

## Panel Members

- Robert Keefer. President of Acousticon Inc. (US and Germany).
- William Starling. CEO of Synecor; and Managing Partner, Synergy Life Science Partners. Palo Alto, CA
- Mika Nishimura. BLG Group. San Francisco, CA
- Dennis Burns, VP of Rotem Inc. (US and Germany)
- J. Greg Davis, Chairman ibiliti, (former CEO of Tryton Medical). Chapel Hill, NC

## We Just Received CE Mark...Now What?

- Which countries should we focus on?
- How will we engage customers?
- What hurdles will we face hiring employees?
- How do we manage pricing differences between countries?
- What is required to receive reimbursement in certain countries?
- How do we deal with logistics and customer payments?
- How are health care systems dealing with rising HC costs?
- How are new products managed in tenders?
- Should we be manufacturing in EU?
- Can we make money in Europe?



# Should We Use Distributors?

## Pros:

- Rapid launch sequence
- Capital efficient
- Bring existing customer relationships
- Knowledge of local tenders/reimbursement
- 30 – 90 day payment terms

## Cons:

- Often over promise and under deliver
- Competition from other products in sales bag
- Less effective if market development/training required
  - Changing physician clinical habits/techniques
- Terminating agreements is costly and time consuming
- Loss of margin (normally 30-50%)

# Or is Direct Sales Force Better?

## Pros:

- Greatest control over engagement and messaging
- Most effective at market development activities
  - Teaching new techniques, changing clinical practices
- Singular focus
- Rapid adjustments to sales approach

## Cons:

- Up front investment
- Ongoing monthly burn rate
- Attracting top sales talent is difficult
  - Less entrepreneurial, long notice periods, expensive
- Often multi-country focus

# Or Should We Commercialize at All?

## (Clinical Trial/Registry Focus)

### Pros:

- Collect clinical data post CE Mark
- Test new product iterations
- Refine sale messaging and approach to training
- Create buzz and engagement with KOLs
- Less costly than direct sales presence

### Cons:

- Does not answer questions about pricing and commercial adoption
- Consumes cash without revenue contribution
- Strategy bridges to what?



## Key Question: What Are You Trying to Achieve?

- Generate cash flow to fund U.S. operations
- Substantiate market potential
- Capture competitive market share
- Create buzz with KOLs and potential acquirers
- Collect additional clinical experience/data
- Iterate design based on clinical experience
- Conduct randomized trial to fine tune U.S. trial
- Ramp-up manufacturing in preparation of U.S. launch

