



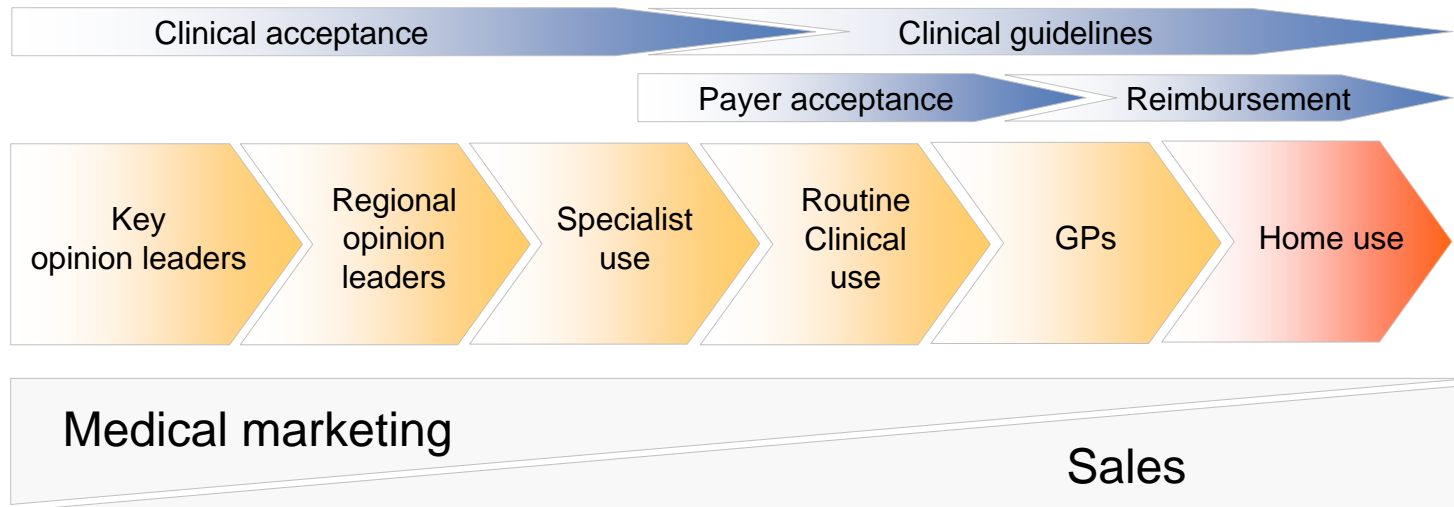
How to Build a Successful Business in the US

Aerocrine AB

Understanding your US-specific starting point

- Current awareness, acceptance and usage of product class or method
- Regulatory status of product class or method
- 510(k) or PMA requirements, timelines and status for your product
- CPT code, reimbursement value and general payer acceptance related to product class or method
- Status US clinical guidelines
- Primary customer target group: size, location, incentives and buying pattern

Establishing a new product class or method



1. Method/product establishment – FDA clearance process – Research sales
2. CPT code AMA/CMS – Initial cost coverage – Niche target sales
3. Guideline inclusion – Broader reimbursement – Traditional sales & marketing

Aerocrine's products



NIOX®
FDA approved 2003

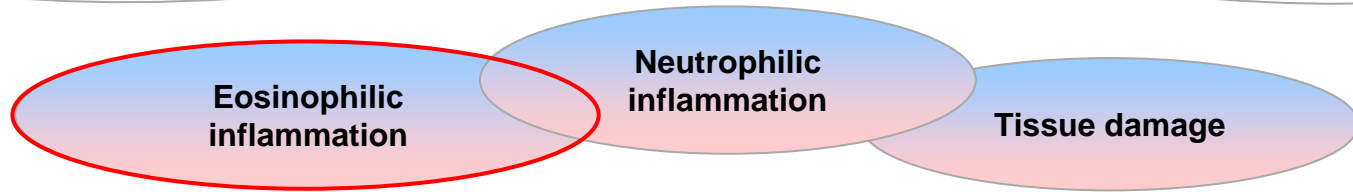
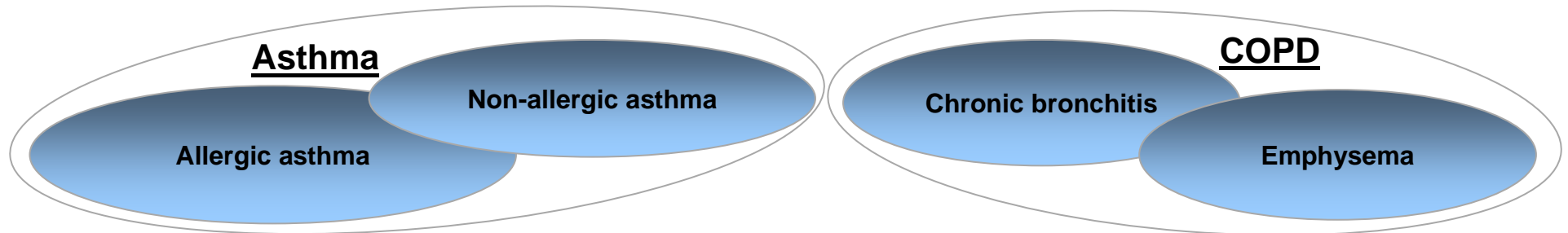
Research tool for academic centers and specialist clinics



NIOX® Flex
introduced June 2007



NIOX MINO®
introduced in Europe 2005, under 510(k) FDA review
Handheld product for hospitals, specialist physicians,
primary care and home use by patients



Excessive mucus
Shortness of breath
Coughing
Wheezing
Chest tightness

Anti-inflammatory Bronchodilators

Inhaled corticosteroids Leukotriene RA β_2 -agonists

Physical examination
Symptoms & history
Spirometry
FE_{NO} measurement



- First product NIOX® functional in 2000
 - No product- or method awareness outside research community
 - No clinical trials performed in the US
 - No FDA clearance or process, no predicative device
 - No payment structures
 - Nothing in guidelines
 - No Aerocrine organization in the US

Aerocrine in the US: 2000-2007

- First product NIOX® ready 2000
- Clinical study in US 2001-02
- 510(k) De Novo filing process NIOX® 2002-2003
- CPT-filing NIOX® July 05 to AMA through ACAAI (consultant)
- CPT code and Medicare coverage NIOX® Jan 07
- Clinical study NIOX MINO® 2006-07
- 510(k) filing NIOX MINO® October 2007
- Staff traveling from Sweden 2000 - Congresses, societies and key opinion leaders
- First NIOX® sold at ATS May 2000
- Aerocrine Inc. established 2002:
 - President in NJ
 - Swedish Trade Council from Chicago
 - 30 independent reps
 - Service in San Diego
- Halftime marketing manager 2004
- One product support staff 2006
- NJ offices established 2006-07
 - Warehouse
 - Service
 - In-house sales, marketing, QA and finance

Aerocrine Inc. today and going forward

- NIOX installed at 98 of 100 key academic centers
- Scientific committee and Educational program in place
- Fourteen people, ready to recruit commercial staff upon 510(k) clearance
- Launch of NIOX MINO® :
 - Own organization for specialist physicians
 - Verify or calibrate business model
 - Geographies and target groups governed by payer acceptance
 - Commercial partner for broad market penetration
- Expand US specific Health Economy outcomes data
- Work with payer groups, key opinion leaders and patient organizations

Reflections

- Do what FDA requests, even if you disagree
- For 510(k) and PMA processes; get US expert advice
- Avoid independent reps and distributors for missionary sales
- Set up on east coast
- Employ US President whom you know
- Consider legal, accounting, QA/QC, FDA and logistics matters alongside sales and marketing
- Do not underestimate challenges vs. payer group
- Make realistic US plan, then multiply timelines and costs by two-three

US represents up to 50% of world market value