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Combination Products

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Combination Products

Combination products include exciting innovations in bioartificial organs, implantable insulin pumps with circulating glucose sensors, implanted or swallowed “pharmacy-on-a-chip”, specially designed catheters that transport stem cells, and drug eluting stents.



Combination Product Examples

- ❑ Products composed of:
 - Drug and Device
 - Drug and Drug
 - Drug and Diagnostic
 - Cells and Device
 - Cells, Diagnostic, and Delivery
 - Diagnostic and Delivery



Types of Deals

❑ Drug / Device

- Drug Eluting Stents (DES): J&J, Boston, Medtronic, Guidant, Angiotech
- Implantable Biologics: Orthocon



❑ Drug / Drug

- Obvious: Pozen <POZN>
- Non – Obvious: CombinatoRx <CRXX>



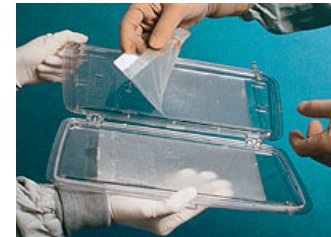
❑ Drug / Diagnostic

- Genaissance <CLDA>
- Adlyfe



Types of Deals Contd.

- ❑ Cells / Devices
 - Aastrom
 - Advanced BioHealing
- ❑ Cells/Diagnostics/Delivery
 - Bioheart
- ❑ Diagnostic/Device
 - Epison



Where do we want to invest?

Limit Novelty

- Approved / Approved
- Approved / Modest Change
- Approved / Novel
 - ❖ Not Novel / Novel

Minimal Sourcing Risk

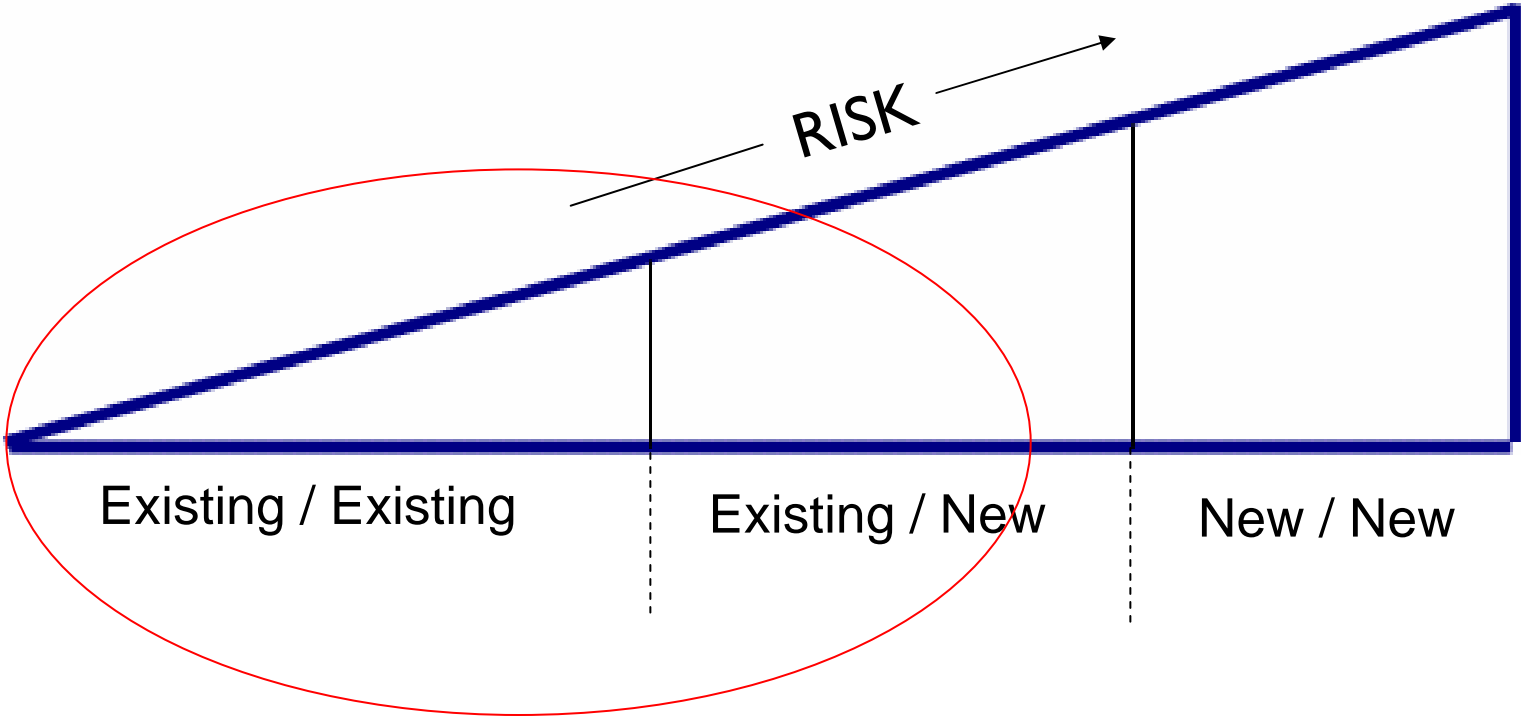
- Multi-sourced biologic or drug
- Easily manufactured device

Shorter Timeframes

- Device-like (Not drug-like)
- Acute and primary end points
 - ❖ (days and weeks)
- Limited capital risk



Acceptable Product Risk



What are the costs?

- ❑ Subadditive
 - ❑ Additive
 - ❑ Synergistic
-
- ❖ Is it more expensive to develop the combination than it would be to develop the device or drug alone?



What are the regulatory concerns?

- ❑ Google drug device and you get more hits from law firms than companies!

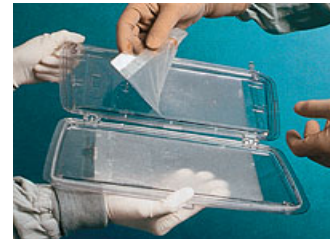
- ❑ FDA likes to assign primary responsibility based on mode of action
 - Drug side more than doubles the cost – need to know early

 - Are you in a portion of the agency that has handled Combo product before?



What are the market risks?

- ❑ Is it a new market?
- ❑ Is it a missionary sell?
- ❑ Is there a general market sense of potential value for the combination?



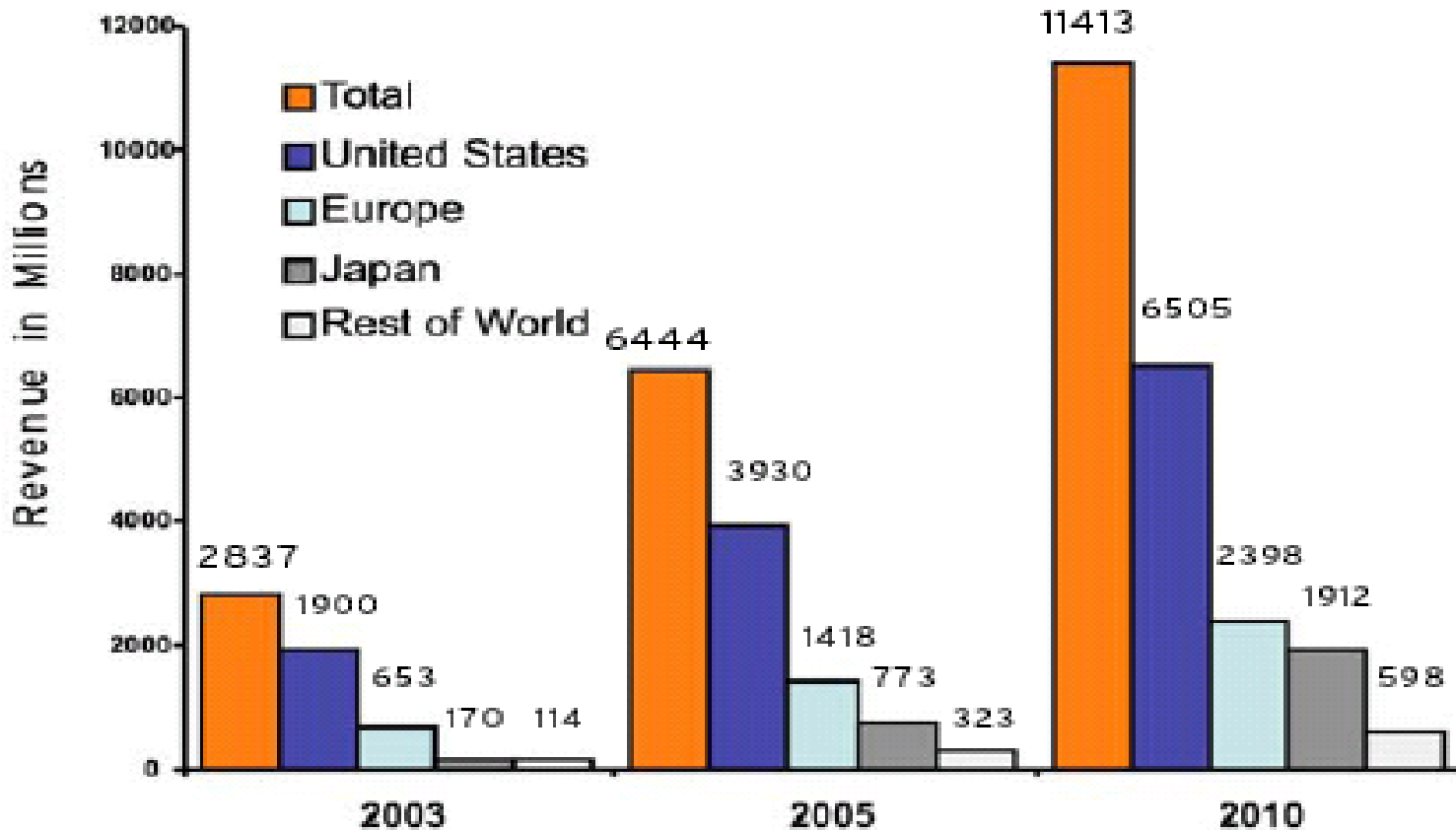
Who are the potential buyers?

- ❑ Clear pathway to acquisition
- ❑ Do the potential buyers already have their own programs?
- ❑ If IPO, is it easy or hard to explain the advantages and can the product platform be leveraged?



Drug-Device Market Growth by Geographic Area

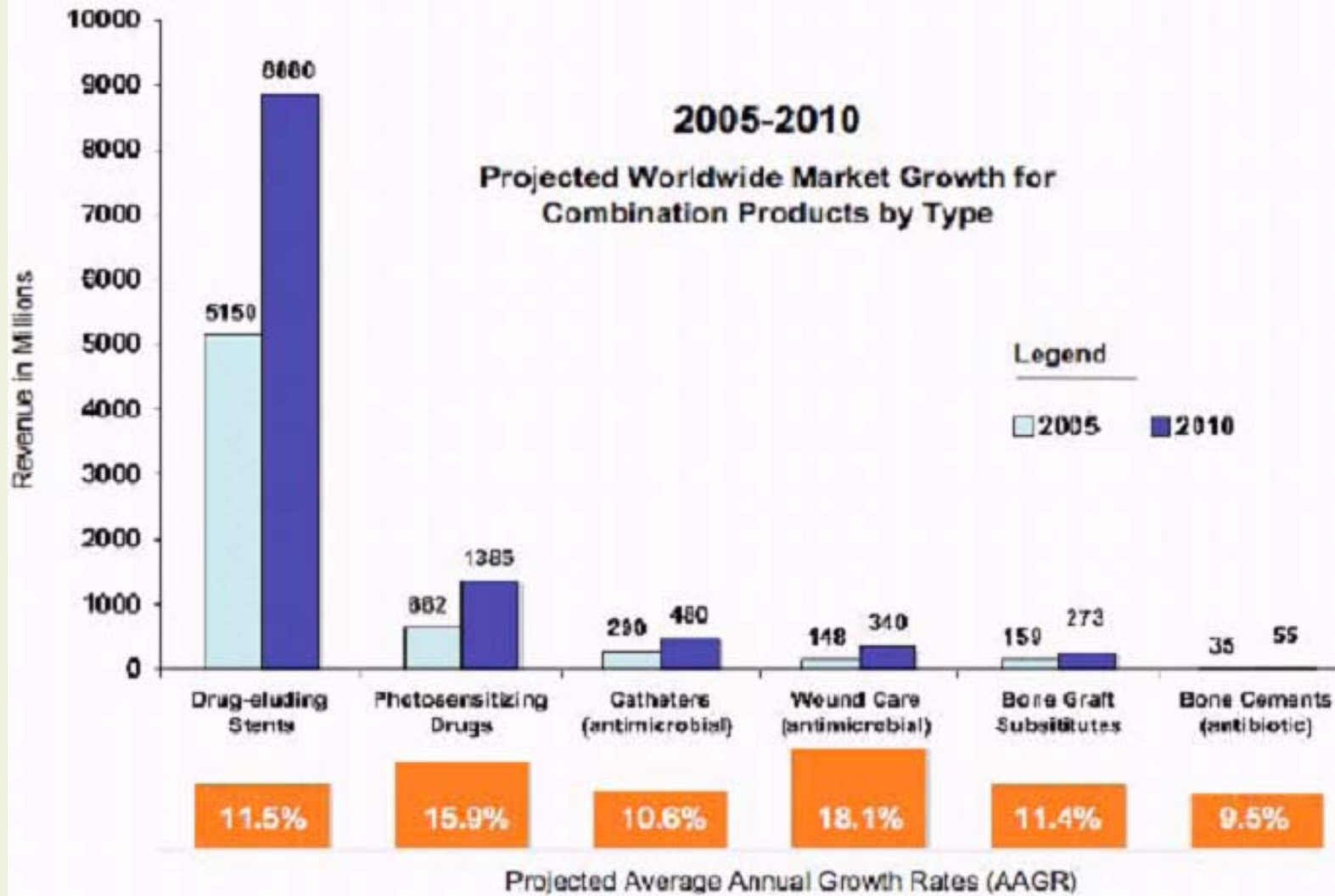
Estimated Worldwide Market for Drug- Device Combination Products by Geographic Area



Data Source: BCC Research, Drug-Device Combinations, June 2005



Growth by Combination Product Type





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