

# Innovation and Entrepreneurship in the Healthcare Sector Ensuring Successful Commercialization

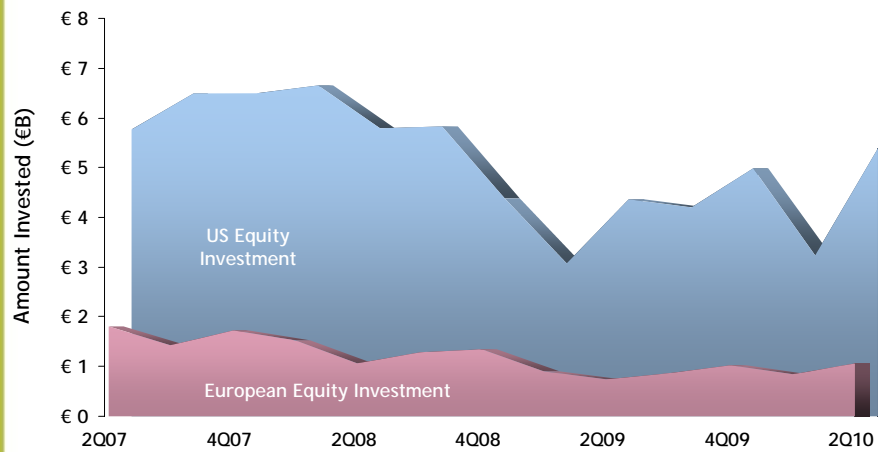
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Strategy Inc. [www.strategyinc.net](http://www.strategyinc.net)



Barcelona, Spain  
November 3, 2010

## 2010 Perspective on European Markets by Quarters

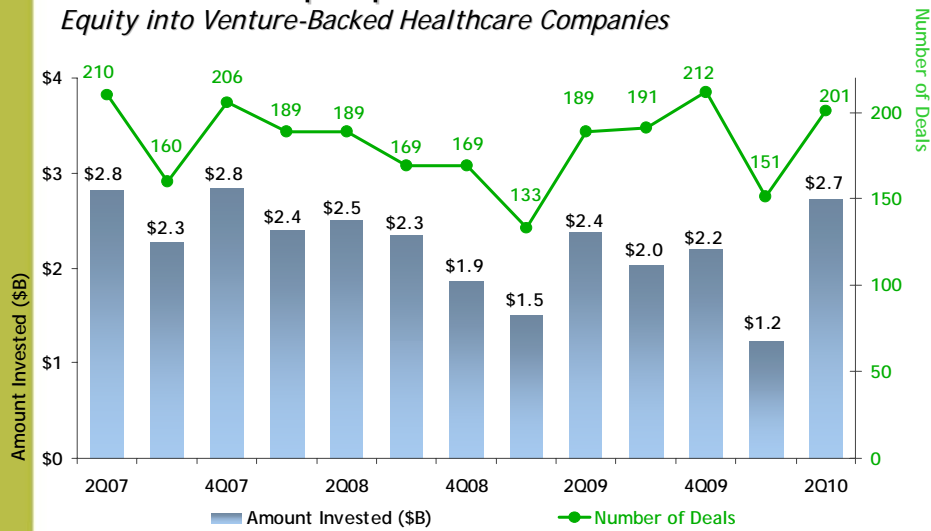
Equity Investment in Venture Capital Companies - US vs Europe



Source: Dow Jones VentureSource

# US Healthcare Deal Flow and Investment by Quarter Jump Up in 1H' 10

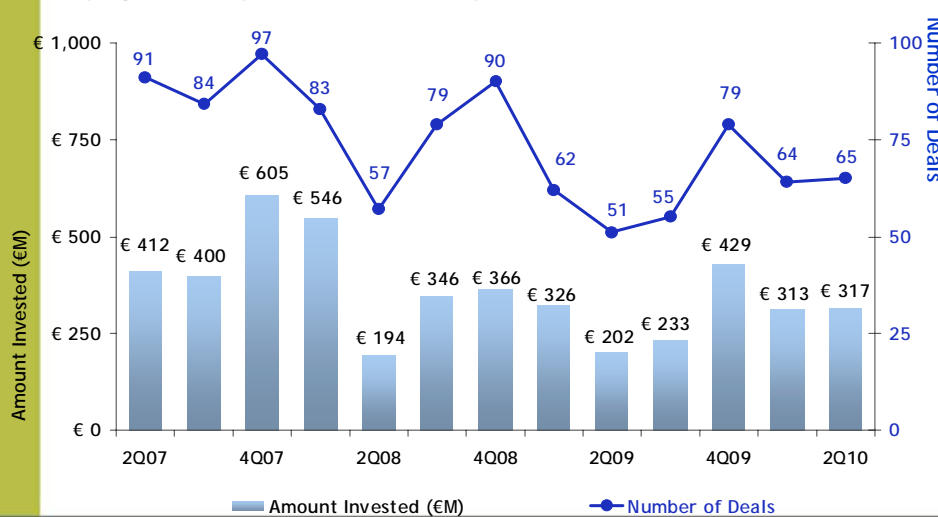
Equity into Venture-Backed Healthcare Companies



Source: Dow Jones VentureSource

# European Healthcare Activity by Quarter Consistent and Rising in 1H' 10

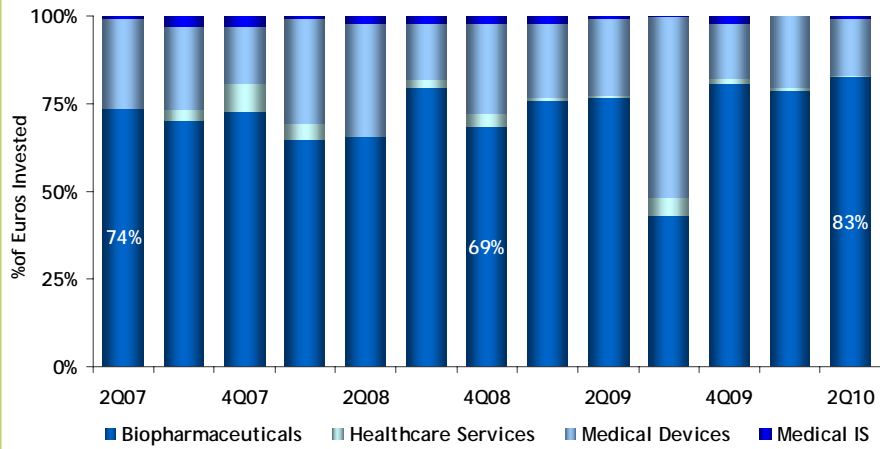
Equity into European Healthcare Companies



Source: Dow Jones VentureSource

# Biopharmaceuticals Lead Healthcare

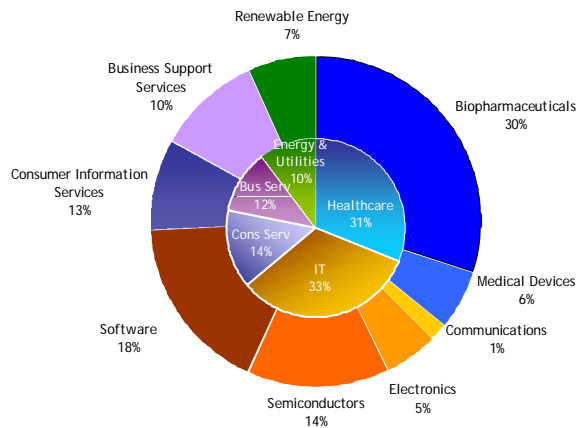
European Healthcare Investment Allocation by Sector



Source: Dow Jones VentureSource

# Biopharmaceuticals Dominate European Investments 1H' 10

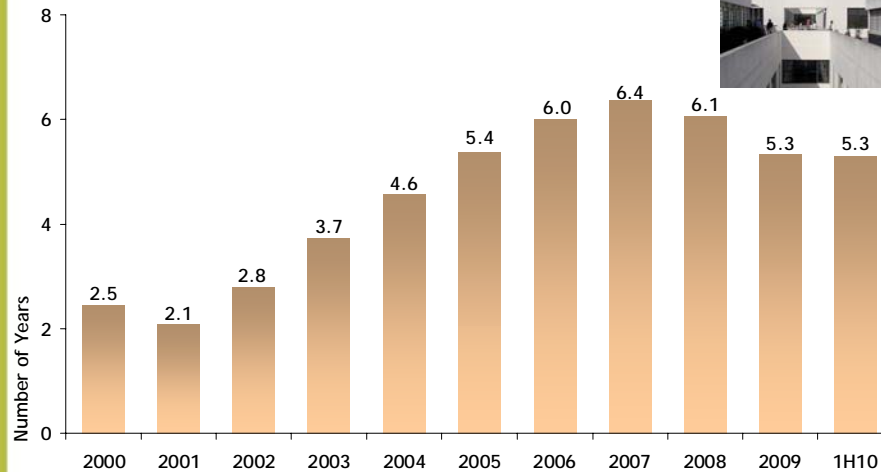
Equity Investment in European Venture-Backed Companies Among Selected Industries



Source: Dow Jones VentureSource

## Age of Acquired Companies Steady in 1H' 10

*Median Time From Initial Equity Funding to M&A*



Source: Dow Jones VentureSource

## Critical Issues Required to Drive Successful Commercialization of Lifescience Technology

- ◆ Be prepared to “stay the course”
- ◆ Secure sufficient funds
- ◆ BIG CHANGE - Grasping the shift from safety and efficacy to comparative effectiveness

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## Critical to Outline Your Exit Strategy From the Beginning

- ◆ VCs flush with cash are pushing against 8-10 year timelines and are hungry for elusive short/shorter term exits
- ◆ Average VC investment in a lifescience entity
 

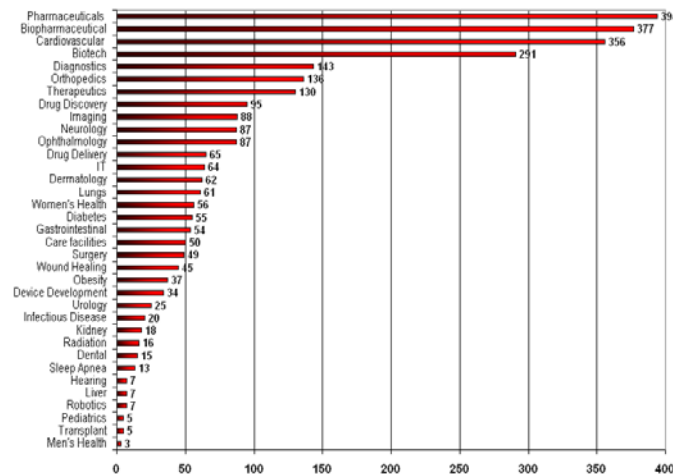
	US	EU
■ 2010	\$ 8.4 M*	4.9 €*
■ 2009	\$ 8.8 M	4.8 €
■ 2008	\$11.0 M	4.7 €
■ 2007	\$11.0 M	5.1 €
■ 2006	\$11.2 M	5.0 €
- ◆ IPO market is still behind an iron curtain, thus the only viable exit is M&A or corporate acquisition
- ◆ Critical to identify your exit strategy early in the development process since the investment community wants to know when they can expect the desired minimum 5X return

\* 2010 US Q1-Q3, EU Q1 - Q2

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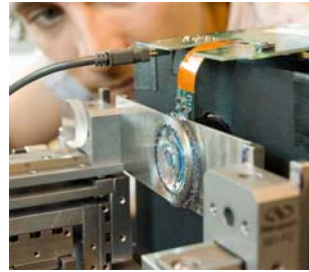
## 35 Categories Where 204 Venture Capital Firms Invest in Medical Device, Lifescience and Biotech

- ◆ 204 VCs investing in 2,959 lifescience emerging ideas 2004 - 2008
- ◆ View all 204 VCs on [www.strategyinc.net](http://www.strategyinc.net) with a hot link to each VC



# A Later Stage Exit

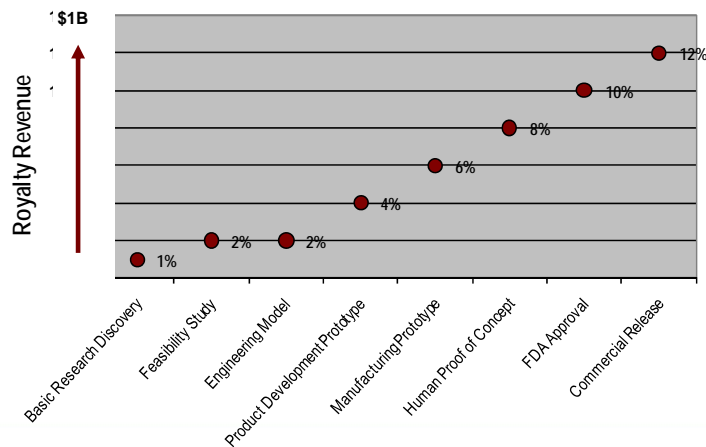
- ◆ **Clinical Study:** Small scale human clinical study under an IRB or IDE agreement.
- ◆ **Transfer Manufacturing:** Engineering design and manufacturing process development completed and transferred to manufacturing
- ◆ **Regulatory Submission:** 510(k), PMA and/or CE mark with an intent to produce and market a finished product
- ◆ **Regulatory Approval:** Approval of a regulatory body to manufacture and market the technology
- ◆ **Commercial Release:** Product is available for commercial sale and may have on-going post market testing



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## Enhancement of Medical Device **Royalty** as a Function of Commercialization Stage

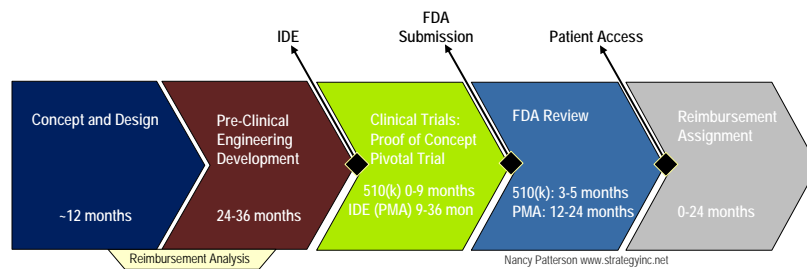
- ◆ Licensing deals are usually a function of the technology commercialization stage with the meaningful royalty stream requiring human proof of concept



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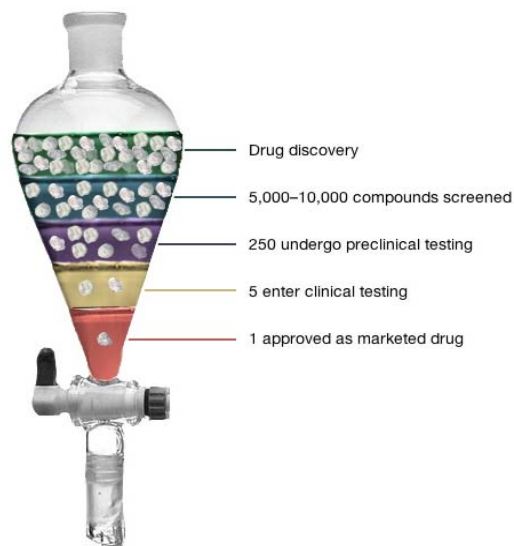
## FDA Medical Device Approval Process Simplified Diagram

- ◆ Medical device from concept to product launch takes between 4-10 years and costs between \$5 and \$300 million dollars; Average is 7.75 years and ~\$145 million USD
- ◆ There are approximately 35 PMA devices approved each year by the FDA and an additional 3,000 510(k) clearances
- ◆ FDA user fees required for regulatory review and range from ~\$200K for a PMA submission down to ~\$3,500 for a new 510(k) submission
- ◆ There are significantly reduced fees for an initial FDA submission from a small business



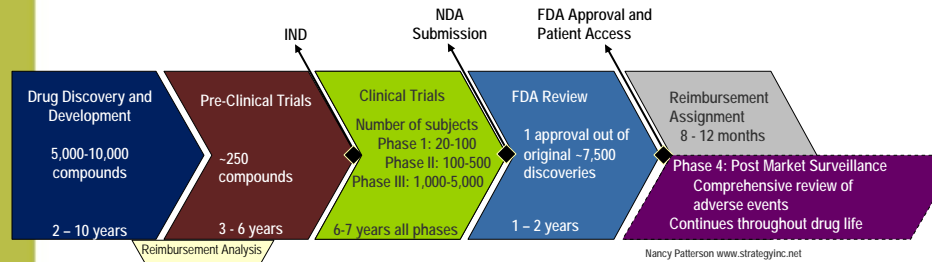
## Pharmaceutical Funnel to Commercialization

- ◆ 5,000 – 10,000 compounds are screened
- ◆ Processing through preclinical and then clinical testing
- ◆ 5 enter clinical testing and ultimately;
- ◆ 1 approved as a marketed drug



## FDA Pharmaceutical Approval Process Simplified Diagram

- ◆ Process of drug discovery to market ranges between 12-20 years and costs >\$1.2 billion
- ◆ Only ~.01% of drugs discovered will ever receive FDA approval



## Current Hot Technology Areas

- ◆ Drug Delivery: Stents, Pumps, Oncology
- ◆ Orthopedics: Minimally invasive spine, Degenerative disc disease, Improved prosthetics, Biomaterials
- ◆ Cardiovascular: Percutaneous valve repair, Endovascular stroke treatment, Vulnerable plaque, Atrial fibrillation, OCT imaging
- ◆ Obesity: Bariatric surgery
- ◆ Plastic surgery: Cosmetic surgery for men and women, Varicose vein esthetic surgery
- ◆ Women's Health: Fibroid, Endometriosis, Incontinence, Breast cancer therapeutics
- ◆ Neuromodulation: Pain management, Epilepsy, Mobility
- ◆ Ophthalmology: Glaucoma, Age related macular degeneration

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## Hot Technologies “On the Horizon”

- ◆ A new model of care: the convergence of biotech and biomechanics (Orthopedics, Cardiovascular, Interventional Neuroradiology, Gastrointestinal)
- ◆ Diagnostic biomarkers and parallel analysis instrumentation
- ◆ Specialty Pharma: Personalized medicine
- ◆ Robotics through direct and remote access
- ◆ Single port minimally invasive surgery, transgastric... “incisionless” through-any-port
- ◆ Advances in sensor technology to diagnose, monitor, predict and manage healthcare
- ◆ Implantable miniaturized neurostimulators to restore body functions including mobility and sight

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## Movement Towards Comparative Effectiveness Research Going to have a Big Impact on Trials

- ◆ What is Comparative Effectiveness Research (CER)?
  - One ‘official’ definition:
    - Institute of Medicine: The generation and synthesis of **evidence** that **compares the benefits and harms** of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will **improve health care** at both the **individual** and **population** levels.
- ◆ What does this mean for trials?
  - Decision-makers point to ‘gaps’ in most current trials
    - **Highly selective patient populations** don't reflect ‘real’ populations
    - Most clinical **trial settings** (research institutions) **not typical**
    - **Endpoints** are often physiologic, surrogate or (worst!) composite
    - Comparators **don't reflect the ‘real world’** of medical practice

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## Movement Towards Comparative Effectiveness Research Going to have a Big Impact on Trials

- ◆ What kinds of trials do decision-makers want? (for CER purposes)
  - Can support a **clinical** or **health policy** decision
  - Conducted in 'real world' settings
  - Measures **outcomes** important to patients
  - Uses **data** and **methods** that 'fit' the decision of interest
  - **Compares at least two alternatives**, including 'gold standard'
  - Generates results that are **relevant to appropriately defined subgroups** or for pre-defined population
- ◆ The reimbursement implications if manufacturers fail to re-think trials?
  - Technologies **will fail to get coverage** due to "limited or poor quality evidence"
  - Technologies will get **restrictive coverage** subject to completion of trials to establish outcomes of interest

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## ◆ Thank You

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President and Founder

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Strategy Inc is a life science due diligence and valuation company that provides business plan generation, market and risk analysis to ensure successful commercialization of emerging technology. Clients include the venture community, global medical device and biotech companies, law firms specializing in emerging biomedical technology, the Alfred E. Mann family of companies, emerging entrepreneurs and university based accelerators.

### **Venture Analyst**

**10 years working with medical technology entities to develop business strategy, valuation and due diligence**

- Includes business case analysis for platform technologies, valuation of early stage technology, market and risk analysis, business plan generation, and strategic positioning
- Staff includes 7 analysts with MBA, BME, MS in ME, MS Gerontology, MS Health Admin, MD and each with >10 years operational experience

**Formerly 18 years of experience in senior business development and marketing roles with emerging technology medical device companies**

- Last three acquired for \$205M, \$387M and \$508M

### **Education**

- MBA with dual major in Finance and Marketing from USC
- BS, Chemistry Graduate focus Immunology