



Wilson Sonsini Goodrich & Rosati  
PROFESSIONAL CORPORATION

# Biotech/Med Device Startup

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## Agenda

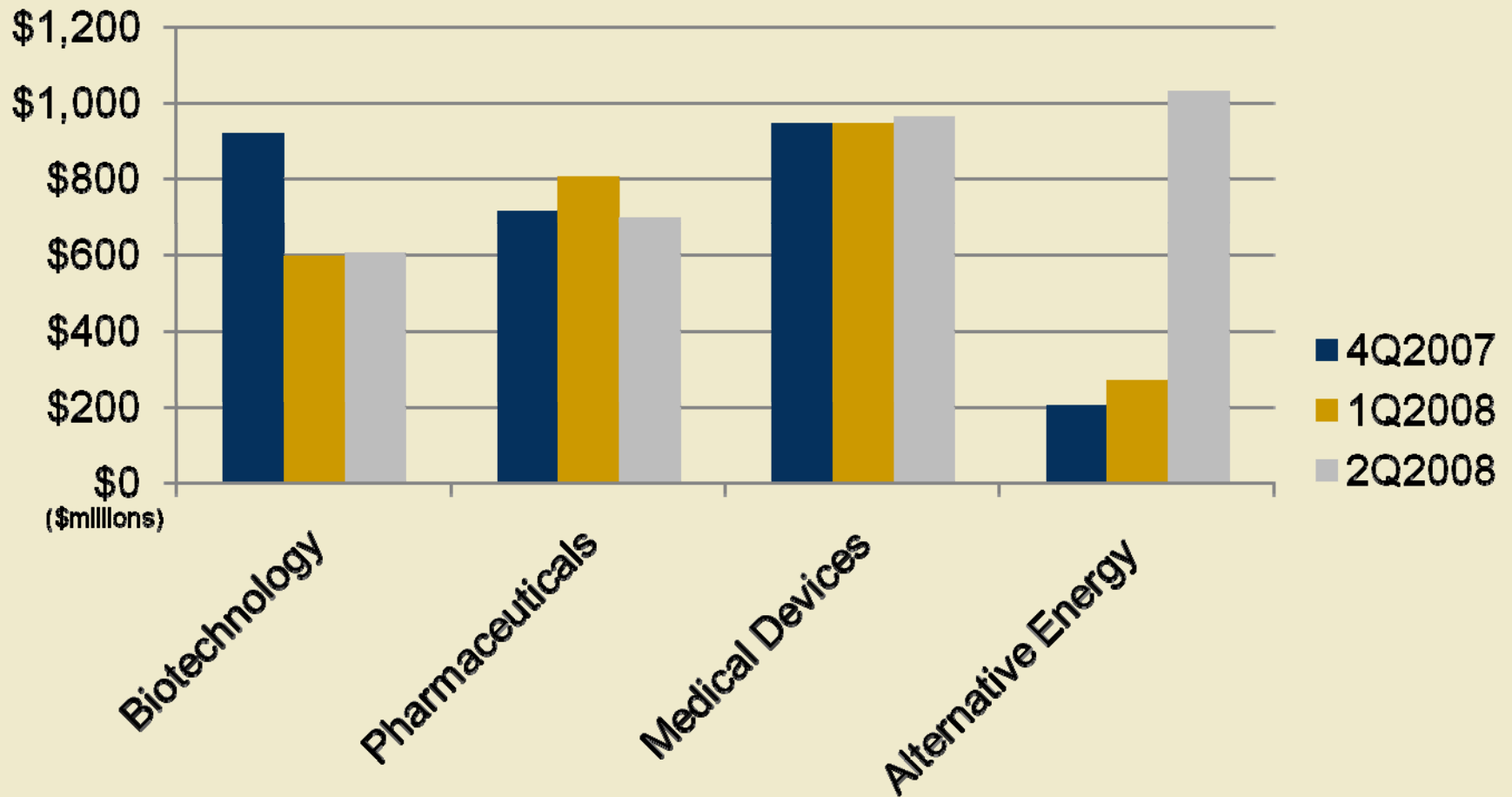
- Objectives of an IP Program in a Startup Company
  - Financing
- FDA Exclusivity
- How the idea gets into the company

## **An editorial commentary: Current Startup Financing Market**

- **Worst IPO Market Ever?** In the third quarter of 2008, venture-backed companies generated just \$4.57 billion in liquidity through initial public offerings (IPOs) and mergers and acquisitions (M&As), down 66% from the \$13.4 billion generated in the third quarter of 2007. (*www.venturecapital.dowjones.com*)
- About \$551 million raised via seven IPOs as of September 2008, thus on pace to be the worst year on record in terms of both number of IPOs and liquidity generated via IPO.
- **Startup Funding Steady?** A study by the Center for Venture Research at the University of New Hampshire put total angel investment in the first half of 2008 at \$12.4 billion, 4.2 percent higher than the first half of 2007. (*"Angel Investors Fly Steady," Red Herring, October 10, 2008*)



## New Venture Capital Financing by Sector\*



\*Source: Venturedeal.com

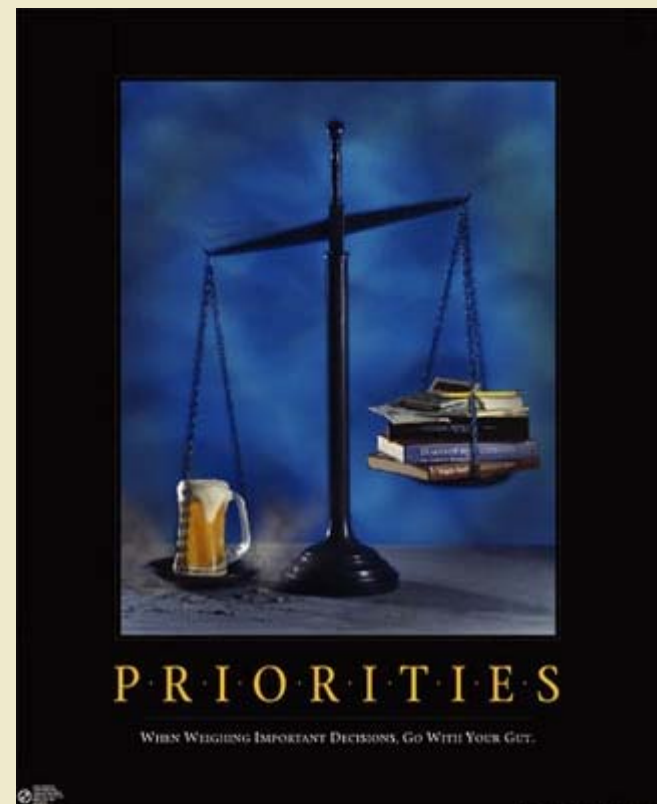
## The Venture Capital Process

- As part of a financing from Angels, diligence may be minimal
  - But, it is better to be prepared, and appear to know your field
- As part of a larger Series A
  - The VC will often hire a diligence firm
  - They will look at
    - ▶ Whether you can get good patents
    - ▶ Documentation issues
    - ▶ Whether you have freedom to operate
      - Often better to know where you stand before they are involved
      - Sometimes this results in buying good patents



## Objectives of an IP Program in a Startup

- The FIRST objective should be to SET objectives
- Possible priorities
  - Make sure others cannot patent your ideas
  - Develop a portfolio as a “trading card” when, e.g. Pfizer comes calling after you are successful
  - Stop others
    - ▶ Two levels- clinical data vs the field
  - Simply ensure freedom to operate via FTO studies



## Typical Start-Up Biotech/Pharma Objectives

- GUARANTEE Freedom to operate vs the *entire world*
- GURANTEE to stop competitors in the entire field
- AT LEAST have patent protection sufficiently broad to protect against data certification
- OR at a minimum have data exclusivity
- Maybe or maybe NOT
  - Minimize cost
  - Develop a broad portfolio (not necessarily covering our products) as a trading card deck
- ***Secure Financing***



## Forms of Protection Used

- Most companies use ALL forms of protection, to some greater or lesser degree
- The types are:
  - Patents
  - Copyrights
  - Trade Secrets
  - Trademark
  - FDA exclusivity
- Patents are arguably the most important form of IP for a biotech/pharmaceutical company



## Another form of protection- FDA exclusivity

- IF the molecule has never been approved before, others cannot use your clinical data- they must run a new clinical trial, e.g for a new indication
- But,
  - The protection is only 5 yrs
  - Someone can use the SAME molecule absent a patent, they must just run their own trial
- Note: IT'S FREE (compared to a patent)!



## Interaction of the FDA and the patent process

- Major fact: It *normally* costs huge huge sums of money to perform a clinical trial SO DEPENDING ON THE BUSINESS MODEL, there are three levels of protection for drugs/devices
  - FDA exclusivity for the molecule MAY be enough, i.e. the market allows for competitors that also have to run clinical trials
    - ▶ Consequence: Narrower patents are acceptable, and “safer”
  - But even in these cases, a patent may have longer life, so they are often desirable
  - If the business model requires you must own the space- You must have a BROAD patent, eg. All regulation of a gene

## Where did the IP come from?

- Be very careful of founders with former employers--- i.e. all founders need to be aware of their prior contracts
- Obviously many companies start from a university license
  - Most “big” universities are “easy” to deal with
    - ▶ Standard terms
    - ▶ Quick turnaround
    - ▶ Realistic about the world
  - Other academics can be tougher, largely by inexperience
- Don’t try to avoid these issues. It is harder to solve prior employer issues later when you have a valuable business than when you have nothing
  - It is very uncomfortable to resolve this as part of a financing
  - Virtually all VCs and underwriters will probe this issue

## Freedom to Operate (FTO)

- A study to determine if you infringe the patents of others
- Tech
  - Usually just a check of direct competitor patents before the fund raising or as part of diligence
- Biotech
  - You really must KNOW if there are issues
  - If you don't do it, the investors will
  - Usually a very expensive process
  - Involves looking at every patent in your area. As well as “background” technologies. Often thousands of patents to review



**The way to get good ideas is to get lots of  
ideas and throw the bad ones away –  
*Linus Pauling***