

Staying Creative: Financing Medical Device Startups

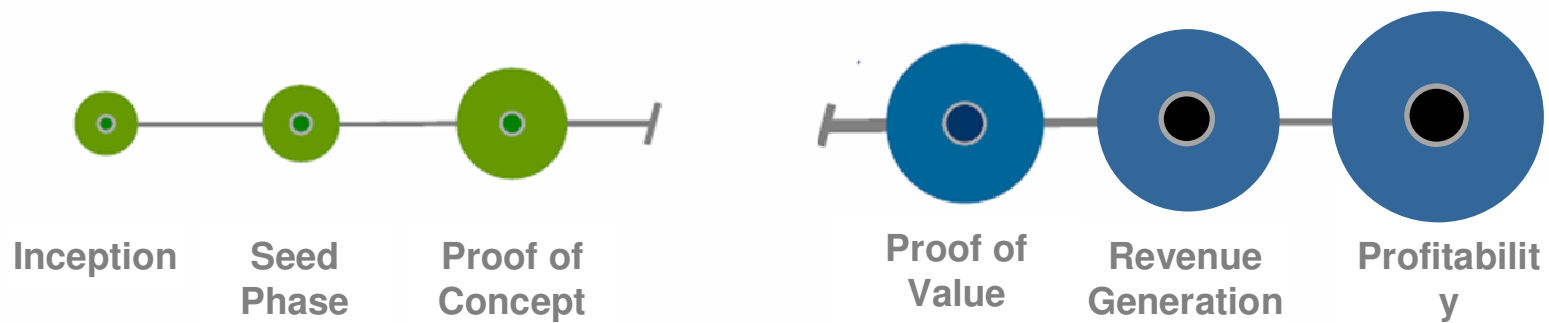
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1. TriReme Medical Inc.
2. Co-chair : ASTM Cardiovascular Standards Group



Startup Innovation Life Cycle

Economic Environment Creates Gaps



Venture Capital Coffers



Running on Empty

- Over 100 VCs invest in medical devices.¹
- 2009: numerous VC could not raise another fund
- Smallest amounts raised since 2003.²
- New LP \$\$ (- 45%) from previous 5 year average.²
- VC Returns (-10%) than small-cap Russell 2000 Index.³

Year Fund Raised⁴	# of Life Science VCs⁴
2009	4
2008	9
2007	9
2006	7
2005	3
2004	3

1. www.medicaldevicelink.com

2. NVCA

3. Over 10 year period, Kauffman Foundation

4. Elsevier's Strategic Transactions; SEC Documents; VC press releases; Morrison C. For Funds Close to Empty Filling Stations May Be Hard to Find. Startup. 2009; 14(9):

Venture Capital Impact on Funding

Funding at a slow drip

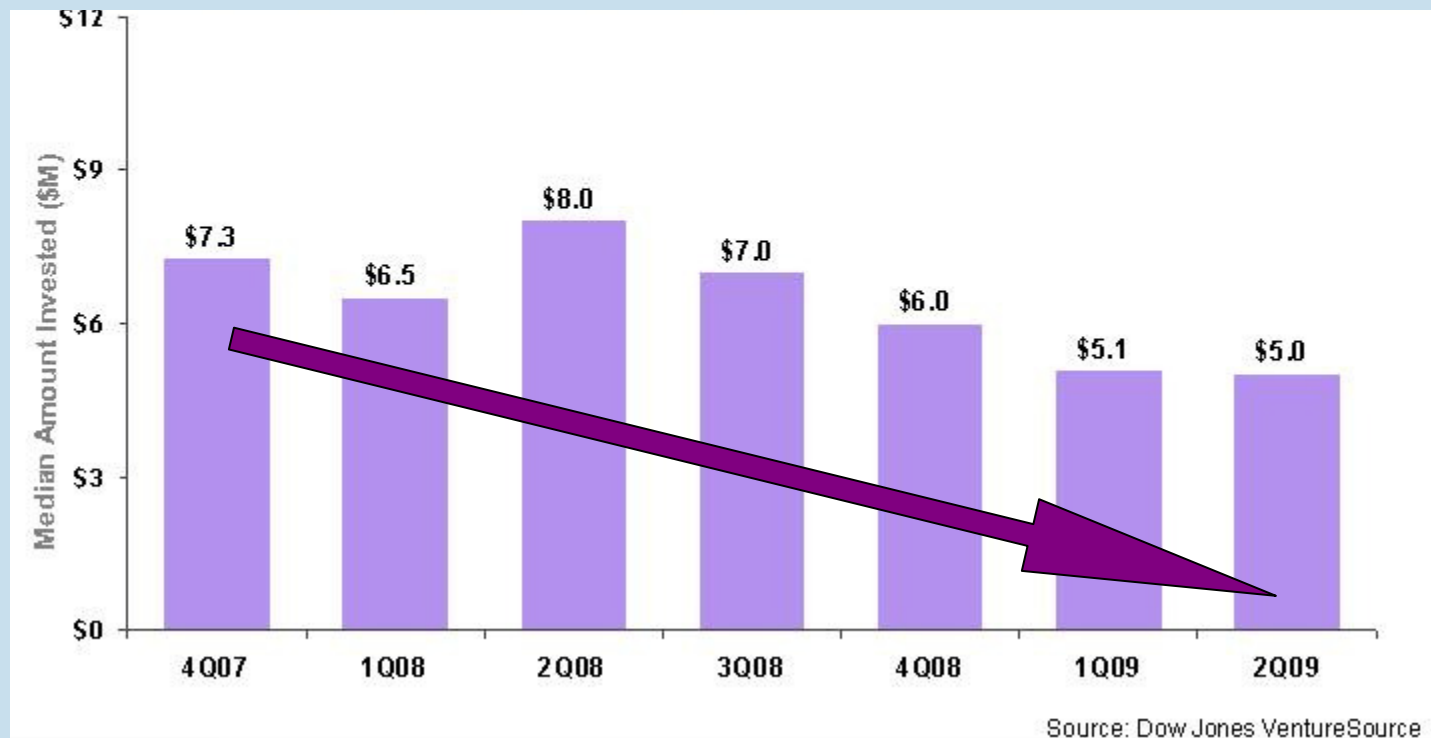
- VCs preserving capital
- Slow syndicates
- Low valuations, difficult protective provisions
- FY 09 funding Projected to be worst year since 1997



New Co (Start-up)

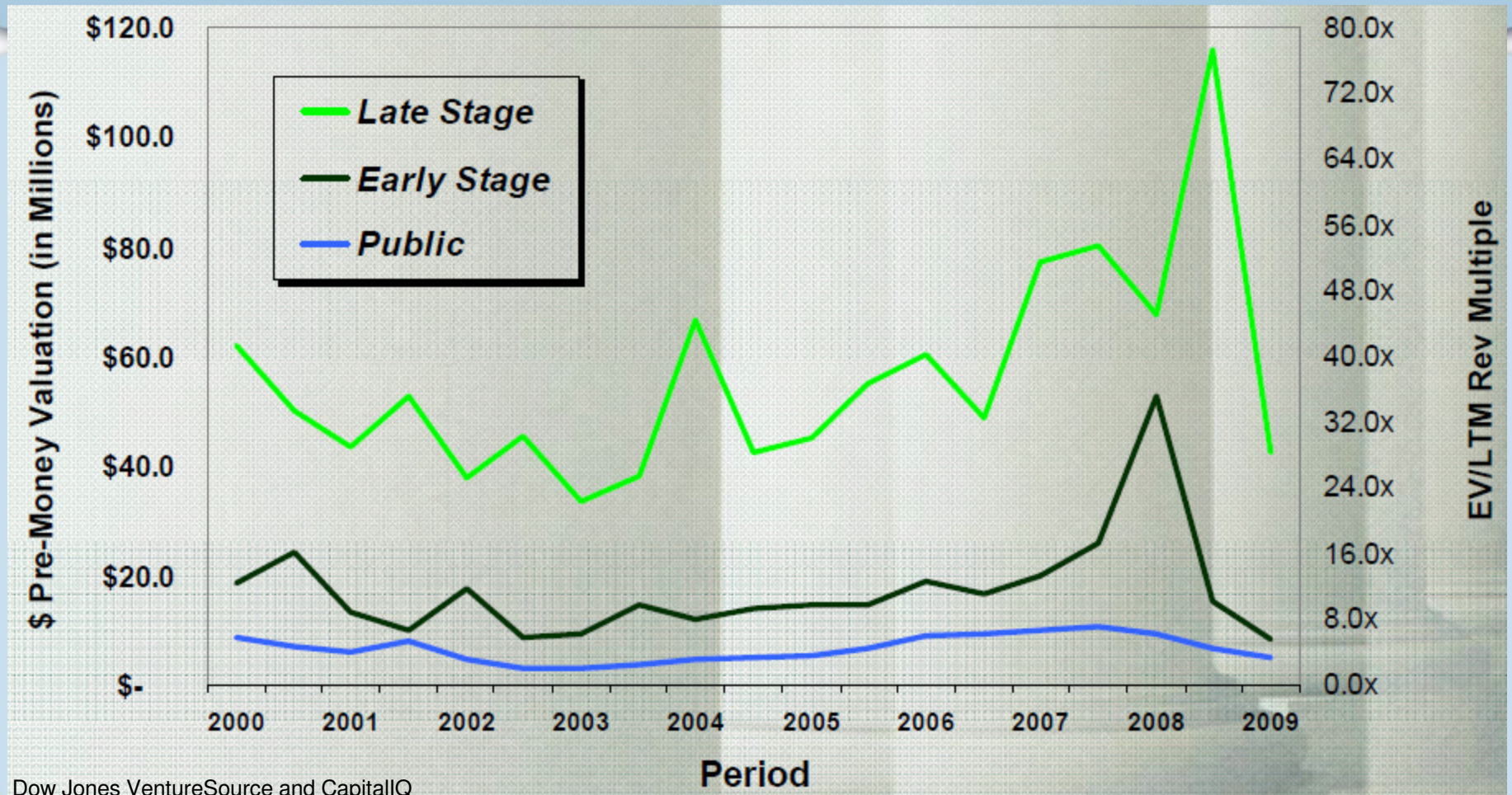


Median Deal Size is Decreasing



Both VC and Angel deals are following this trend

Valuations Index



Dow Jones VentureSource and CapitalIQ



Current Risks

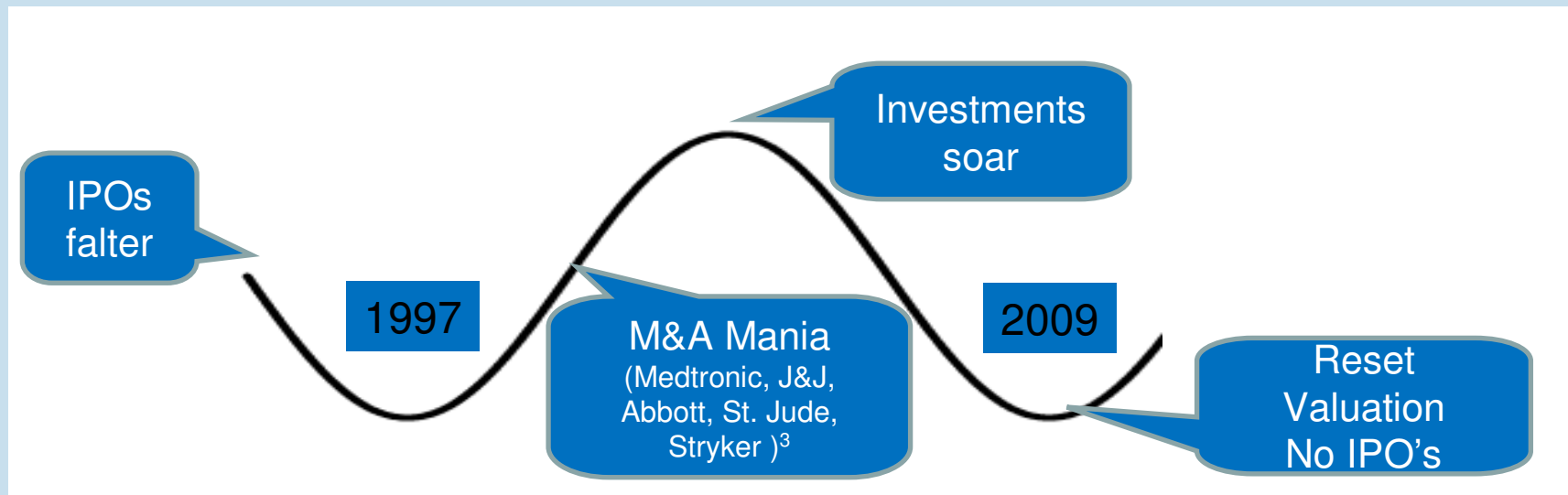
“It is going to get worse before it will get better”

(Hank Plain, General partner, Mortgenthaller and a Silicon Valley icon)

- FDA focus: compliance, enforcement and modifying the 510k route
- US market “entry ticket” is more expensive/higher risk
 - 510k: Significantly higher scientific burden of proof
 - PMA: Larger pivotal studies and post marketing requirements
 - More devices will be re-directed from 510k to PMA
- Healthcare reform and unknowns about cost effectiveness
- Higher capital requirements and smaller returns in cardiology

Medtech Industry Rollercoaster¹⁻³

- Current issues mainly linked to macro-economy
- Industry specific contributes (FDA, Health-care Reform)



"You have to work your way through the tough times. . . just weed out the weak players."
(P. LaViolette, SV Life Sciences)

1. Levin, S. Device Investing in Tough Times: The Venture View. *In Vivo*. 2009; Jul.
2. Salemi, T. Device CEOs Who Find the Funding. *In Vivo*. 2009; Apr.
3. Cassak, D. Are the Good Times Over. Windohover Information, 2006.

Opportunities

- Sizable acquisitions in the CV space (Evalve, CoreValve, Ventor, A. Frontiers)
- Valuations and round size slightly improving in Q4 09
- Demographic trends continue to support the industry
 - 33% of population above 60 in 2050 (vs. 19% in 1999)¹
- The Asian medical device markets are waking up
 - Chinese market is growing 20%+ per year
 - Japanese margins still high. Regulatory requirements sometimes less than FDA
 - South East Asian markets

1. Suneja VH. International Opportunities and Challenges, Global Market Overview. MDMA Annual Meeting. June, 2009.

The Industry is Evolving

- Convergence of technologies¹
- More companies are focusing on international markets¹
- Increased regulatory burden in all markets (CE, FDA, SFDA)
- Reimbursement scrutiny (Japan, USA)
- VC model/funding is changing,
- Longer time to exit

1. Hodson, et.al. Market Trends Prompt Need for a Better Operating Model. *MDDI*. 2008

To get funded...

With limited runway (cash)...



1) re-think your value proposition

2) choose the right path to takeoff

USA?

More data?

China?

Partnerships?

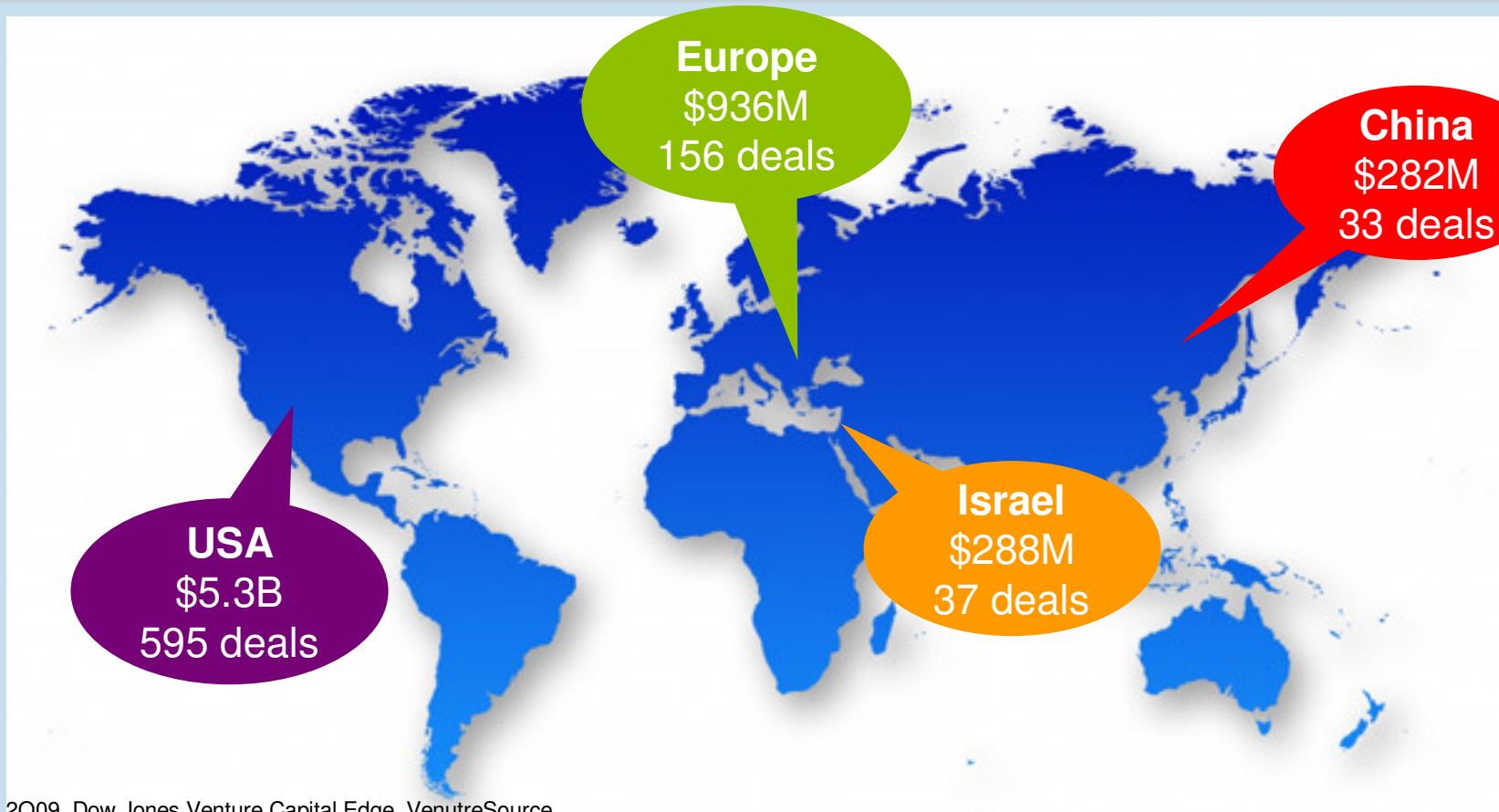
Other?

Moving down the Runway

- Be committed to lean and smart execution
- Leverage partnerships to improve your viability
- Identify the market that can prove your value
- Strive to get early revenue
- The end goal should be profitability

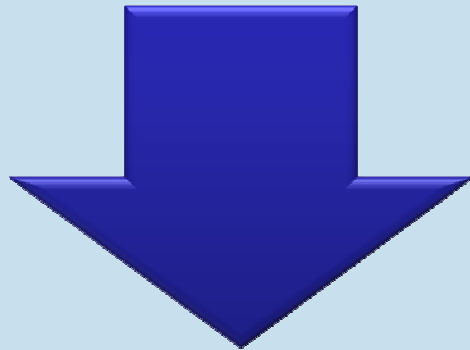
Where is the Money?

2009 Worldwide Total Investments - \$6.806B in 821 deals

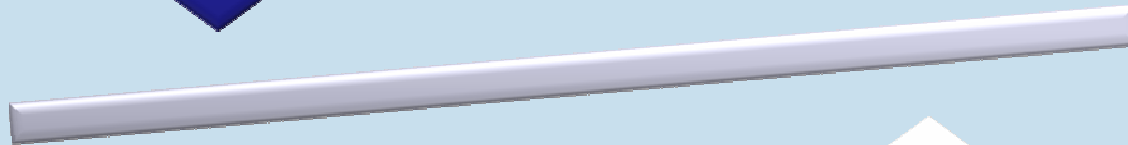


2Q09, Dow Jones Venture Capital Edge, VenutreSource

Expand Creativity Beyond the Technology



Invest in proving your value



Preserve cash:
outsource, collaborate, run lean



Fund Raising Resources

- Leverage internal rounds and bridge loans
- VCs are not the only source
 - Debt financing
 - Government grants (Israel, Europe, US, Singapore)
 - Creative development deals with larger players
 - Corporate investors
- Revenue is a funding source
 - European market is large but convoluted
 - Asian markets are attractive
 - US

Personal View from TriReme Medical

Prepared to 2009 crisis by

- Cutting costs in 2008
- Accelerated income from revenue by adding Glider technology:
 - Europe
 - US market
 - China
- Identified long term value in combination devices and created partnership
 - DES
 - DEB

Financing is not a hobby

- Requires full strategic vision; know the pathway
- Costs money to raise money
- Must commit to the process
- Get out of your comfort zone
- Customize your presentation for each meeting
- Identify company strategies that attract term sheets