Hot Emerging Biomedical Technologies and Their Successful Commercialization

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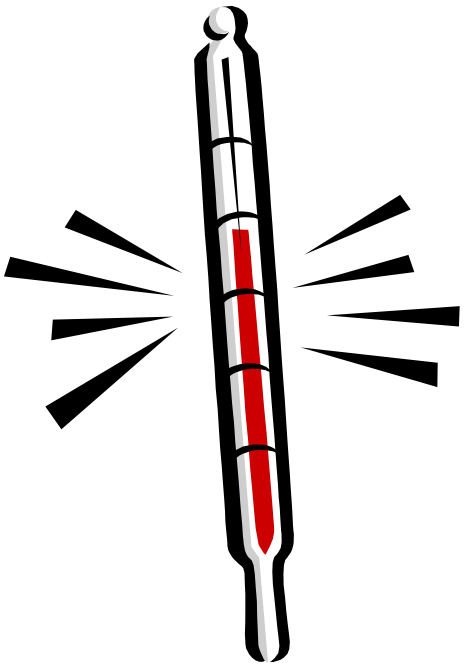
March 30, 2005

Taking the Temperature of Technology

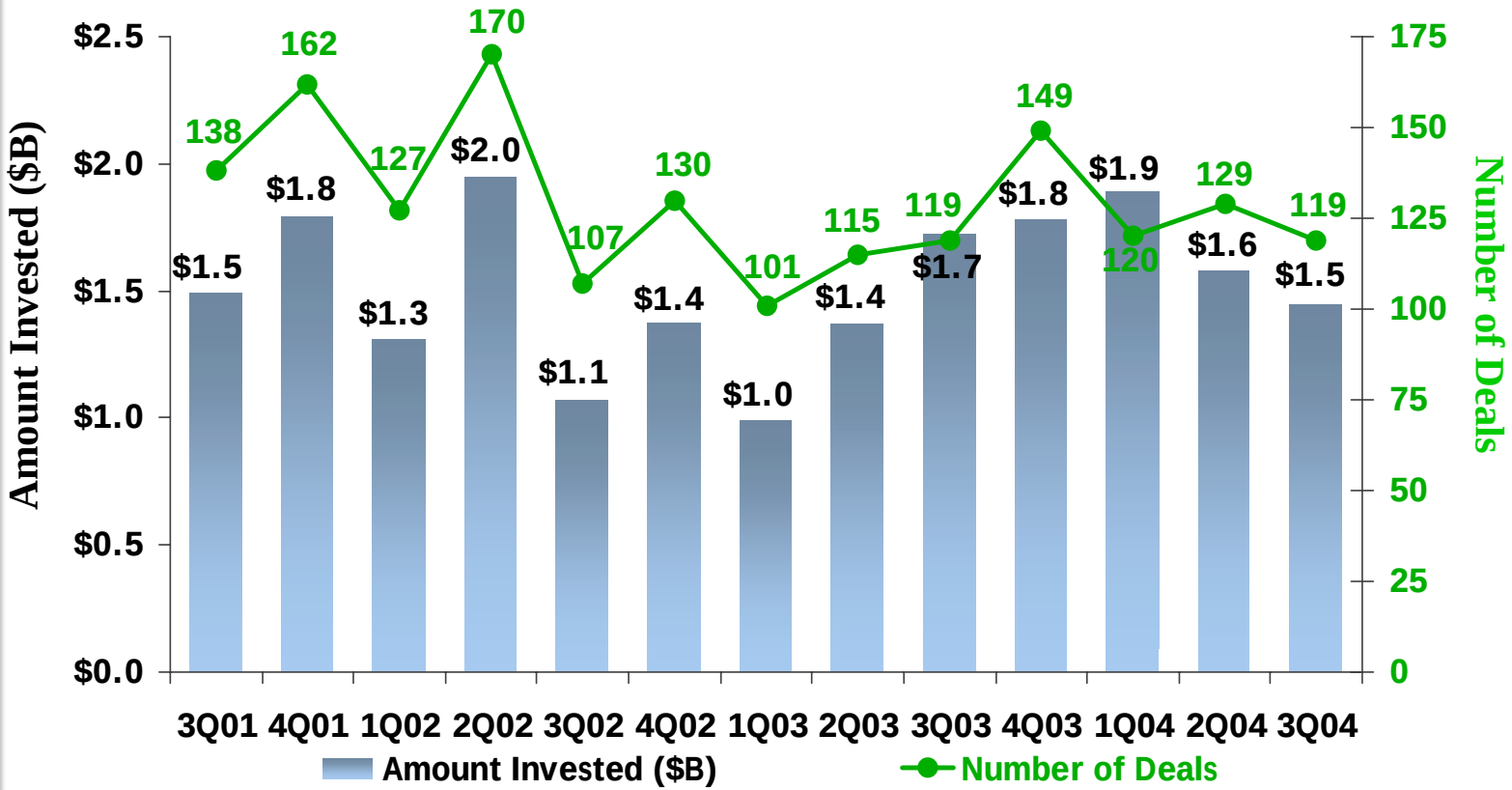
- Follow the money
- How do you find out what is **Hot**?
- Current **Hot** technology areas
- **Hot** technologies “On the Horizon”
- Betting on the winners
- Critical success factors
- Executive summary presentation



2005 Financial Climate for Innovation

- Review of the Venture Capital markets
- Medical device mergers and acquisitions
- How to find what is **Hot**
- Compelling technology sells

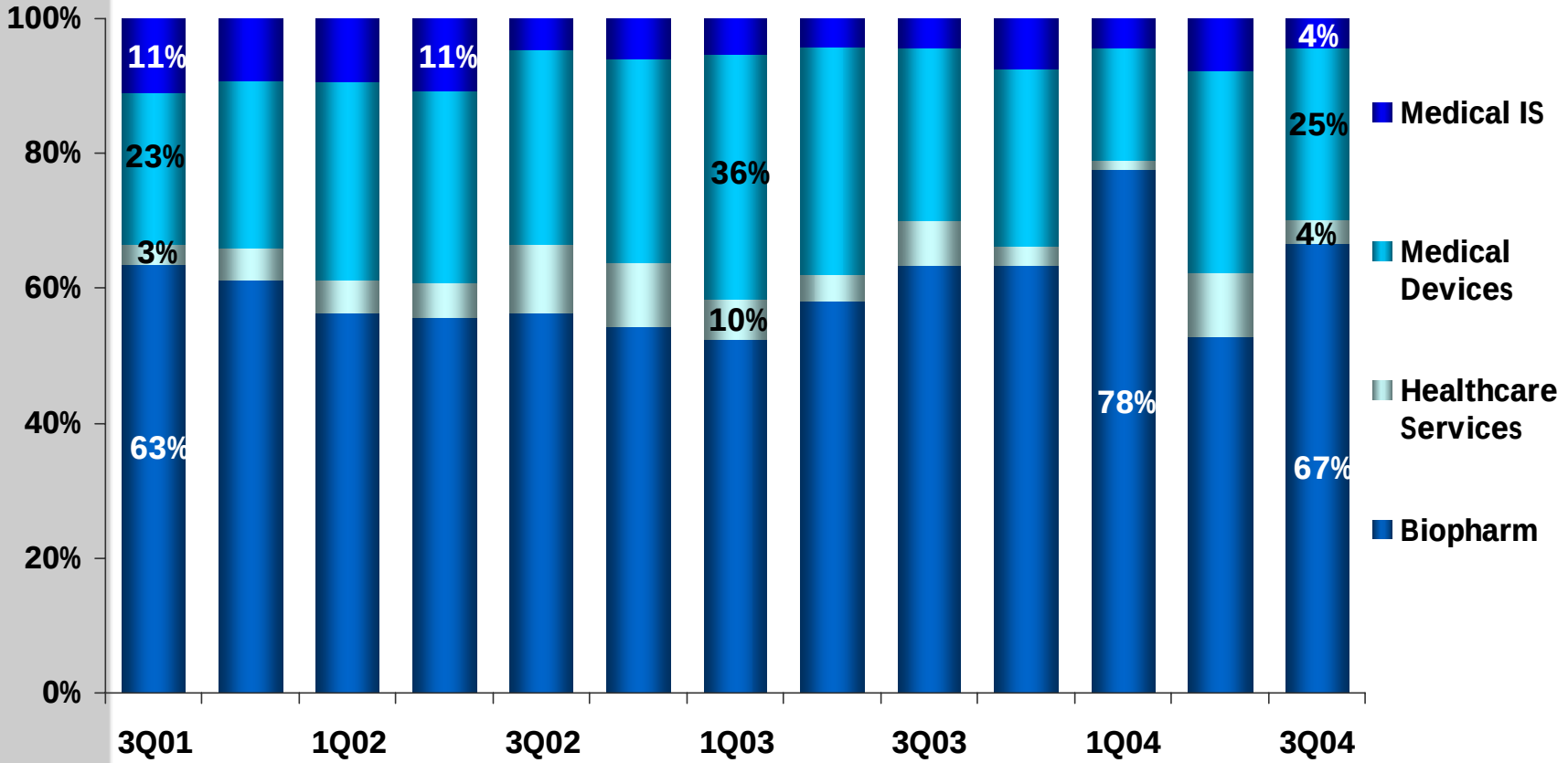
US Investments in Healthcare Companies



Source: VentureOne/Ernst &Young

Devices and Biopharm Dominate HC Investment

Healthcare Investment Allocation by Sector

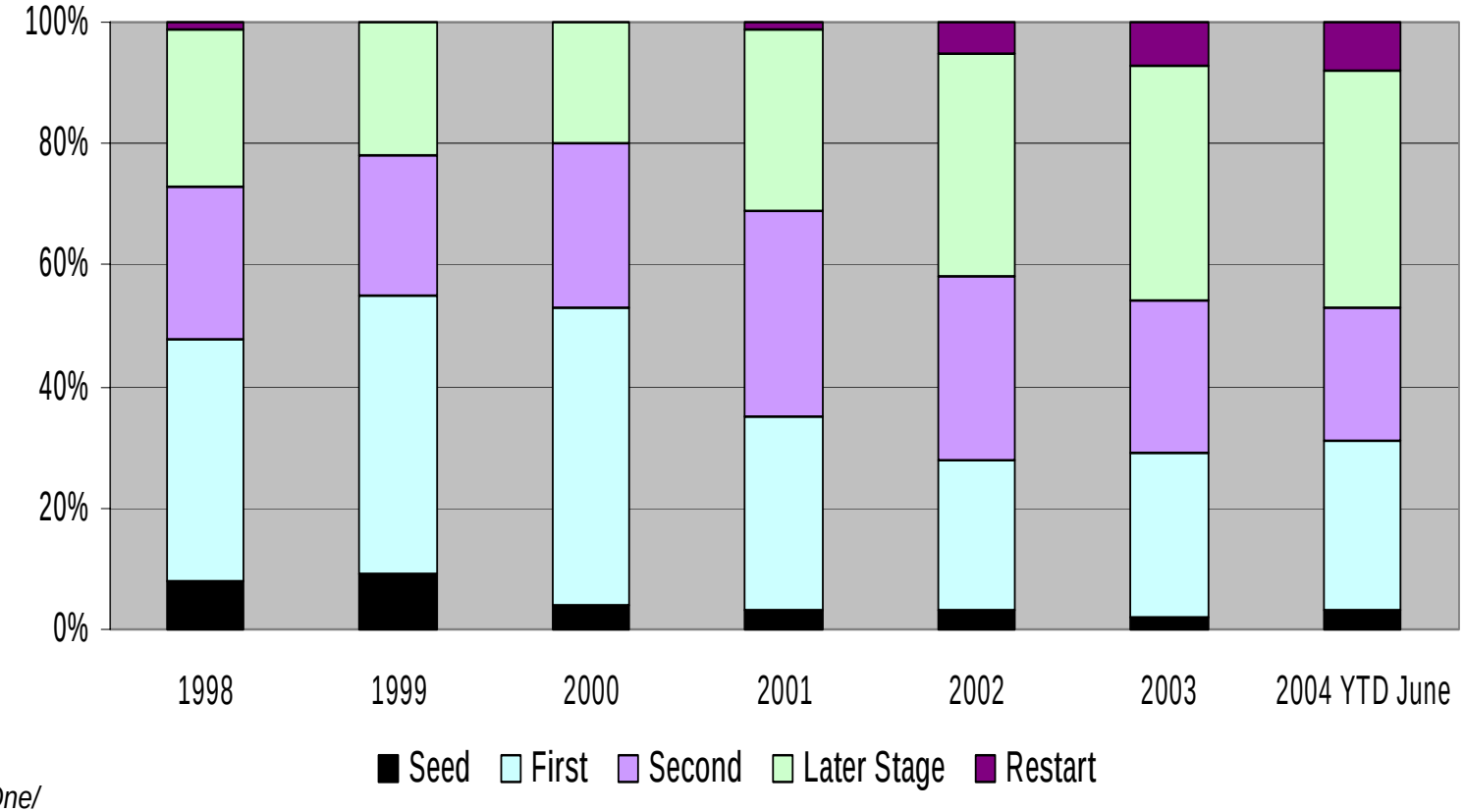


Source: VentureOne/Ernst &Young

Venture Capital Stage of Investment

1998-2Q 2004

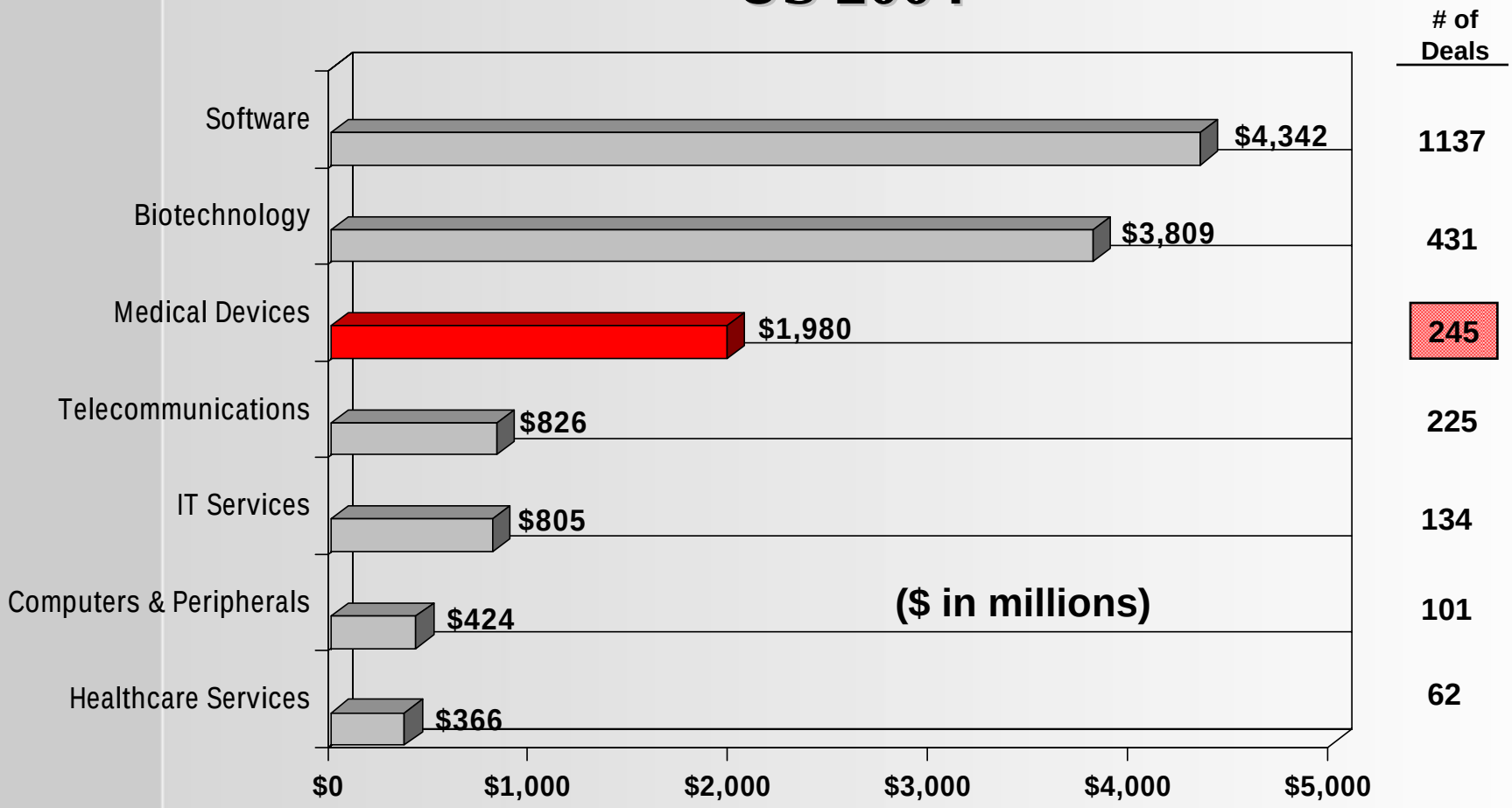
- 2003 - 2004 Later stage financing accounted for ~ 40.0% deals



Source: VentureOne/
Houlihan, Lokey, Howard & Zukin

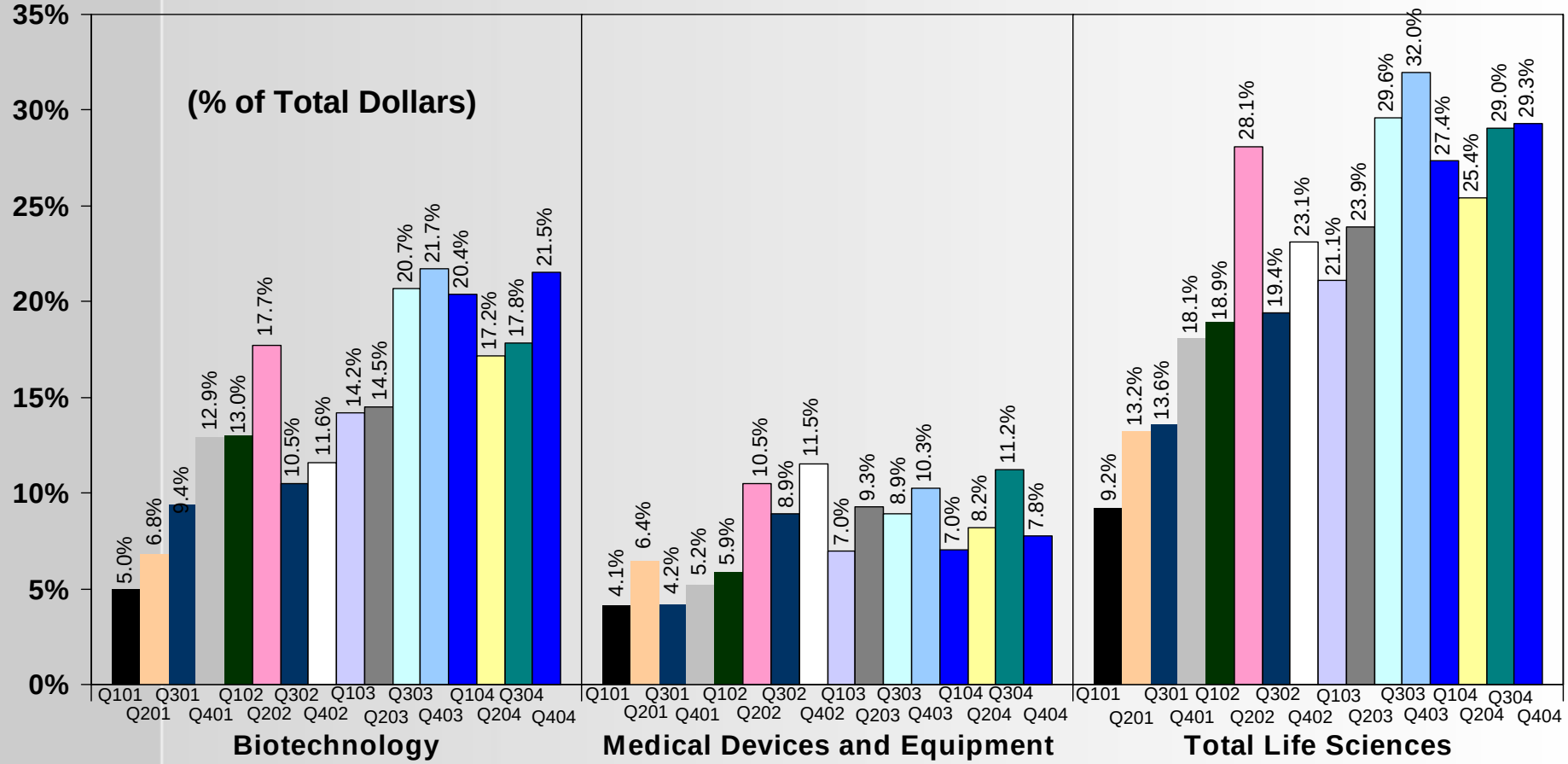
Top VC Investments by Industry

US 2004



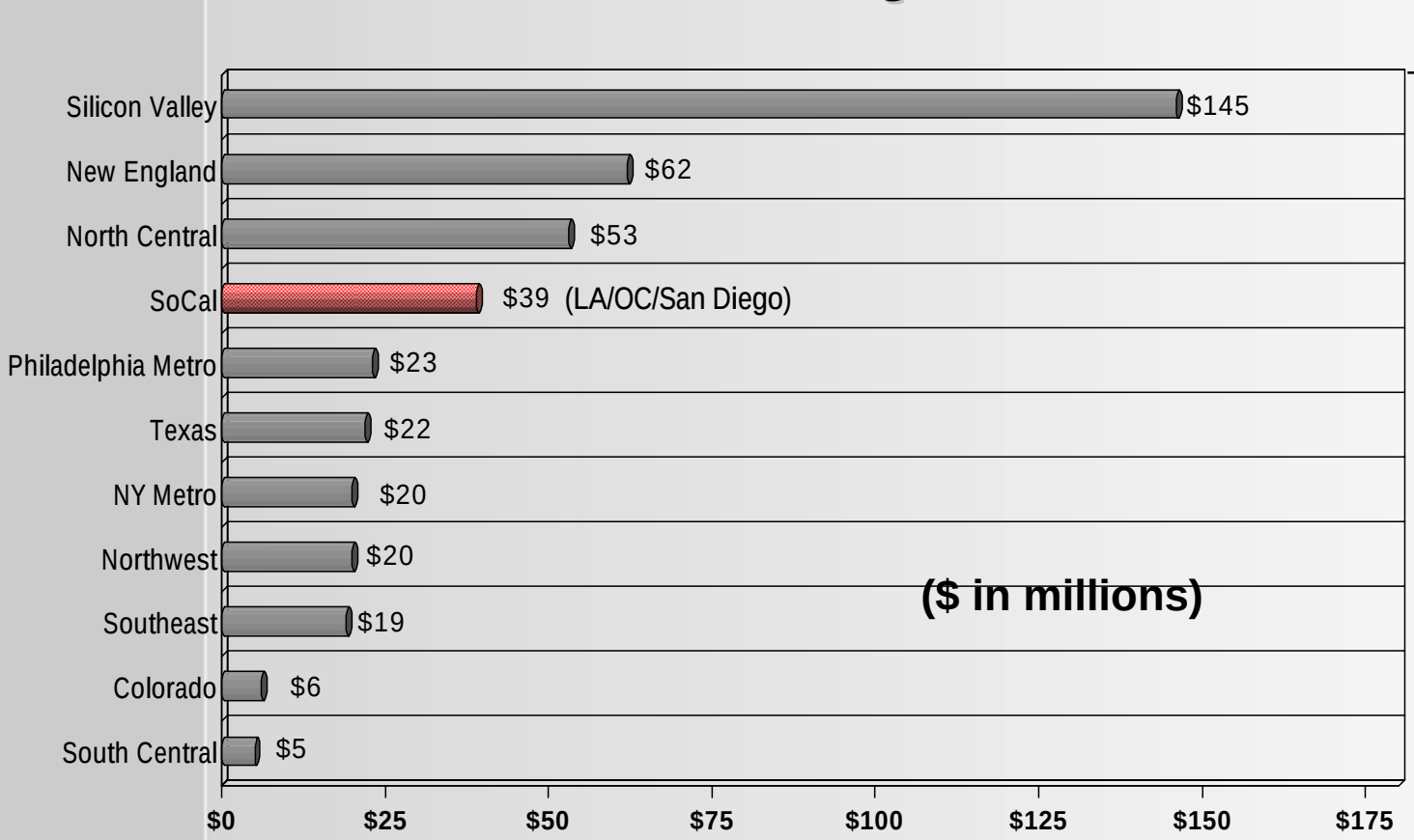
Life Science Investments

2001 – 2004 Percent of Total US Investments



$416M Medical Device VC Funding

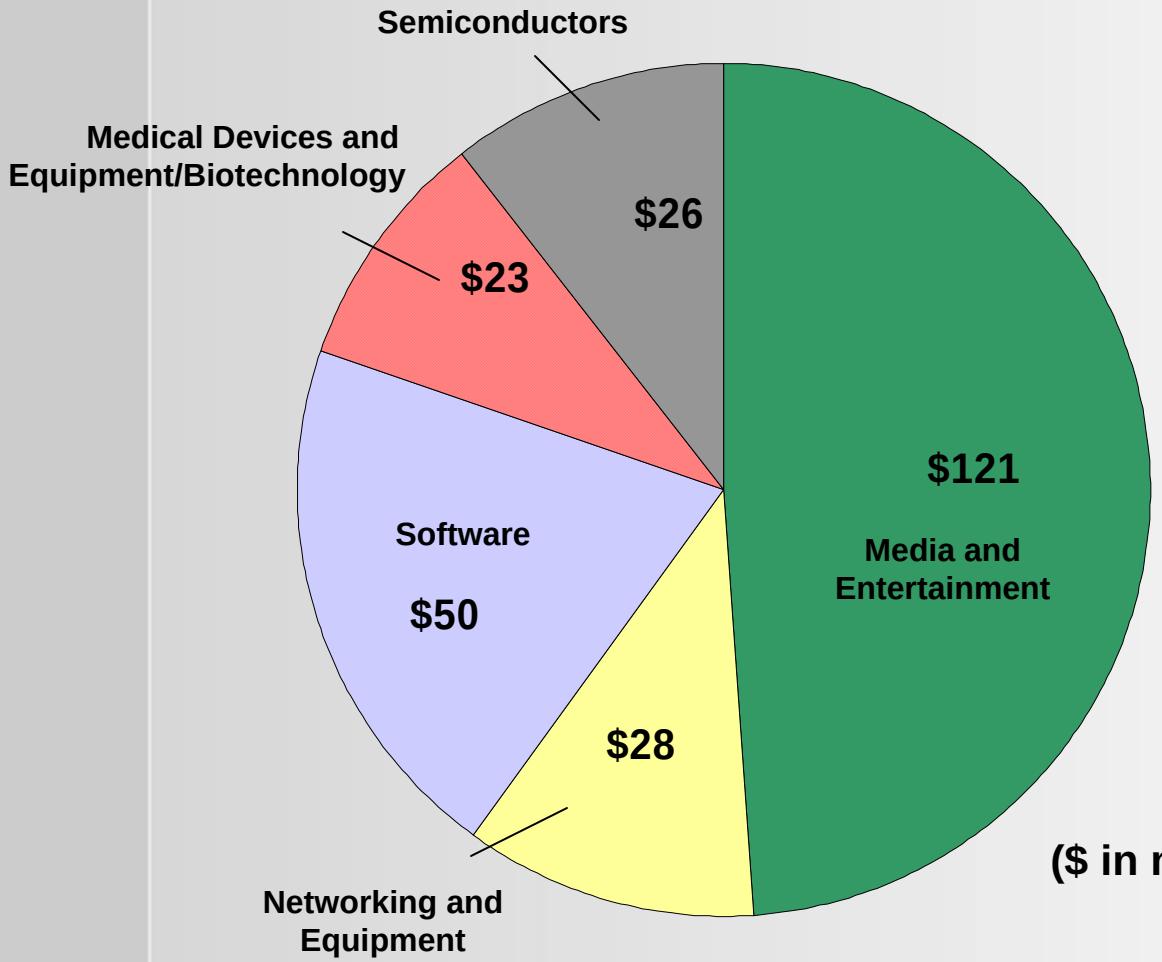
US Q4 2004



	# of Deals	% of Deals Q4 '04
Silicon Valley	18	35.0%
New England	10	14.9%
North Central	4	12.8%
SoCal	5	9.5%
Philadelphia Metro	5	5.5%
Texas	4	5.2%
NY Metro	2	4.7%
Northwest	3	4.9%
Southeast	7	4.7%
Colorado	1	1.4%
South Central	1	1.2%

Top VC Investments by Industry

LA/Orange County Q4 2004

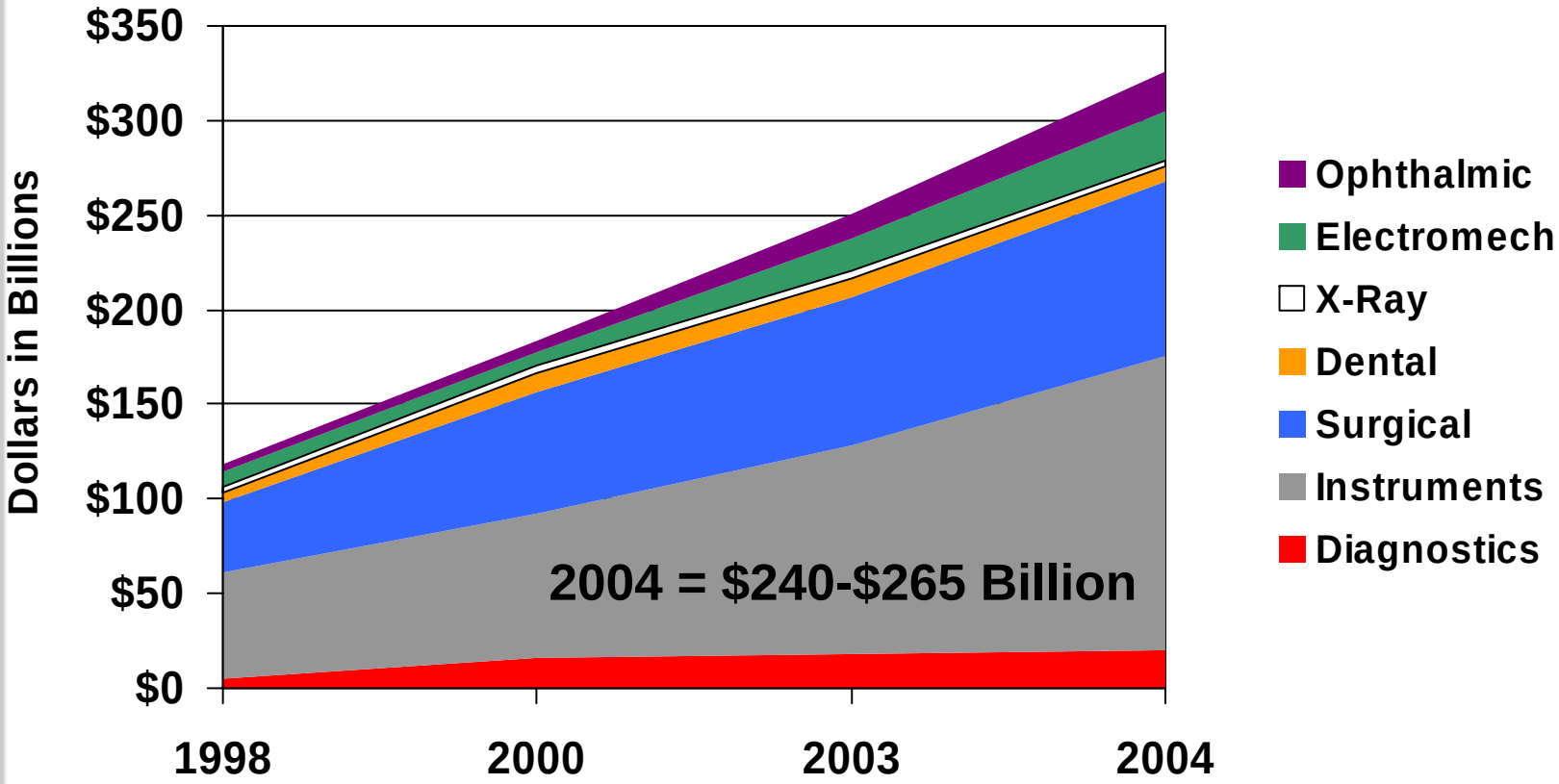


Industry	# of Deals
Software	13
Networking and Equipment	5
Medical Devices and Equipment/Biotechnology	4
Semiconductors	4
Media and Entertainment	3

($ in millions)

Annual US Medical Device Sales

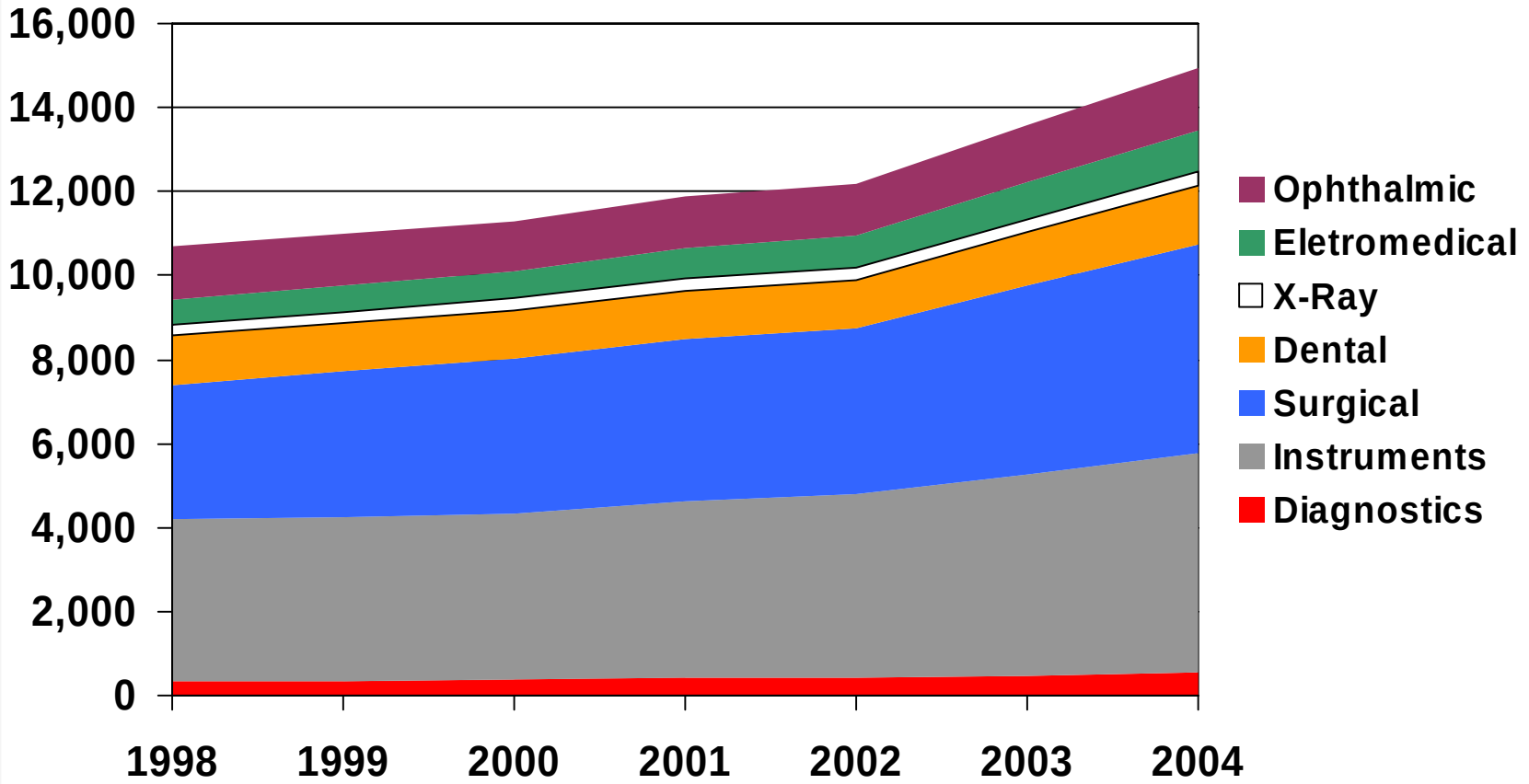
Sales Volume Growth 1998 – 2004



Source: Dun & Bradstreet Medical Device Firm Data
Note: No Economic Adjustment to Dollar Value

Medical Device Industry Growth

Number of Manufacturers by Year



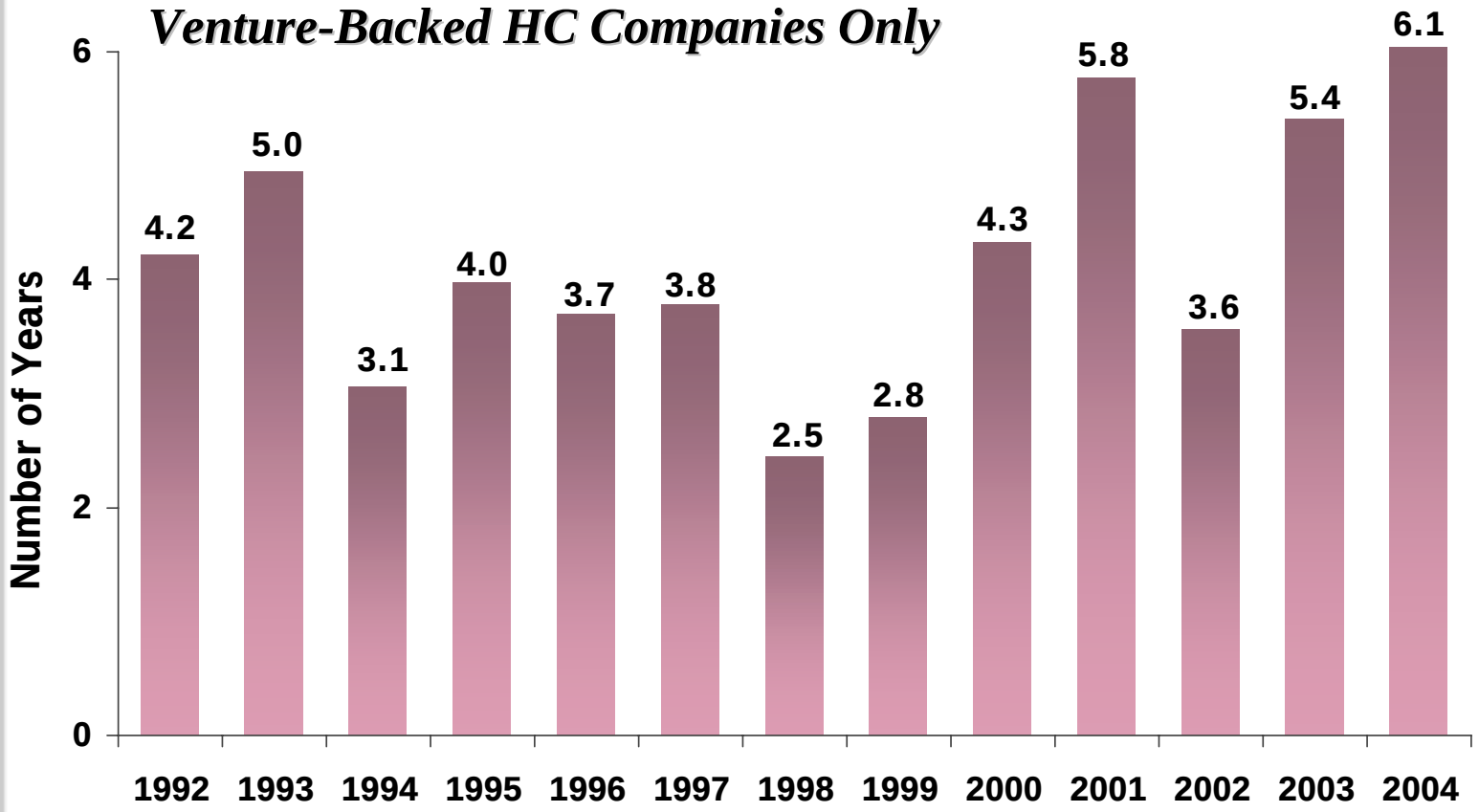
Source: Dun & Bradstreet Medical Device Firm Data

Medical Device Exit Strategies

- Merger/Acquisition by one of the shrinking number of global corporate entities
- Equity investment
- Initial Public Offering (IPO) in US or Foreign public markets
- Licensing of intellectual property for the royalty stream at various stages of development

Time to IPO Increases in 2004

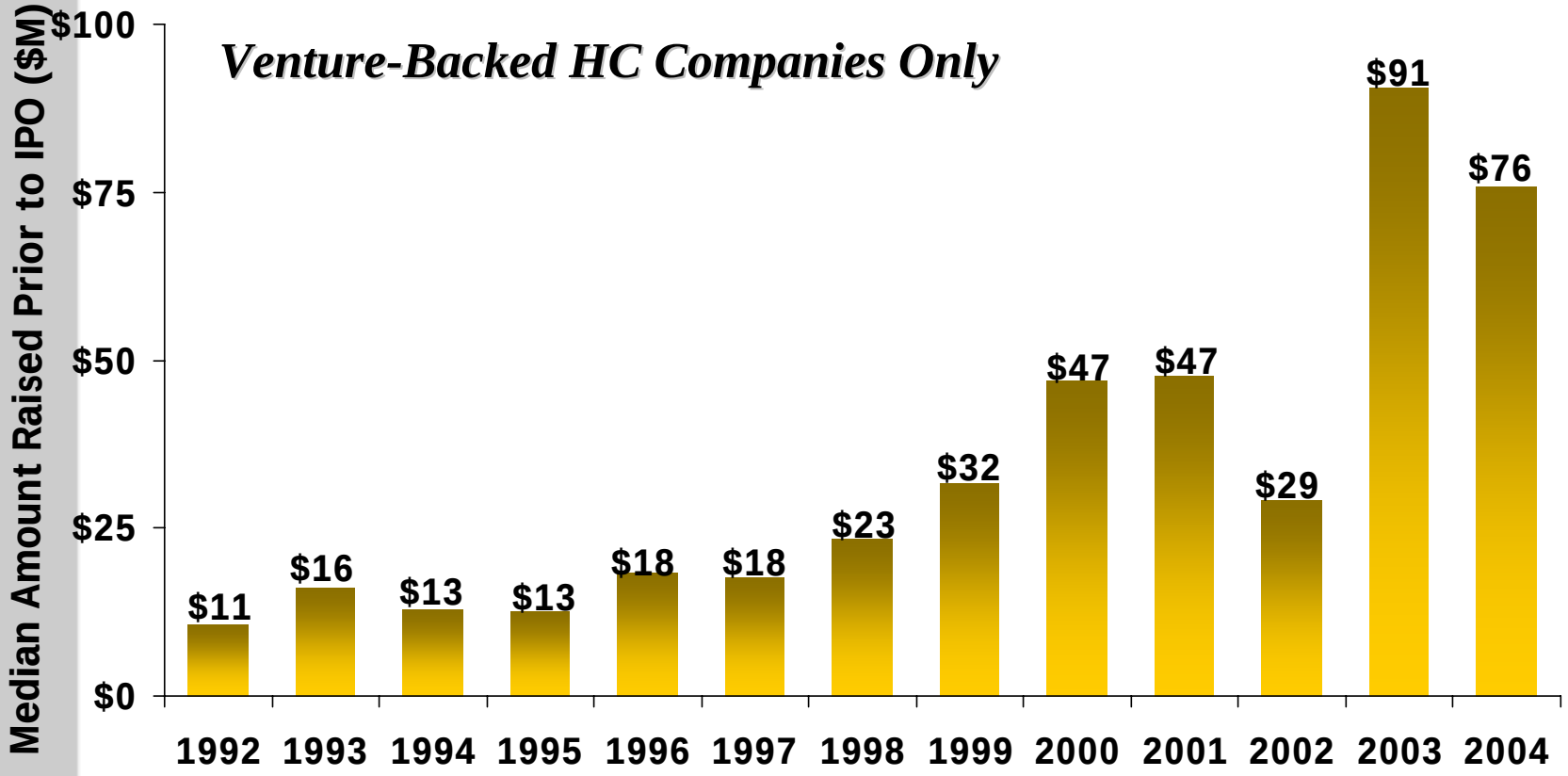
Median Time From Initial Equity Funding to IPO



Source: VentureOne/Ernst &Young

Companies Raise More Prior To Going Public

Median Amount Raised Prior to IPO

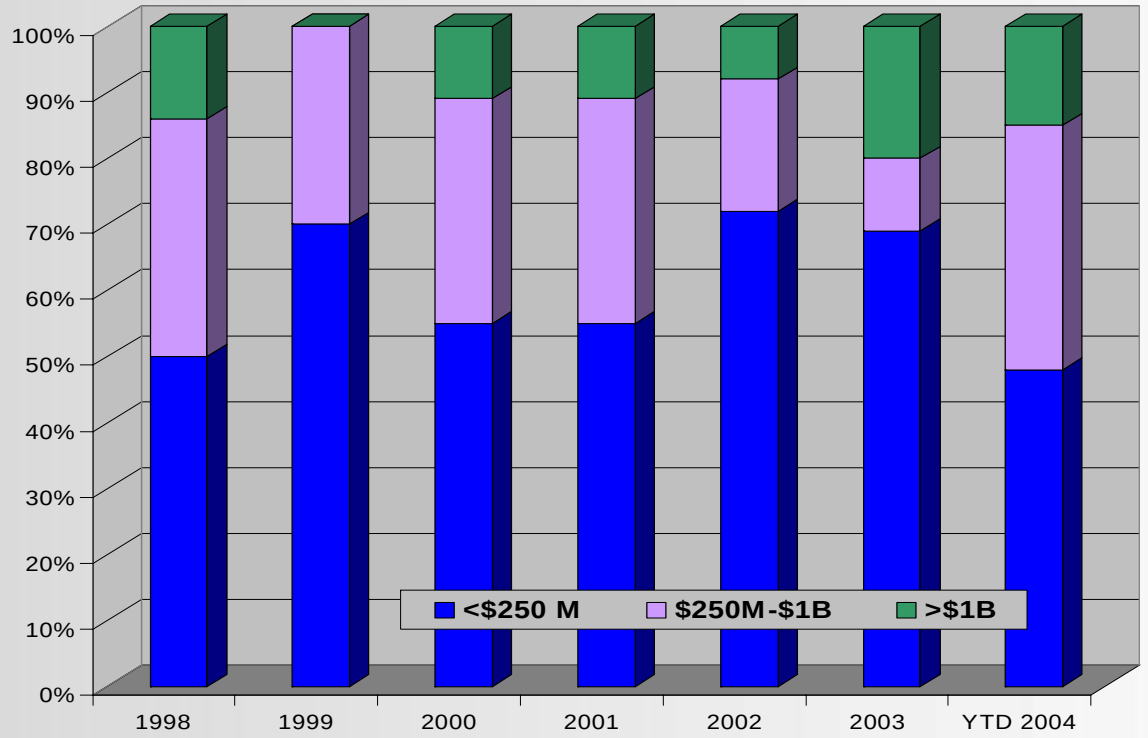


Source: VentureOne/Ernst &Young

Device Mergers and Acquisitions

1998 - 2004

- Several large deals drove transaction volume up in 2003, while 2004 M&A transactions have been, on average, less than half the 2003 levels.
- Smaller transactions tend to dominate the MedTech M&A market with transactions under $250 million representing 60-70% of M&A deal activity.

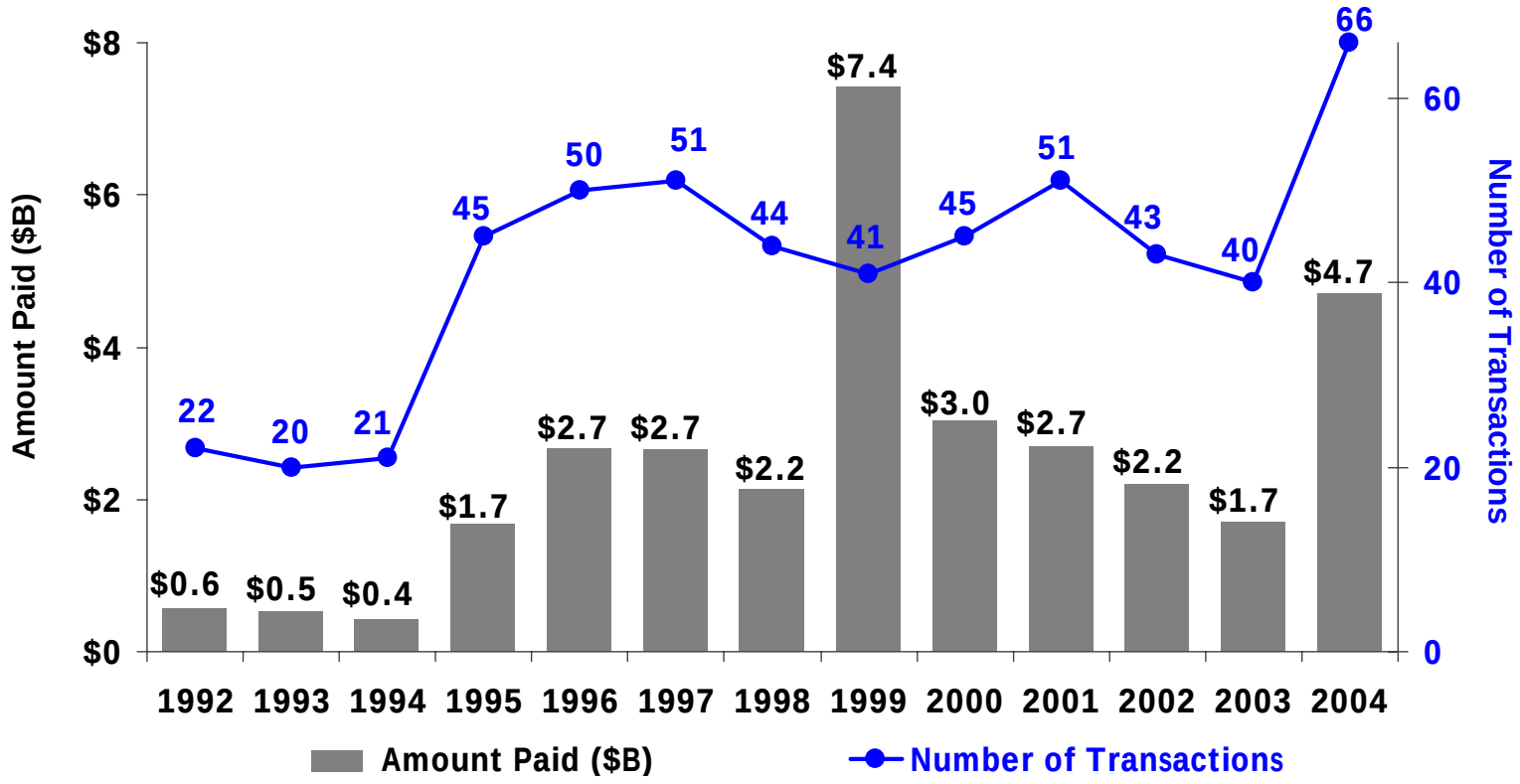


	1998	1999	2000	2001	2002	2003	Q1-Q2 2004
Average Deal Size	$682	$243	$526	$454	$282	$782	$431

Source:
Securities Data Corporation/
Houlihan Lokey Howard &
Zukin

2004 Record Year for Healthcare M&A

Transactions and Amount Paid in Healthcare M&As

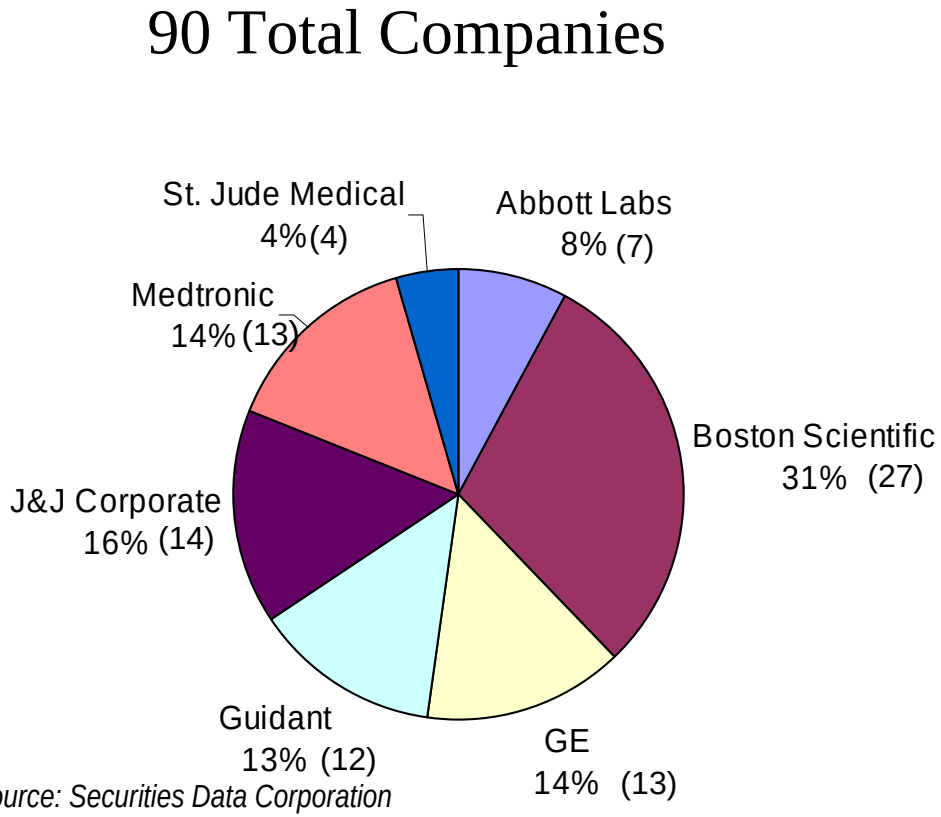


Source: DowJones Venture Source

2000 - 2004 Device Investments/M&A

Top 7 Device Conglomerates Invested in 90 Companies

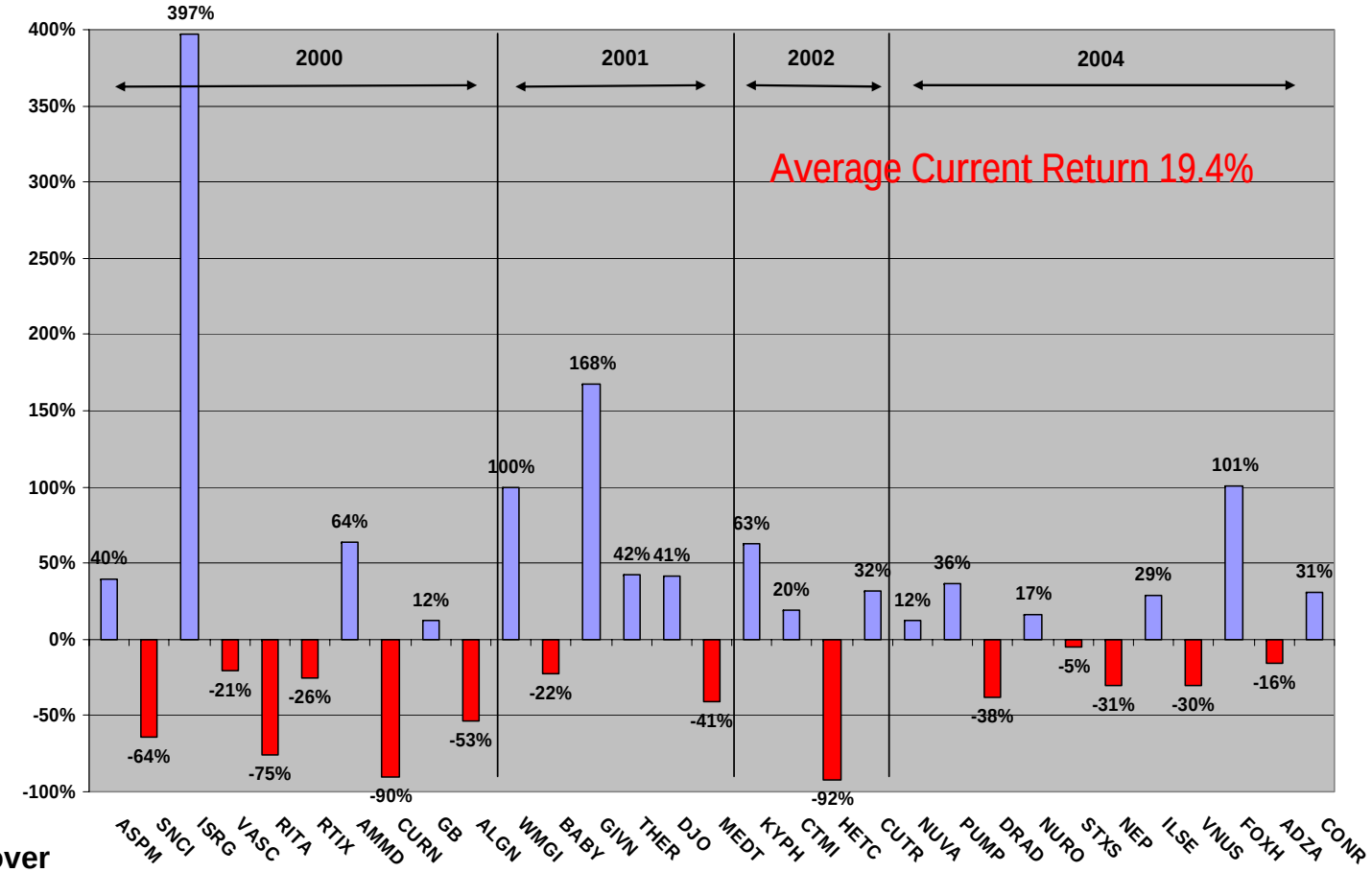
- Since 2000, large MedTech corporations have been more aggressive at providing “growth” financing to early stage companies.
- These investments are often staged and may also carry a right of first refusal to acquire the “target”.
- Boston Scientific has been the most prolific with 27 acquisitions or strategic investments.



Source: Securities Data Corporation
Houlihan, Lokey, Howard and Zukin

Medical Device IPO Stock Performance

2000 – 2004 (As of March 22, 2005)



Concept:
D. Cassak: Windhover

www.strategyinc.net

April 2004 Abbott acquired TheraSense
June 2004 UTI Corp. acquired Medsource Technologies

How To Find Current Hot Technologies

- Identifying today's hot technology means monitoring markets for funding, Merger/Acquisitions and Strategic Alliances
- An investment by one of the leading 20 Medical Device VCs into an area (Rotator cuff, Varicose vein treatment, Total In-ear hearing aids) sends the other VC's hunting
- Subscribe to Medtech Insight, StartUp, InVivo, Red Herring
- OnLine: Private Equity Week, VentureOne, Obtain Analyst reports for Merrill Lynch, Piper Jaffray
- Review the Annual Tech Transfer Summary Report available from Association of University Managers (AUTM)

What is Driving Today's Medical Device Innovation

- Aging demographics creating a demand for technology that diagnoses, treats and sustains diseases of the elderly
- Increased awareness and expectations for medical care from patients driven by access to information through the internet
- Advances in technology (wireless communication, sensing technology, robotics, nanotechnology, increased computing power, advanced biomaterials, recombinant genetics, combination products, lab on a chip, microelectromechanical systems (MEMS))
- Overwhelming cost containment pressures in every aspect of Healthcare means new technology receives tremendous cost benefits analysis through committee-based product evaluation
- Increased availability of investment capital (VC, Angel, Corporate Development, Institutional) post Dotcom bust

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
- Obesity: Bariatric surgery
- Women's Health: Cosmetic surgery, Fibroid, Endometriosis, Incontinence, Breast cancer therapeutics
- Neuromodulation: Pain management, Epilepsy, Mobility
- Ophthalmology: Glaucoma, Macular degeneration

Hot Technologies “On the Horizon”

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

Betting On the Winners

- Selection of Medical Device Technology destined to succeed is based on 12 criteria
- Each driver contributes to the ability to achieve commercial success, weighted by their effect on predictable outcomes
- Evaluation requires a robust analysis based on historic peer reviewed clinical data, market analysis of proven factors and input of industry leaders.
- Projections of tomorrow's technology based mostly on today's market numbers will not deliver financial accuracy tomorrow. Need to project adoption at market launch based on the dynamics that will be present at that time.

Market Drivers for Commercial Success (1 – 4)

Market Driver	Summary	Assessment Criteria
Clinical Efficacy	Demonstrated or potential effectiveness of treatment	Demonstrated Animal trial results Demonstrated Human trial results Theoretical mechanisms
Market Opportunity	Patients refractory to current treatments	Disease Incidence and Prevalence Rate at which patients seek treatment Number of refractory patients
Product Development Efforts/Risks	Product development efforts required to produce a product for an identified application	Incremental Hardware/software development requirements Resources required: In-house expertise
Competitive Advantage	Advantages of the technology applied to the specific clinical indication	Advantages of technology over existing/emerging therapies/technologies Ability to relieve symptoms of indication

Market Drivers for Commercial Success (5 – 8)

Market Driver	Summary	Assessment Criteria
Regulatory Effort/Risk	Effort and risk associated with achieving regulatory approval	510 (k) - PMA review/ Off-label use Clinical trial requirements Lifesaving or Quality of Life application
Patient Motivation/Acceptance	Willingness of the patient to adopt the technology	Acceptance of surgical procedure Ease of use of system Patient interest in technology to address clinical need/patient motivation Intensity/duration of required patient education
Physician/Healthcare Professional Adoption	Willingness of the physician to adopt the technology with focus on ease of use	Accessibility of clinical access for treatment Training required Procedure complexity
Reimbursement	Current reimbursement level and/or reimbursement potential	Current reimbursement coverage and/or reimbursement potential technology anticipated to be available for a specific indication.

Market Drivers for Commercial Success (9 – 12)

Market Driver	Summary	Assessment Criteria
Competition	Status of competitive environment	Direct competitors/ efficacy of their solution Emerging competitors/products Current treatment status
Strategic Fit	Strategic fit of each indication as it compares to product portfolio	Opportunity for synergy with current products and distribution channels.
Intellectual Property	Freedom to operate Strong defensible position	Breadth and strength of patent protection Competitive patient strength
Impact and Cost	Impact in dollars of cost of indication in US	Direct treatment costs Productivity loss – dollar value or lost work days

Venture Capital Selection Criteria

- Quality of the Product/Idea
- Quality of the Management Team
- Competition/Barriers to Entry
- Potential for High Return

Convey Critical Success Factors

- A tangible, overwhelming, and measurable value proposition for customers
- Strong, “unfair” competitive advantages and barriers, preferably technology-based
- A large, expanding, emerging marketing with revenues >$50M and market capitalization >$400M
- A clearly defined reimbursement strategy for the physician and the institution
- A solid and committed management team
- Ability to achieve investment exit in 4 – 7 year timeline

Compelling Technology Sells

- Objective: Establish investor interest to seek additional information
- Anticipate questions: Market, clinical acceptance, intellectual property, regulatory, reimbursement and management issues.
- Address anticipated concerns with well conceived strategy and defined value proposition.
- Answer the question: Why is this concept the one out of thousands that is destined to succeed?

What To Include In Your Presentation

- Product –
  - Acme Gadget Company has developed a recovery predictor instrument, the size and shape of a standard flashlight that costs less than $100 and can be operated by a high school graduate. When shined into the eyes of a patient, an instant readout predicts not only the 99.8% probability of recovery in 48 hours, but also the life expectancy of the patient within 1 yr.
- Target Market –
  - More than 98 million people in the US are admitted to emergency rooms annually with stage three trauma, and 84% have extensive and costly life saving measures to save lives. Only 88% of the critically ill patients survive. The remaining 12% (9.9 million) die within 48 hours, after expensive and painful treatment. $396 billion could be saved if these 12% of patients could be determined instantly.

Excellent Results Managed by a Proven Management Team

- Clinical Results –
  - Multicenter clinical studies on over 5000 patients at five institutions have confirmed the accuracy of the recovery predictor to be 99.8% and reliability to be 99.5% and were recently published in the New England Journal of Medicine. Patients included men and woman between the ages of 8 and 80 who were admitted to the ER for any diagnosis. A preliminary trial, performed on 90 race horses showed equally promising results, and further work is in progress.
- Management Team –
  - CEO, Donald Trump, renown for his decisive management, working with VP of R&D MC Hammer, and Medical Director Dr. Dre, created the recovery predictor to select patients who will profitably use hospital resources.

Recovery Predictor FDA Approved and Reimbursed

Regulatory

- The 510(k) approval has been received, and the recovery predictor has been CE marked allowing full global launch once resources for a global sales team is available.

Reimbursement

- The recovery predictor is projected to receive a CPT code for physician reimbursement January 1, 2006. Predicted levels of reimbursement are $117 based on meetings with AMA and Resource Utilization Committee and recommendations of the American Association of Emergency Room Physicians for comparable procedures.

$4.1B Revenue and Rock Solid Intellectual Property

Intellectual Property

- 14 patents have been issued to our company, Acme Gadget, in the US using the firm of Hogan and Hartson in Washington DC. An additional 9 patents are pending. The broad spectrum patents have overlapping claims and a verbal opinion of freedom to operate. European patents have also been issued in 6 countries.

Revenue

- Using a projected average sales price of $500 and COGS of $100, five year revenue predictions yield $4.1B, and an 80% gross margin using a 10% adoption rate just for the emergency room. Experienced sources at the Pentagon project that the market could conceivably double with military use alone. Additional applications have been identified, and will be fully studied with investment capital.

Thank You

- Nancy Patterson

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