Biomedical Business: Current Trends, Product Challenges and Future Outlook

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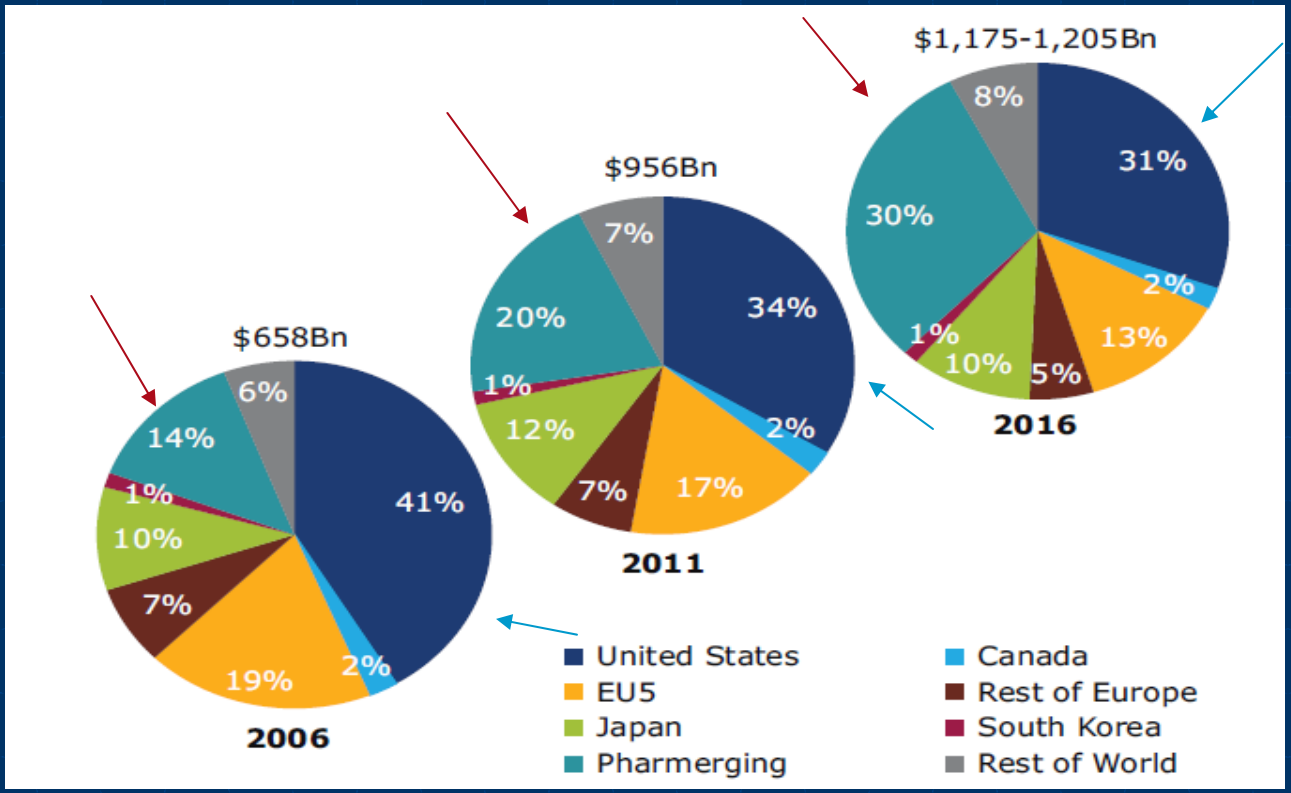
Topics to be Covered In Presentation

- Challenges, trends and events driving the paradigm shifts in:
  - Financing/funding
  - R&D development
  - Pricing and reimbursement
  - Regulatory
- Outlook for future

Stronger BioPharma Product Growth Rates Outside U.S. and Europe



Data includes IMS Total Unaudited and Audited Global Pharmaceutical Market By Region0

IMS worldwide forecast--$1.2 trillion in 2016 with brands valued at $645 billion and generics, $430 billion. Driven by growth in pharmerging volume and higher prices in developed markets.

U.S. Public Biotech Companies Grow But Private Stagnate

	2012	2011	% change
Public company data			
Revenues	20,385	18,951	8%
R&D expense	4,902	4,940	-1%
Net income (loss)	236	(19)	-1,324%
Market capitalization	79,829	71,497	12%
Number of employees	51,740	47,700	8%
Financings			
Capital raised by public companies	2,882	1,530	88%
Number of IPOs	3	8	-63%
Capital raised by private companies	1,243	1,332	-7%
Number of companies			
Public companies	165	169	-2%
Private companies	1,799	1,847	-3%
Public and private companies	1,964	2,016	-3%

Source: Ernst and Young and company financial statement data, Beyond Borders: Global Biotechnology Report 2013, p. 30

U.S. Medtech Numbers

- Estimated U.S. Medical Device market value - $94.9 billion in 2010* and worldwide, $331 billion in 2012 with latter slowing growth rate of 3% vs. 2011
- Over 50% of the leading global medical device companies based in U.S
- Industry troubled by new device tax and lack of seed funding

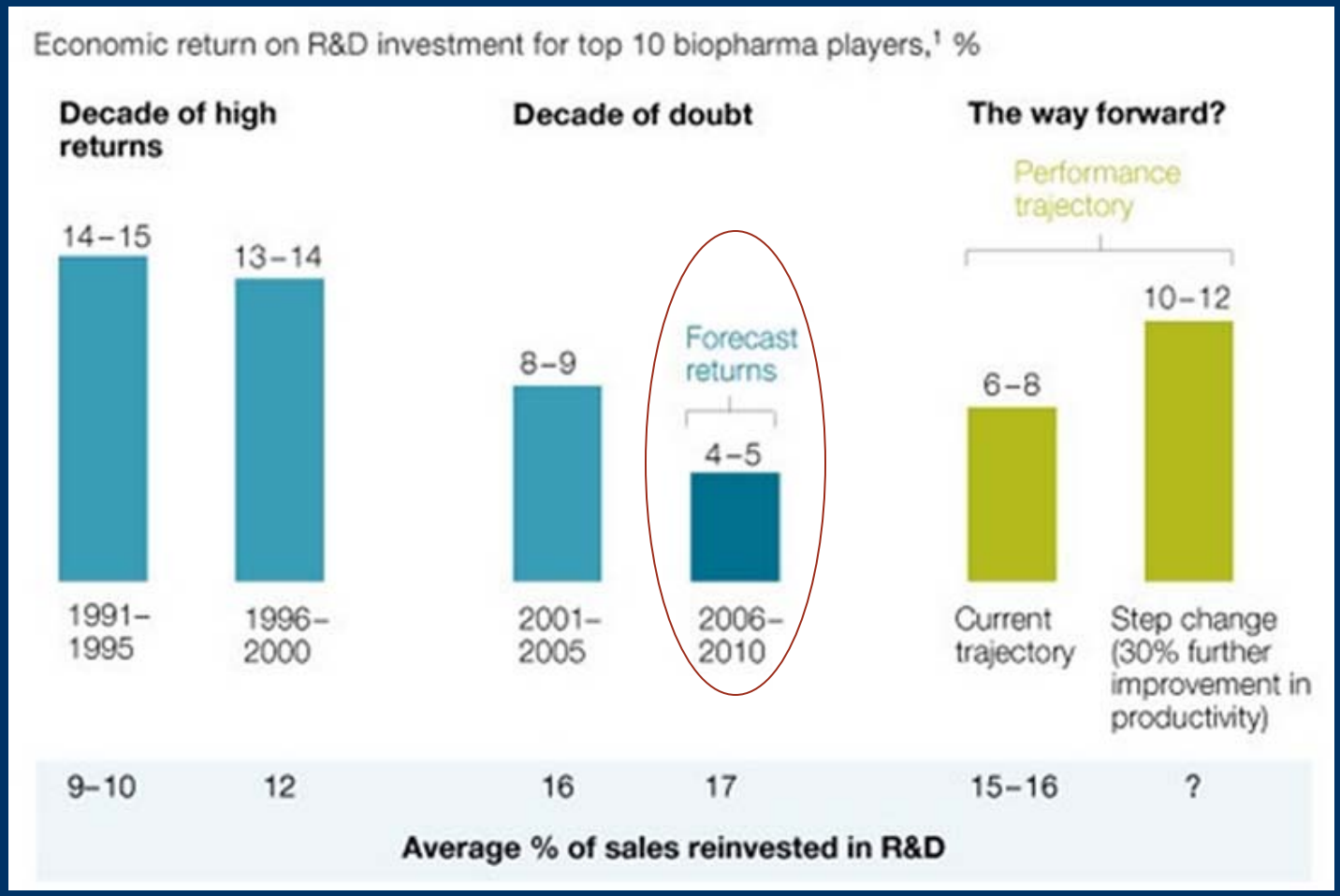
Source: *Medical Device Numbers 101, Published in *MDDI Magazine* , 11/29/2010; balance from "The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad," published on MDDI online on 7/17/2012

Biomedical Industry Trends

Moderating U.S. Drug Sales Trends

- Patent cliff from roughly 2008 to 2012 severely impacted $ revenues of pharma; loss of $250 bn. until 2015
- Continuing impact of growing generic drug usage at 84% of prescriptions in 2012
- Fewer and more narrowly indicated expensive unique meds reaching smaller # of patients as biologics grow in usage and focus moves to rare diseases
- Closer scrutiny for safety by regulatory bodies
- Rapidly changing payer practices on pricing

Pharma's R&D ROI Looks Like a Gambler's Game

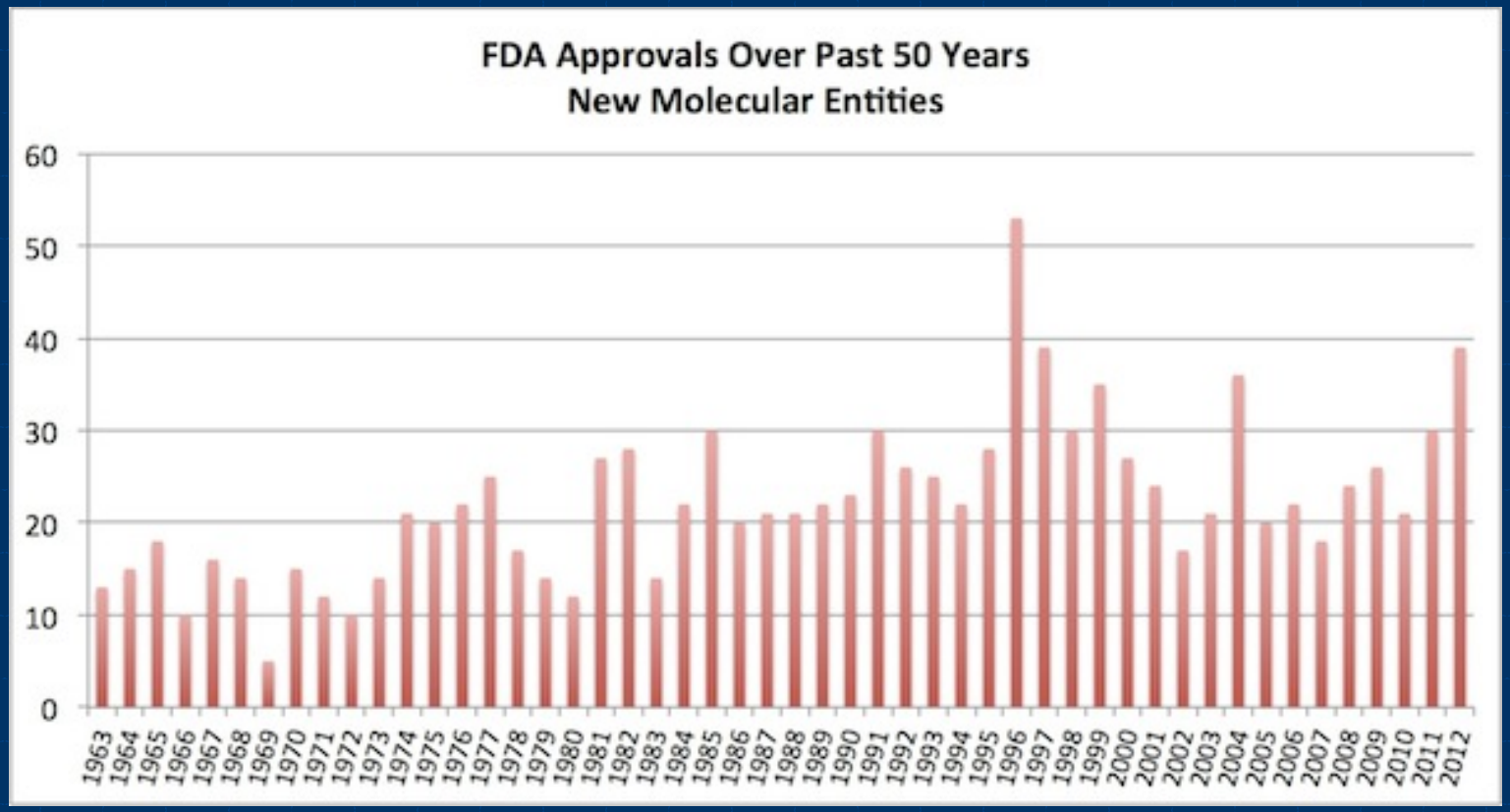


Source: "Restoring Value to Biopharmaceutical R&D," Mckinsey and Company, August 2012

Current Big Pharma Solution—Embrace Biotech Products and Specialty Focus

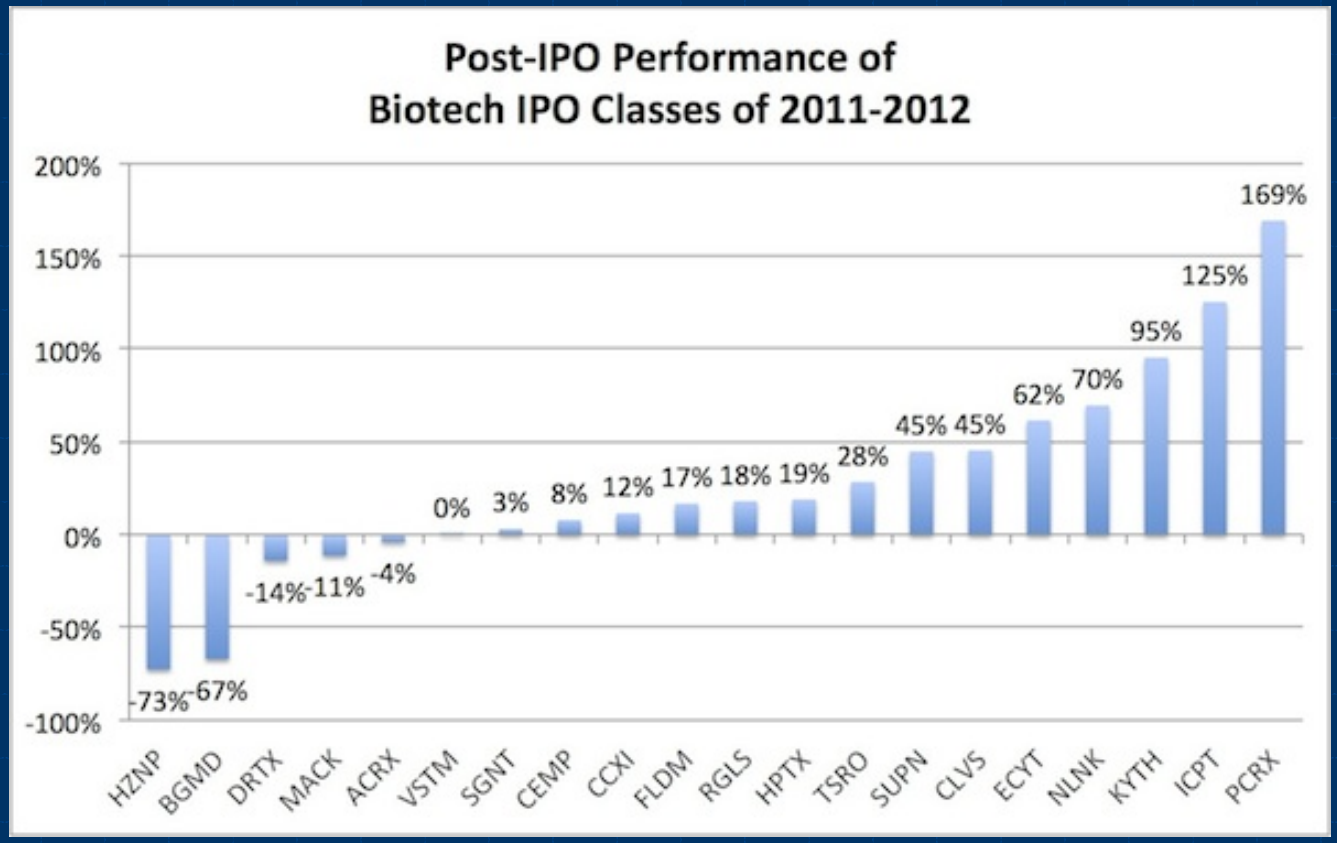
- Pipelines moving toward specialist products, mimicking biotech success—"progressive blockbusters"
- Companies weaning off primary care blockbuster model as focus—primary care blockbusters won't disappear entirely but not sole objective of R&D as earlier
- Big Pharma looking for new source of products while they shed their too expensive in-house R&D

Good News! 2012 One of Three Best Approval Years in 50 Years



Source: Bruce Booth, Early Stage Life Science VC, "**Early Stage Biotech Showing Positive Signs of Scaling Its Wall of Worry,"** www.Forbes.com, Jan. 15, 2013

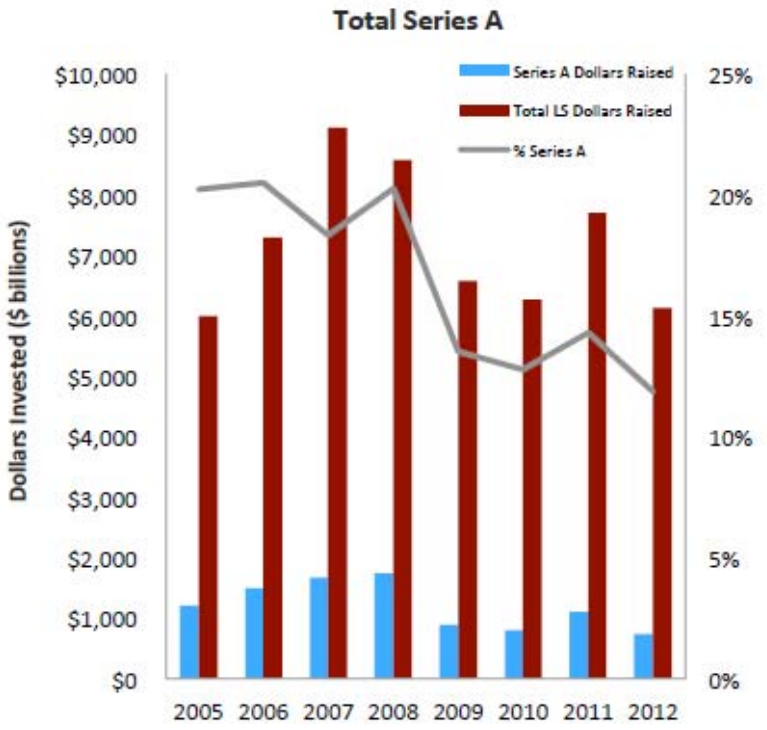
And Post Biotech IPO Performance Not So Bad!

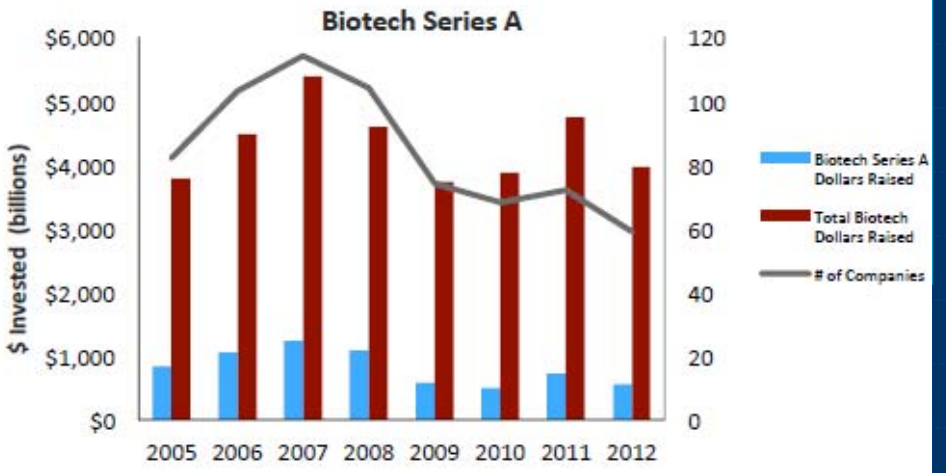


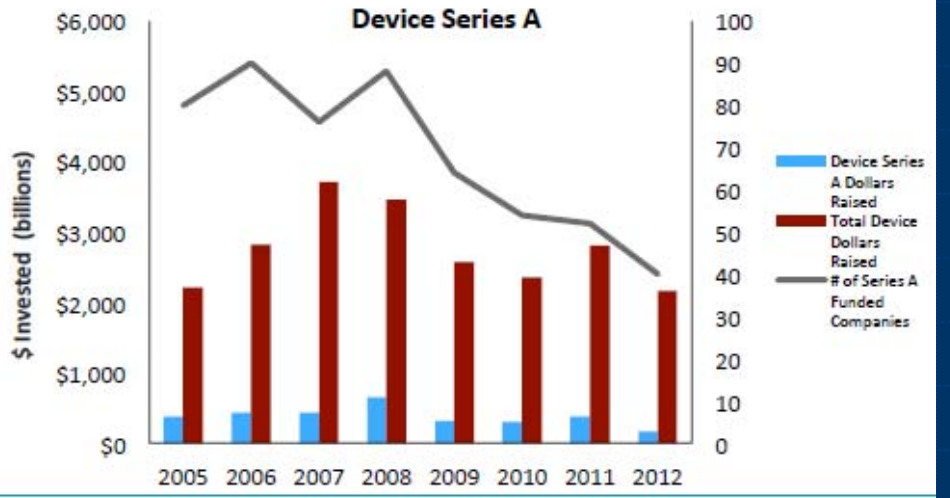
Source: Bruce Booth, Early Stage Life Science VC, "**Early Stage Biotech Showing Positive Signs of Scaling Its Wall of Worry," www.**Forbes.com, Jan. 15, 2013

Series A Decline 2005-2012

- Substantial decline in Life Science Series A activity in both Device and Biotech in 2012
- Normal average from '05-'08 was 20%







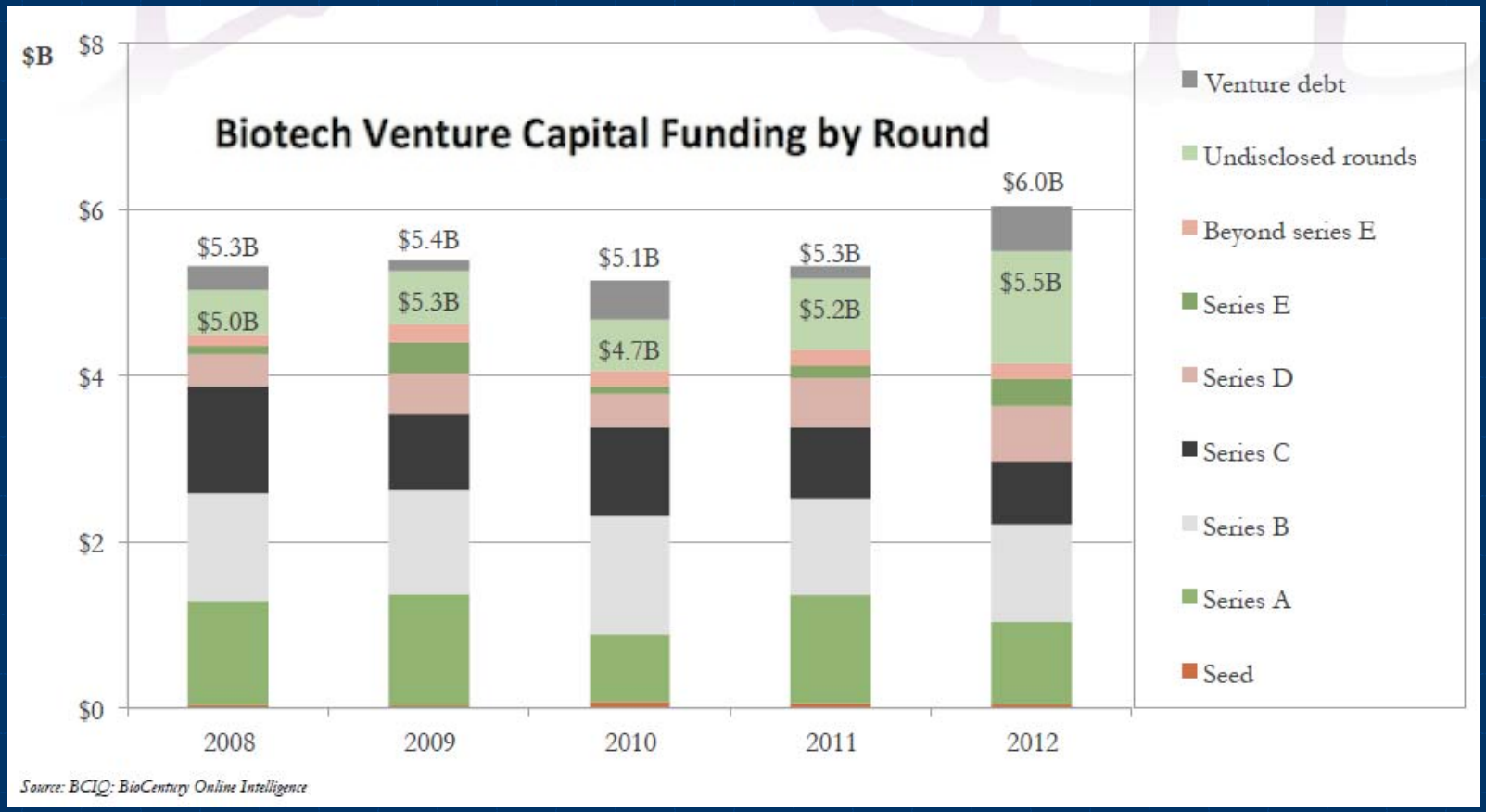
*Includes Series A companies raising at least $500,000 in equity

Source: PWC +Thomson Reuters for Total LS Dollars Raised; Venture Source + SVB Proprietary Data for Series A Dollars and Number of Companies

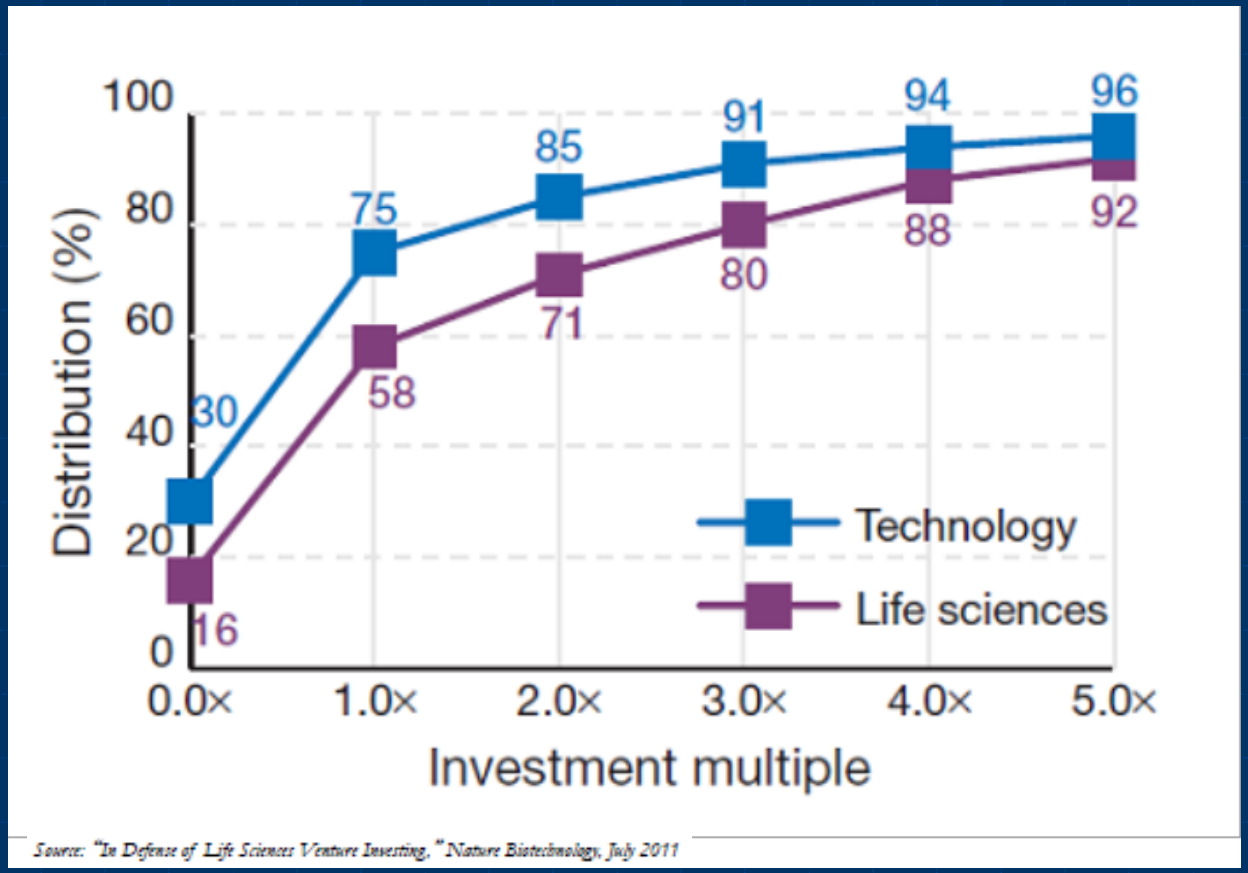
Silicon Valley Bank 5

Source: Slide from presentation by Jonathan Norris, Silicon Valley Bank, Jan. 2013

BioCentury Data Suggest Funding Drought Impact Not So Bad



Comparative Distribution of Life Science vs. Technology Returns



Source: Karen Bernstein, Ph.D., BioCentury Publications, Inc. " The Challenges of Finding and Funding Innovations and Research," Jan. 8. 2013

Life Science Product Challenges

- Achieving the product goals in face of:
  - Difficulty in establishing prices that provide sufficient profit level to shareholders yet remain affordable and reimbursable and avoid lawsuits with government
  - Ever-increasing regulatory demands and constraints from FDA, OIG, state AGs and restrictions on physician/industry relationships, especially, with sunshine laws for medtech
  - More crowded competition in specialty space and greater price resistance from payers

Outlook for Future…

FDA Working with Pharma

- FDA receptive to working to speed up drug development
  - Breakthrough drugs can get approval after Phase I
  - Supporting changing clinical trial infrastructure and other efforts
- Encouraged by Janet Woodcock's talk at Personalized Medicine Coalition conference: "We are going to have to change the way drugs are developed. Period."
- Source: http://www.medpagetoday.com/PublicHealthPolicy/ClinicalTrials/39330)

U.S. Drug Discovery Future

- Increase in pre-competitive collaborations and initiatives (10 pharma group formed TransCelerate to first work on improvement in clinical trial design and monitoring)
- More risk sharing with academic and biotech because NIH research funding has failed to grow since 2000
- Equilibrium in domestic job erosion—jobs move from Big Pharma to CROs and CMOs and geographically

Source: *The Global Use of Medicines: Outlook Through 2016," by IMS Institute for Healthcare Informatics, July 2012

Future Trends in BioPharma

- Systems biology is future—more in whelm of fundamental research and should be funded by federal government—Obama administration favors investments in science and discovery/innovation but moves toward austerity by Congress a threat
- Innovation is moving across boundaries and disciplines—people talking to each other should help
- Academics' commercial focus is uneven—some are developing, hiring staff with industry experience but not necessarily drug development focused
- Big Pharma needs to beware destroying unique skills, e.g., medicinal chemistry, pharmacology, etc.

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Future Trends in BioPharma (cont.)

- Biosimilars will not be same as small molecule generic—some erosion of branded biologics but not patent cliffs—will account for only $4-6Bn, or 2%, of the $200-210Bn* in spending on biologics by 2016
- Some overseas outsourcing but limited; routine aspects can be outsourced but more difficult work, more collaborative work can't be more efficient overseas where they have less experience. Floor below which you can't cut your internal resources
- Growth in developed markets will rebound from $3Bn to $18-20Bn as U.S.,EU5 and Japan all contribute more later in the five-year period. 2012-2016 with growth in US spending in 2014-2016 anticipated to double as result of ACA*

* IMS, "The Global Use of Medicines: Outlook Through 2016," July 2012

Cost Matters! Pricing and Reimbursement Central to Funding Startups: Case Study

- "At Memorial Sloan-Kettering Cancer, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.
- The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at $11,063 on average for a month of treatment — is more than twice as high.
- In most industries something that offers no advantage over its competitors and yet sells for twice the price would never even get on the market."

Sanofi lowered price by ½ in reaction to criticism

Source: "In Cancer Care, Cost Matters," by Peter B. Bach, Leonard B. Saltz And Robert E. Wittes, **NY Times,** Oct. 14, 2012

Health Care Is Changing: Affordable Care Act Law of Land

- Changing landscape—new doctors are employees and providers and insurers are teaming up
- Buying decision is shifting from doctors to boards, agencies and other third parties
- Insurance requirements are limiting doctor's range of discretion but less a problem for new breed of MDs
- Mandated use of electronic medical records
- Increased role of competitive bidding
- Payers and patients expect evidence-based value—real distinction in outcomes

Health Outcomes Future Indicator for Spending

- Evidence-based guidelines—clinical pathways—expected to play major role in ensuring both high quality patient care and better outcomes in future
- These guidelines are an important first step in moving away from traditional fee-for-service mechanisms that reward docs for prescribing ever more expensive products
- “Patient-driven” goal not just patient-centered any longer

Promises for Future

- Big Data as basis for new diagnostics and drugs
- Replacement of expensive laboratory tests by new technologies like smart phone apps that improve doctor/patient interaction
- Totally new structuring of clinical trials—one large trial with more primary care investigators ready to participate with new drugs coming in and out of protocol—major impact on cost of trials and changes in FDA requirements
- EU medtech regulations will get tougher and more like FDA, potentially eliminating positive product launch lead time vs. U.S.

New View of Emerging Markets Going Forward

- Revocation of patents in India becoming commonplace and has started in China
- Chinese government won't fund expensive Western-branded drugs for citizens
- Markets will grow in access to medicines, but they will be cheap generics for the most part

Non-Dilutive Sources of Capital

Sources

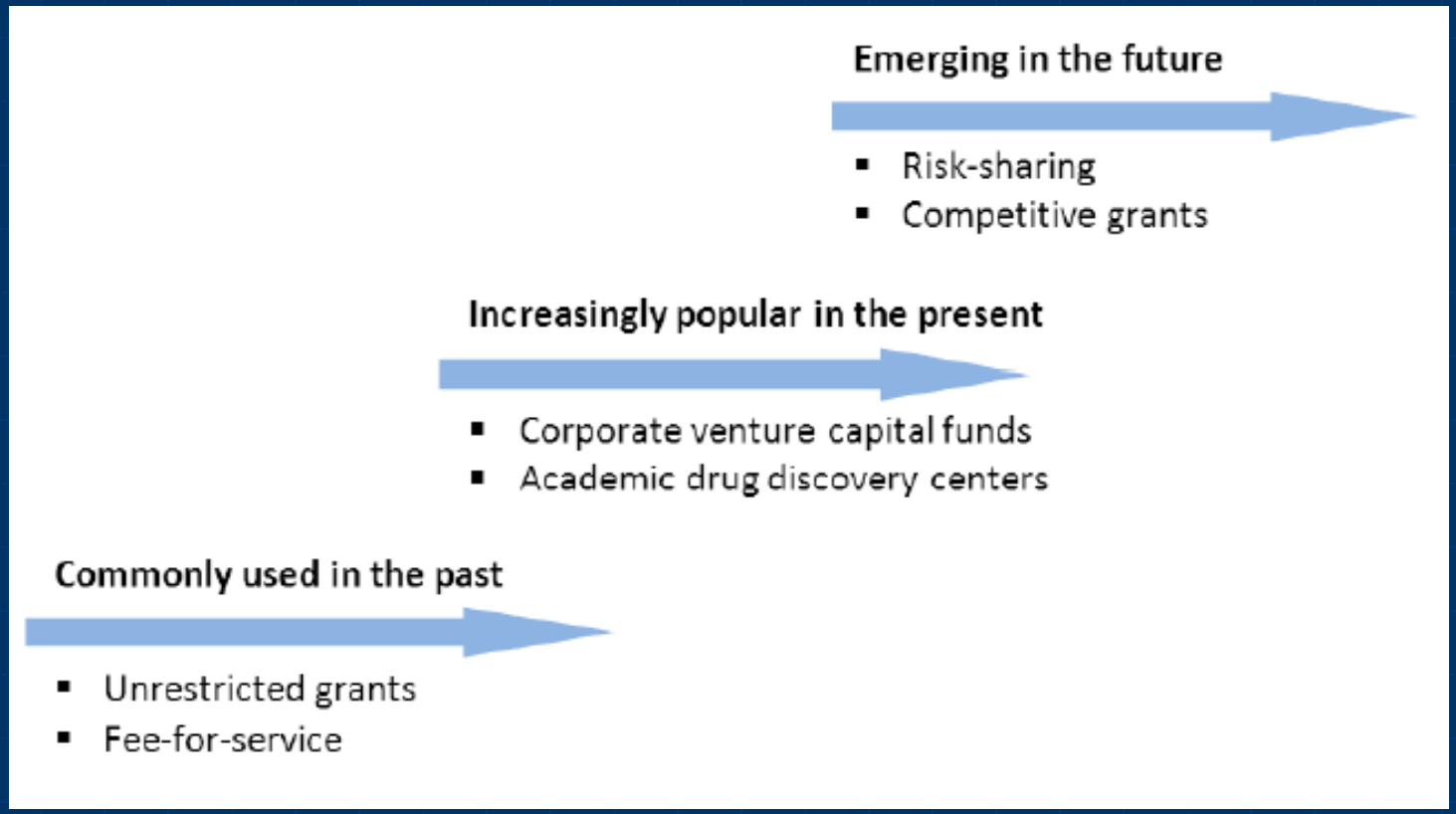
- Government Industry Grants
- Government Research Grants
- Industry Partnerships with Foundations
- Drug Discovery Partnerships
- IP Generating Royalties/ Royalty Monetizations

Examples

- Establish research partnerships to leverage core competencies (e.g.,medchem)
- Establish collaborations with academic centers
- Establish sponsored research and leverage infrastructure
- Establish deals that maximize value of IP assets (e.g., royalty monetization)

Source: "How to Enter into Collaborations to Leverage Capital, "Christopher Kiritsy, MBA, CEO, Arisaph and Elizabeth Krutoholow, *Editor*, *Bloomberg Brief*: *Healthcare Finance*, Bloomberg LP presented at New Paradigms 2013, Jan. 2013.

Trends in Academic/Industry Relationships Changing

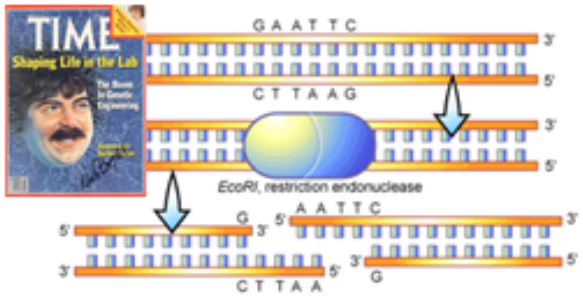


Source: "Academic-Industry Partnerships for Biopharmaceutical Research & Development: Advancing Medical Science in the U.S.," Christopher-Paul Milne, Associate Director, and Ashley Malins, Research Analyst Tufts Center for Study of Drug Development, April 2012

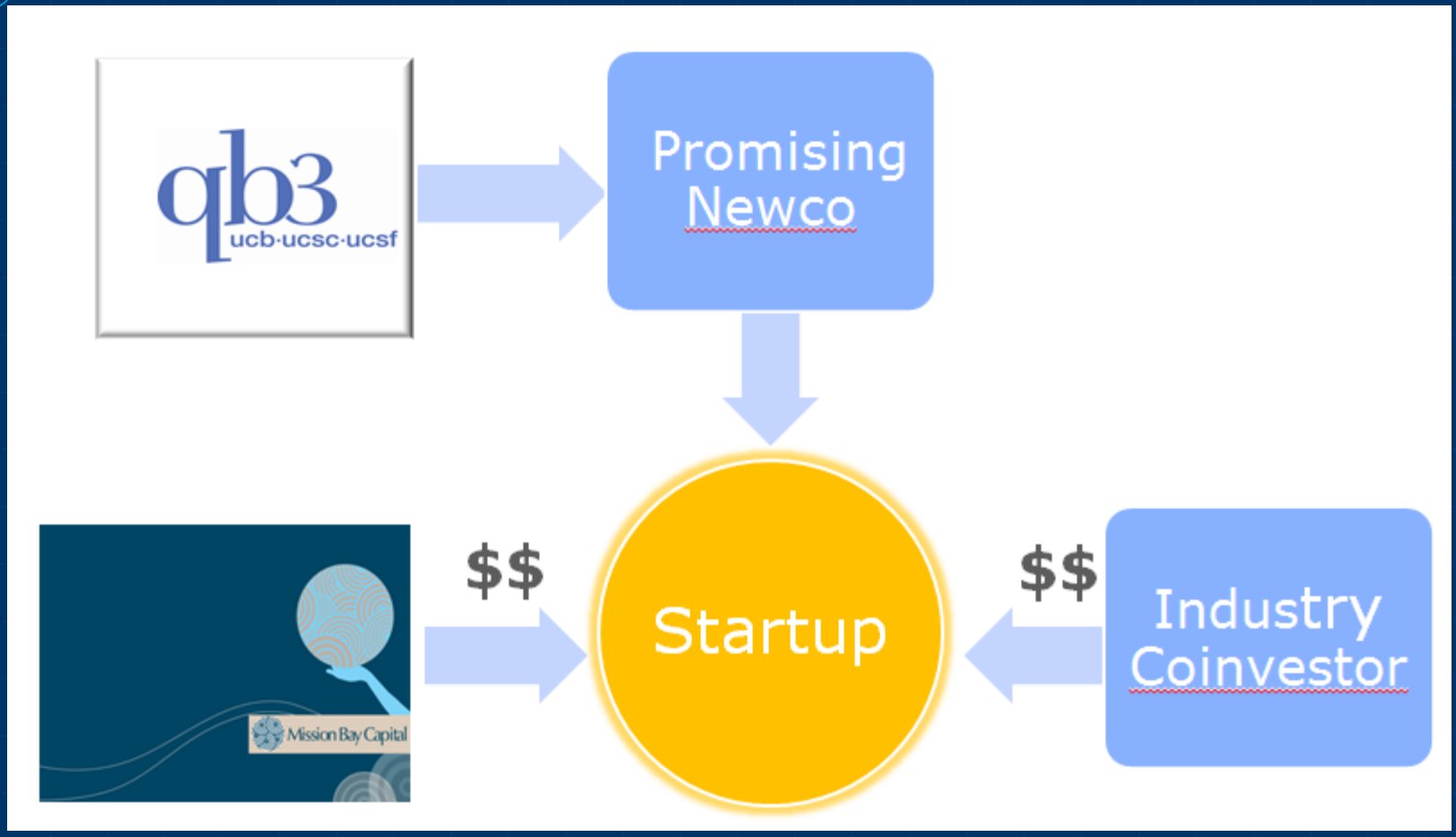
Traditional Funding Model

Venture Investment

University Research → Start-up Company → Successful Company



Collaborative Investment Program



In Summary, Biomedical Industry Is Being Pushed To Achieve:

- New and improved (differentiated at minimum but breakthrough preferred) product efficacy and safety
- Development efficiency and productivity delivering potentially lower pricing but
- Continuing to deliver a satisfactory return on investment for their investors