



# Strategic Outlook for 2015 and Strategic Plan

April 2009

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## Background and Objectives

The Massachusetts Biotechnology Council (MBC) embarked on an important strategic initiative aimed at ensuring that MA maintains its position as a world-class center for the biotechnology industry.

- The key objectives for this project were to:
  - Perform a **global competitive market analysis** to identify key strengths, weakness, opportunities and risks for the MA biotechnology cluster across the biotechnology value chain
  - **Document key trends and define their impact** on MA and the global biotechnology industry
  - Define the **critical needs of the MBC membership and identify opportunities** for the MBC to grow as an organization (e.g., by adding new enabling and revenue-generating offerings)
  - **Develop a clearly articulated vision** for the MA biotechnology cluster through an inclusive, consensus-driven approach
  - **Develop a forward-looking strategic plan** to achieve this vision and anticipate changes in the biotechnology industry over the 2015 horizon
  - **Create an implementation and communication roadmap** that identifies specific action items for MBC member groups and socializes the report's findings to generate buy-in to the MBC vision and strategic plan

The 2015 Strategy Report defines an integrated vision for the biotechnology industry in MA; this vision sets the scope of the implementation roadmap to be executed by MBC on behalf of academia, industry, investors, and medical centers in the state

## Face of the MA Cluster

The MA life sciences super cluster is among the largest in the world, comprised of leading biotech and pharma companies and supported by world-class academic medical and research centers.

### Key Facts About MA Biotech Cluster

- **240 biotech / pharma companies – mix of both start-up and veteran companies**
  - Big pharma has a substantial presence, 8 of the largest 11 have operations in the state
- **450+ medical device companies**
- **Top 5 funded research hospitals in the country**
  - 16 Academic Medical Centers
  - World-class expertise in medical research and clinical translation
- **2nd in NIH funding (lower than CA) but highest NIH funding per capita**
- **1st in the number of life science patents per capita awarded to MA institutions (2001- 2005) – 3X national average**
- **30 major VCs actively focusing on the industry**
- **20,000 + employed in the Biotech sector**
- **High public policy awareness of the biotechnology industry**
  - Number of legislative acts – Life Sciences Initiative; Life Sciences Talent Initiative (LSTI) and BioTeach; BioReady Communities Campaign
- **MA's education system produces the steady stream of skilled workers**
  - 13 local colleges granting life-science doctorate degrees, three are ranked in the national top 20

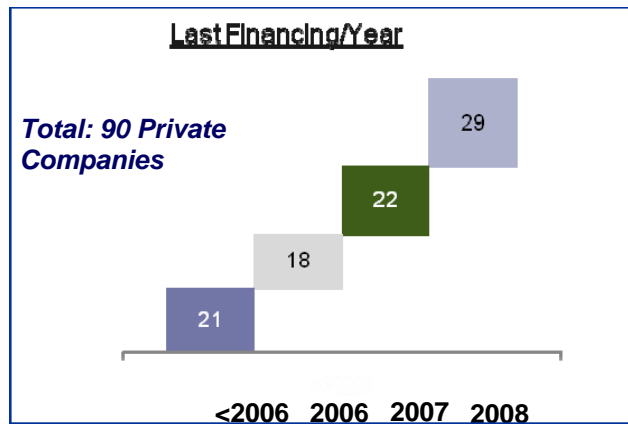
## Face of the MA Cluster

MA has historically been a hotbed for innovation, relying on strong venture capital support and key financing events to fuel translation from bench to business; however, the current economic environment is pressuring both private and public companies in MA

### Private Companies

Since 1999, 253 recorded rounds of VC financing raising \$5.32 billion

- 135 companies have raised VC Funding since 1999
- 38 companies completed IPO, Reverse Merger, or Trade Sale
- Seven companies liquidated or closed
- **90 Current Active MA Private Companies**

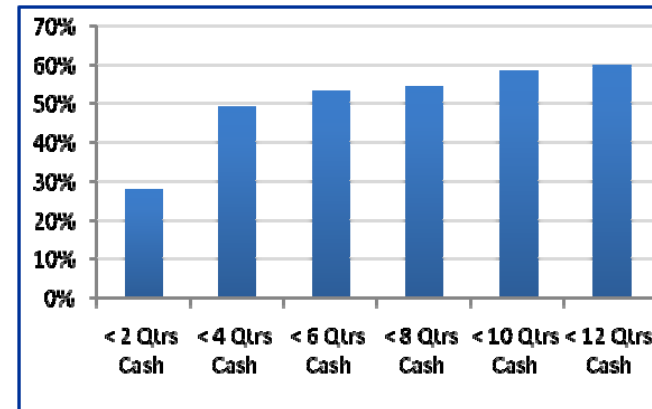


- **1/2 - 2/3 will be looking to raise their next round of financing in 2009**

### Public Companies

~83 public companies - Market cap of ~\$80 billion

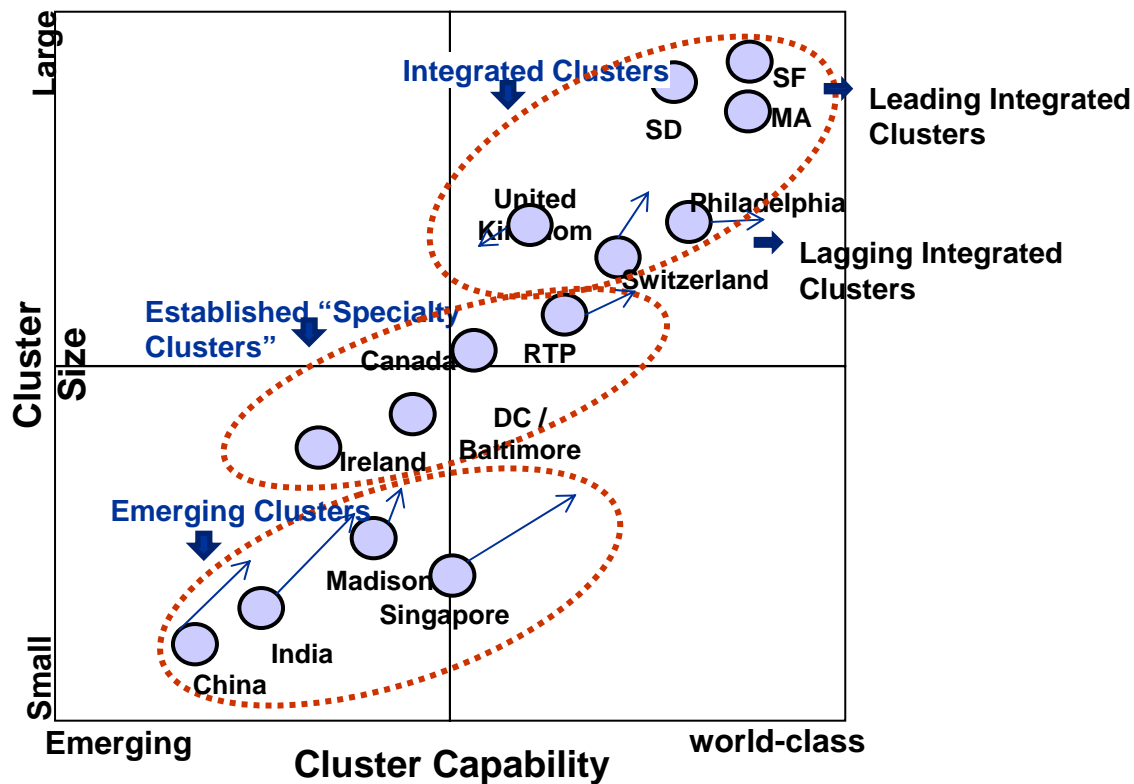
- 46 companies have market cap <\$100 million
- 63 companies have market cap <\$1 billion
- Genzyme has the largest cap ~\$17.5 billion



- **Almost fifty percent of companies risk running out of cash by the end of 2009**

# Competitive Analysis Summary

Based on a qualitative and quantitative analysis of select clusters, MA is in a leading position with SD and SF; however, many clusters are investing in biotechnology, positioning themselves for future growth



Specialty and emerging clusters are becoming increasingly attractive as pharma and biotech companies strive to reduce costs and increase flexibility

# Key Challenges and Barriers

Many barriers are in place limiting the growth potential of emerging, specialty and lagging integrated clusters, while leading integrated clusters face collective challenges

<i>Leading Integrated Challenges</i>	<i>Barriers to becoming a Leading Integrated Cluster</i>		
<i>Leading Integrated</i>	<i>Lagging Integrated</i>	<i>Specialty Cluster</i>	<i>Emerging Cluster</i>
<ul style="list-style-type: none"> <li>▪ <b>High costs</b> - sustaining innovation while balancing cost and value</li> <li>▪ <b>Limited talent</b> pool for less complex but critical activities</li> <li>▪ <b>Collective challenges</b> from emerging and specialized clusters, some of which are focusing on specific functions or types of activities</li> <li>▪ <b>Slow down in VC funding</b></li> <li>▪ <b>Lacks deep commercial talent</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>High costs</b></li> <li>▪ <b>Limited VC funding</b> or non availability of funds</li> <li>▪ Some have <b>clinical trial limitations</b> (Europe based)</li> <li>▪ More mature outlook due to significant influence of big pharma</li> </ul>	<ul style="list-style-type: none"> <li>▪ Focused on <b>one or few functions</b> along the value chain</li> <li>▪ <b>Limited biotech innovative research infrastructure</b> and scale (network is absent)</li> <li>▪ <b>Limited VC funding</b></li> <li>▪ <b>Clinical trial limitations</b></li> <li>▪ <b>Lacks significant network</b> of key biotech stakeholders</li> <li>▪ <b>Limited scientific and commercial talent</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Limited breadth of funding</b>; significant funding for “less complex and more standardized” activities across the value chain or unique platform technologies</li> <li>▪ <b>Reliance on importing innovation</b> due to lack of innovative research infrastructure</li> <li>▪ <b>Innovative business models</b></li> <li>▪ <b>Limited VC funding</b></li> <li>▪ <b>Regulatory uncertainty</b> in India and China</li> </ul>

While the three leading clusters are in a “class of their own”, MA is a maturing cluster and will need to proactively address its key challenges in order to retain its preeminent position

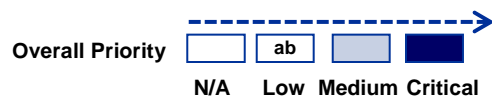
# Key Biotech Industry Trends

In addition, the biotechnology landscape is changing and MA will have to adapt to address global trends in both the near term and long term

<p><b>Strategic Partnerships</b></p>	<ul style="list-style-type: none"> <li>Driven by weak pipelines and decreasing R&amp;D productivity, big pharma is becoming increasingly active in acquisitions and partnerships with biotech companies</li> </ul>	<p><b>Innovative Technologies</b></p>	<ul style="list-style-type: none"> <li>Personalized medicines and targeted therapies pose significant opportunities and challenges</li> <li>The combination of drugs, devices, and diagnostics is leading to innovative health care solutions</li> <li>Novel technologies such as RNAi, stem cells and MAb continue to provide innovative therapeutic potential</li> </ul>
<p><b>Availability of Funding</b></p>	<ul style="list-style-type: none"> <li>The current economic crisis has resulted in reduced funding for biotech companies</li> <li>Many companies are unable to secure funding and are operating with dangerously low cash levels</li> <li>VCs are increasingly funding late stage companies</li> </ul>	<p><b>Government Policy</b></p>	<ul style="list-style-type: none"> <li>Healthcare reform is a major priority for the incoming president and congress</li> </ul>
<p><b>Growing Reimbursement and Regulatory Concerns</b></p>	<ul style="list-style-type: none"> <li>In an effort to control the rising costs of biologics, payers are beginning to scrutinize treatments, taking into account both comparative effectiveness and cost-effectiveness</li> <li>Increasing industry regulation and litigation are forcing life science companies to be more cautious and increase their focus on product quality</li> </ul>	<p><b>Shifting Markets</b></p>	<ul style="list-style-type: none"> <li>External pressures are affecting many healthcare sectors and will impact biotech in various ways             <ul style="list-style-type: none"> <li>These include the growth of emerging markets, global talent shortage and the shifting drug commercialization paradigm</li> </ul> </li> </ul>

# Prioritized Stakeholder Needs

Needs Category	Med-Large Biotech / Pharma	Small Biotech	Academic Medical Centers	Investors
<b>Policy / Regulatory</b>	<ul style="list-style-type: none"> <li>More favorable policies/regulations re: IP protection, bio-generics, importation, reimbursement, S&amp;M and green technology</li> </ul>	<ul style="list-style-type: none"> <li>Secure <b>benefits from LSI funds</b></li> <li><b>Improve access to SBIR funding</b></li> <li><b>R&amp;D tax credits</b> to promote investments in early stage research</li> <li><b>New suite of tax incentives</b> for non-commercial biotech</li> </ul>		<ul style="list-style-type: none"> <li><b>Regulatory policies</b> and pathways to clear the way for profitable investments</li> </ul>
<b>Access to Capital/ Funding</b>		<ul style="list-style-type: none"> <li><b>Immediate access to capital</b> to support survival</li> <li>Connections to <b>new sources of government funds</b> and non-traditional funding sources</li> </ul>	<ul style="list-style-type: none"> <li><b>Increased NIH funding</b> to continue innovation and retention of key research personnel</li> </ul>	<ul style="list-style-type: none"> <li><b>Current company survival and/or exit/sell opportunities</b></li> </ul>
<b>Operational</b>	<ul style="list-style-type: none"> <li>New business models to <b>improve cost structures</b></li> <li>Effective processes for <b>expanding infrastructure</b> in MA</li> <li><b>Retention</b> of top talent and scientists</li> <li><b>Efficiencies</b> in transferring innovation from academia</li> </ul>	<ul style="list-style-type: none"> <li>Gain better <b>cost efficiencies</b> through purchasing consortium/ outsourcing/shared services</li> <li><b>Retention</b> of top talent</li> <li><b>Reduce start-up costs</b>, burn rate, and need for capital</li> </ul>	<ul style="list-style-type: none"> <li><b>Accelerate discovery</b> and translational capabilities</li> <li><b>Expedite novel compounds</b> to clinical trials</li> <li><b>Retention of scientific talent</b> when grants are constrained</li> </ul>	<ul style="list-style-type: none"> <li><b>Transparency into operational efficiencies</b> of invested companies</li> </ul>
<b>Collaboration / Partnering</b>	<ul style="list-style-type: none"> <li><b>Multiple collaboration/partnership opportunities</b> exist across all LS industry sectors</li> <li><b>Virtual R&amp;D</b> opportunities with both U.S. and ex-U.S. companies</li> </ul>	<ul style="list-style-type: none"> <li>Collaborations/partnerships for <b>new innovation and commercialization</b></li> <li><b>Shared operations</b> partnerships</li> </ul>	<ul style="list-style-type: none"> <li><b>Innovation and disruptive technology</b> collaborations for future commercialization</li> <li><b>Collaborations w/Industry</b></li> </ul>	<ul style="list-style-type: none"> <li>Connect with <b>innovations with good potential</b> in academia and other sectors</li> </ul>



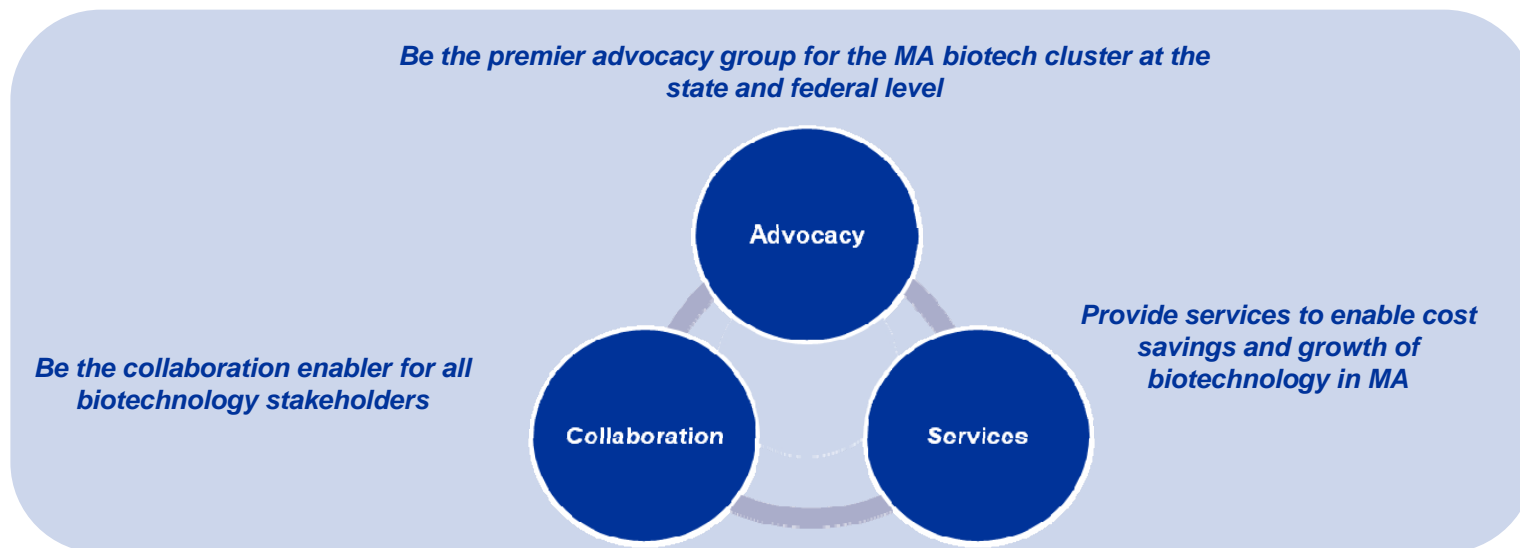
# MBC Vision and Enablers

Based on input from the competitive analysis of biotech clusters, industry trends, and interviews with stakeholders, participants at the visioning workshop developed a vision statement for MBC.

## DRAFT MBC Vision Statement

*MBC will help MA enhance its premier biotech position by strengthening its focus on novel research and development, facilitating scientific and business collaboration, and advocating for supportive public policies, ultimately transforming patient treatment globally while driving the growth of the Massachusetts economy.*

## Levers for MBC to Achieve Vision



***MBC's vision will be enabled by a combination of the organization's key levers: services, advocacy and collaboration***

## MBC Strategic Focus Areas

Strategic focus areas were developed to help MBC realize its vision.

### MBC Strategic Focus Areas

- **Scientific Collaboration and Innovation:** Promote continued innovation and collaboration in research and development so that Massachusetts can retain and enhance its world-class position in this area
- **Capital Formation:** Improve access to capital in the short and long-term by promoting collaborations and enabling access to various funding sources through meaningful events and advocacy
- **Business Services:** Provide services to that help companies increase their operational efficiencies and reduce their burn rate
- **Talent:** Enhance and accelerate efforts to attract, develop and retain biotech thought leaders and talent at all levels
- **Company Retention and Recruitment:** Improve company recruitment and retention efforts through proactive strategies and marketing efforts aligned with initiatives undertaken by the Commonwealth and other economic development partners
- **Industry Representation:** Improve the industry's representation and raise MBC's level of influence through collaborations with other associations and clusters and by raising public awareness of biotech through continued marketing campaigns and advocacy

# Initiative Roadmap

Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3 & Q4 2010	2011 and on
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## Milestones

- Annual Mtg.
- Investors Forum
- New web / database

### Capital Formation

- Increase the frequency and quality of capital formation events
- Advocate for allocation of parts of the MA economic stimulus package to Biotech



### Business Services

- Provide advisory and information services to members
- Connect buyers and providers of "bio" services
- Evaluate opportunity for the establishment of a public – private biotech center / incubator
- Provide support to companies with government program applications



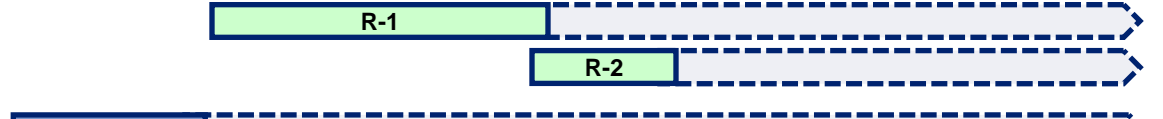
### Talent

- Advocate for incentives to retain talent
- Enhance professional development course offerings through MassBioEd



### Company Retention and Recruitment

- Develop and implement a proactive company retention / recruitment strategy
- Establish MA as an international gateway



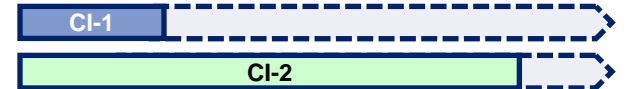
### Industry Representation

- Collaborate with other associations
- Increase awareness of biotech in MA
- Increase CEO engagement in MBC



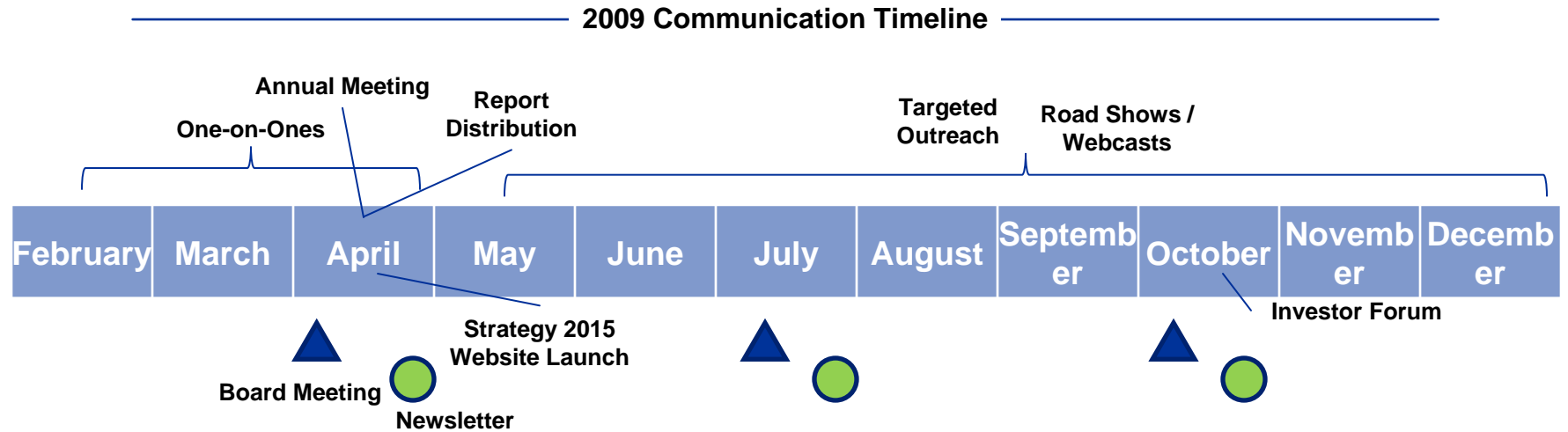
### Scientific Collaboration and Innovation

- Increase the frequency and relevancy of scientific events / forums
- Create a partnership with MA hospital trade associations to address clinical development issues



# 2015 Strategy Communication Plan: Timeline

A communication plan will facilitate leadership alignment, stakeholder engagement, and awareness and understanding by key cluster constituents.



## Guiding Principles

- Consistent and coordinated communications externally and internally are critical to the success of 2015 Strategy
- Communications are not only meant to inform people, but to align efforts in a common direction, build momentum and generate enthusiasm
  - Leverage board members and key industry leaders to present strategy highlights
  - Highlight achievements early and frequently
  - Leverage existing events to promote 2015 Strategy Report
- Provide a forum for two-way communication and feedback; gauge the level of stakeholder buy-in and feedback to alter communication strategy appropriately or to modify initiatives

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## Background and Objectives

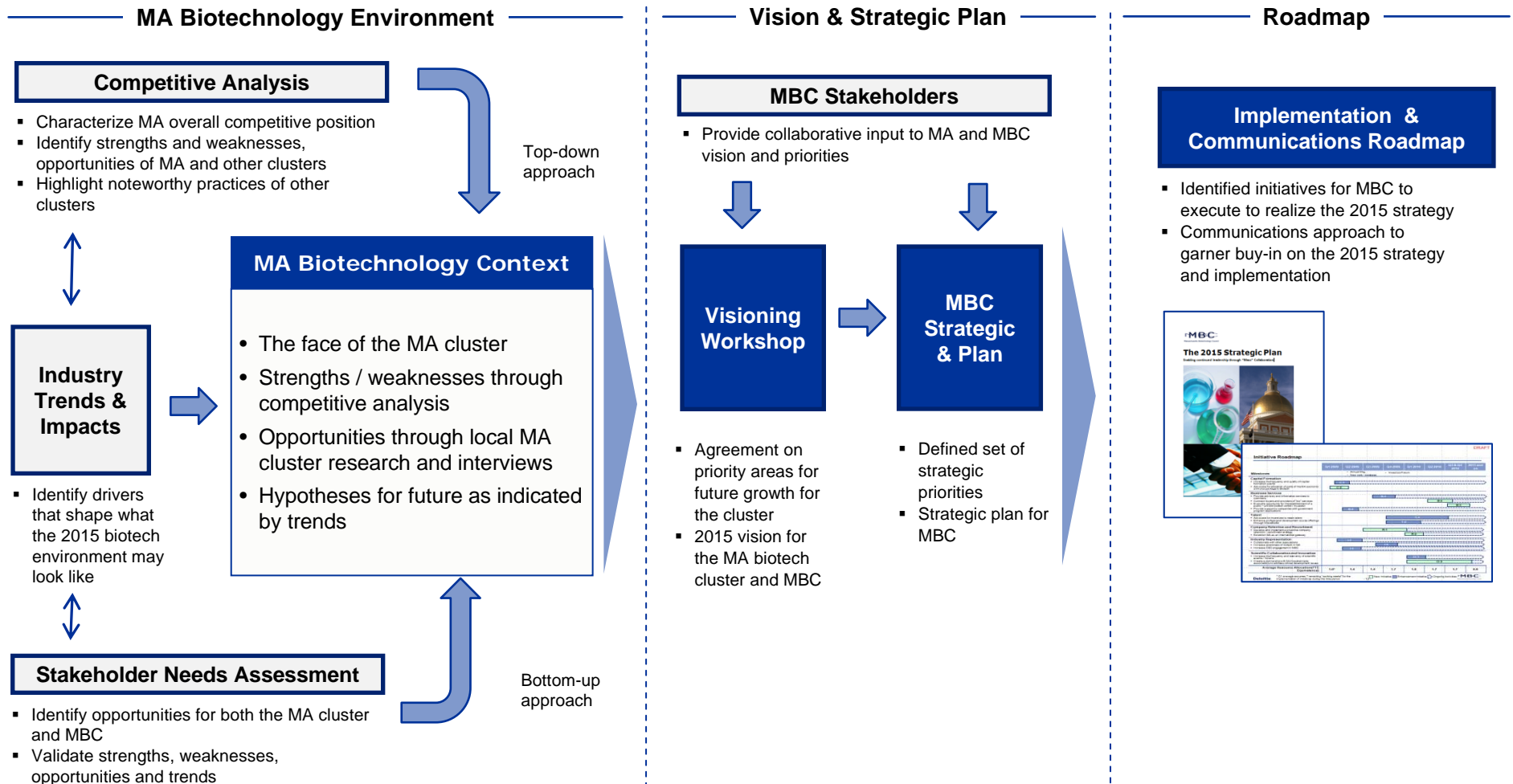
The Massachusetts Biotechnology Council (MBC) embarked on an important strategic initiative aimed at ensuring that MA maintains its position as a world-class center for the biotechnology industry.

- The key objectives for this project were to:
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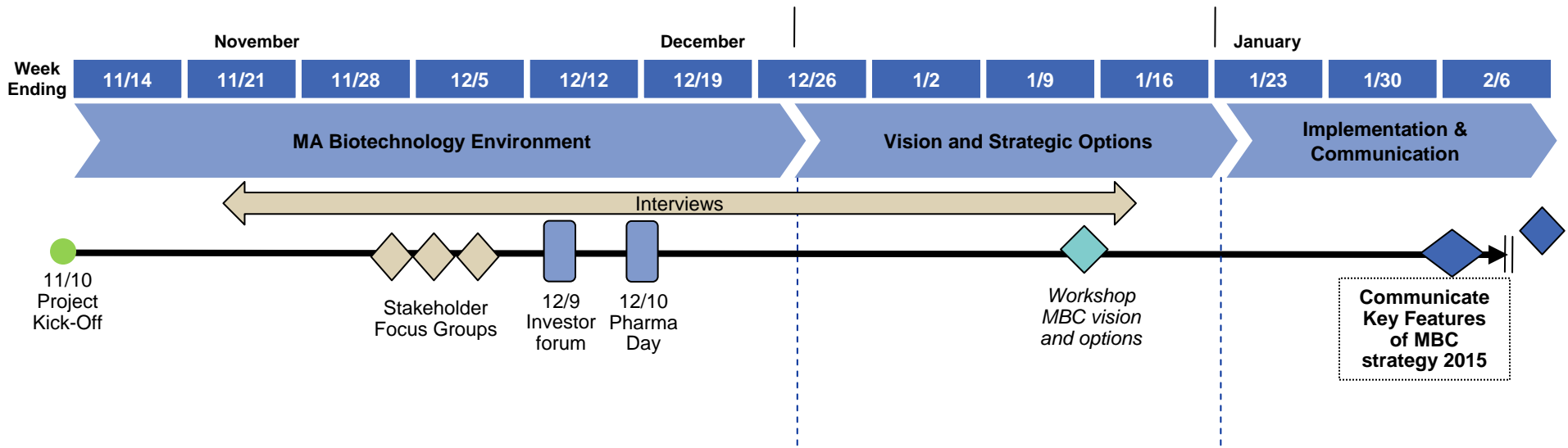
# Approach

A highly-collaborative, phased approach with inputs from multiple sources was employed to develop a strategic plan and the corresponding implementation and communications roadmaps.



# Timeline

The approach spanned 10 weeks and leveraged key MBC events and to maximize engagement from both MBC staff and member representatives.

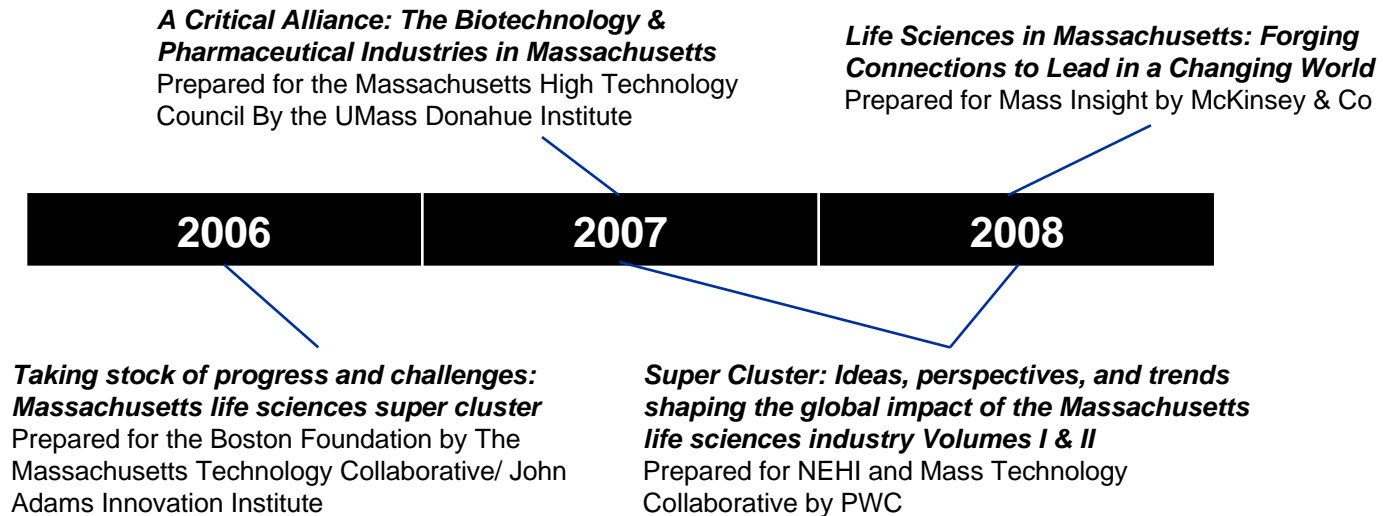


ACTIVITIES	MA Biotechnology Environment	Vision and Strategic Options	Implementation & Communication
	<ul style="list-style-type: none"> <li>Identified key industry trends and implications</li> <li>Conducted stakeholder interviews and focus groups</li> <li>Defined MBC stakeholder needs</li> <li>Conducted global and national competitive analysis of biotech clusters</li> </ul>	<ul style="list-style-type: none"> <li>Developed initial strategic options for MBC and validate and prioritize with key stakeholders</li> <li>Assessed capabilities needed for the strategic plan to be executed</li> <li>Developed business case for core and contingent strategies</li> <li>Drafted strategic plan for MBC</li> </ul>	<ul style="list-style-type: none"> <li>Developed high level implementation roadmap and change management plan</li> <li>Developed communication roadmap for MBC Strategy Plan 2015</li> <li>Gain buy-in from key stakeholders</li> </ul>

# The MA Biotechnology Cluster: Past Reports

The MA life sciences industry has been the focus of several reports over the past three years; each highlighted MA's strengths and identified opportunities for improvement.

## Recent MA Biotechnology Reports



- While past reports have identified recommendations for the MA biotech community to address, they have not had significant impact in driving an executable strategy with specific initiatives and necessary ownership
- In addition, due to report timing, previous reports have not addressed the acceleration of many key trends and the impact of the current economic crisis on the biotech industry
- It is therefore necessary to take a deeper look at these trends and the status of the MA cluster with respect to competing biotech clusters to develop a clear, prioritized and actionable strategy for the MBC to pursue in order to best position the MA biotech cluster for continued growth and success

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## Face of the MA Cluster (1 of 5)

The MA life sciences super cluster is among the largest in the world, comprised of leading biotech and pharma companies and supported by world-class academic medical and research centers

### Number of Key Cluster Stakeholders<sup>1</sup>

Pharma / Biotech	240
Med. Device	450
Venture Capital Firms (Biotech Focus)	30
Academic Medical Centers	16
Industry Associations (Addresses Biotech)	10

### Pharma / Biotech / Med. Device

- The MA cluster contains an estimated 240 biotech / pharma companies, with a density of both start-up and veteran companies
- Of biotech companies developing human therapeutics, there are 83 public companies and 90 current active private companies
- Big pharma has established a substantial presence in the state, 8 of the top 10 are located here
- In 2007, more than 100 MA companies were Biotechnology Industry Organization members, while over 200 are members of the MBC

### Public and Private Funding

- MA continues to attract a leading share of public and private financing
- MA biotech companies received \$707 million from VCs in 2007
- In 2007, MA received \$2.2 billion in NIH funding, second among all states to CA, but first in NIH funding per capita
- However, NIH funding increases have slowed in recent years and the value of NIH grants to MA researchers has not increased significantly since 2003

### University / Med. Centers

- MA is home to the top five NIH funded research hospitals
- The number of life science patents per capita awarded to MA institutions between 2001 and 2005 was more than triple the U.S. average
- MIT and Harvard are leading universities in terms of both innovation and technology transfer outcomes

### Industry Associations

- MA's biotech industry is served in various ways by 10 industry associations
- The associations focus on a variety of issues, ranging from distribution of government funds, education and training, economic development, and industry advocacy

<sup>1</sup> Estimates using Deloitte Research, MBC website and business plan

## Face of the MA Cluster (2 of 5)

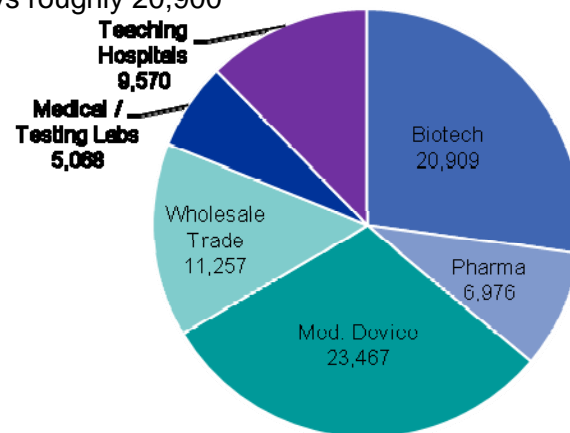
The diverse and high concentrated set of stakeholders has produced a platform for the MA cluster's sustained growth to date.

### Economic Contributions

- Biotechnology is the fastest growing segment of the life sciences industry and grew by 28 percent over the past five years
- MA's life sciences sector contributes approximately \$8.8 billion annually to the state's economy

### Employment

- The MA super cluster employs over 77,000 people and is home to a skilled labor pool of scientists and entrepreneurs
- The biotechnology industry employs roughly 20,900



### Education

- MA's education system produces the steady stream of skilled workers that have supported the growth of the cluster
  - Among 13 local colleges granting life-science doctorate degrees, three are ranked in the national top 20
  - Many MA Universities are beginning to offer innovative / interdisciplinary degree programs in anticipation of industry's future workforce needs
- World-class expertise in medical research and clinical translation
  - The quality of the skilled workforce in MA, typically those with advanced graduate degrees and doctorates, is among the finest in the US

## Face of the MA Cluster (3 of 5)

The cluster has maintained its leadership position by expanding on its strengths and addressing identified opportunities for improvement, as demonstrated by recent milestones and initiatives.

### Recent Initiatives

#### \$1B Life Sciences Initiative

- The \$1B Life Sciences Initiative will be instrumental in further growing MA's biotech strength
  - Funds include \$500 million in capital spending, \$250 million in grants and financing and \$250 million in tax incentives
  - The entirety of the money has yet to be allocated, but over \$180 million will go to new facilities and equipment at the University of Massachusetts including, \$90M for construction of a facility that will house the world's foremost stem cell bank and registry, established as a collaboration among UMass, Harvard and MIT

#### Life Sciences Talent Initiative and Bio Teach Program

- Successful implementation of the Life Sciences Talent Initiative (LSTI) and execution of the BioTeach program is essential to maintaining the competitiveness of MA's life sciences talent base
  - LSTI was a study conducted to develop a collaborative statewide strategy between business, government and higher education to ensure that the state's talent needs in life sciences are met
  - The goal of BioTeach is to promote biotechnology methods and inspire scientific curiosity and understanding at the high school level, which is aimed ultimately to help address the challenge of maintaining a steady pool of lab techs and researchers in MA

#### Bio-Ready Communities Campaign

- The BioReady Communities Campaign will be key to attracting biotech companies to MA
  - The focus of the campaign is to help prepare MA communities for biotech laboratory and manufacturing opportunities in an effort to increase the inventory of real and potential biotech facilities / sites in MA
  - Additionally, the program encourages expansion of the biotech sector to other MA areas, beyond the Boston / Cambridge area which has relatively high costs

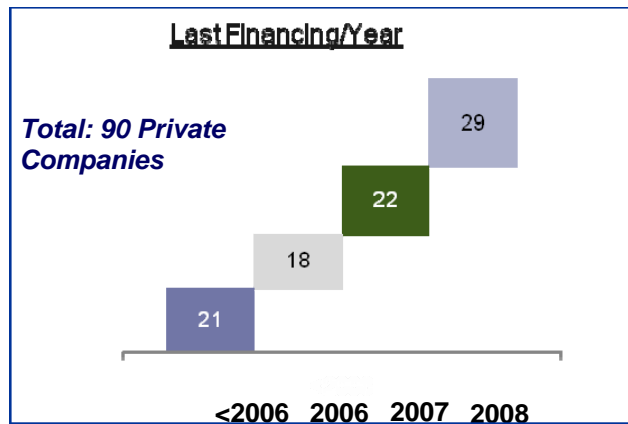
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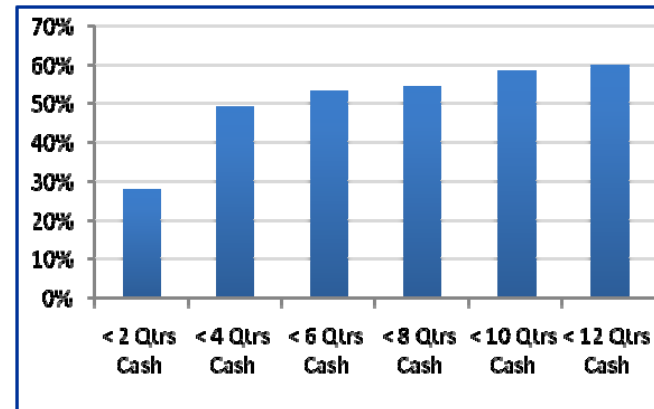


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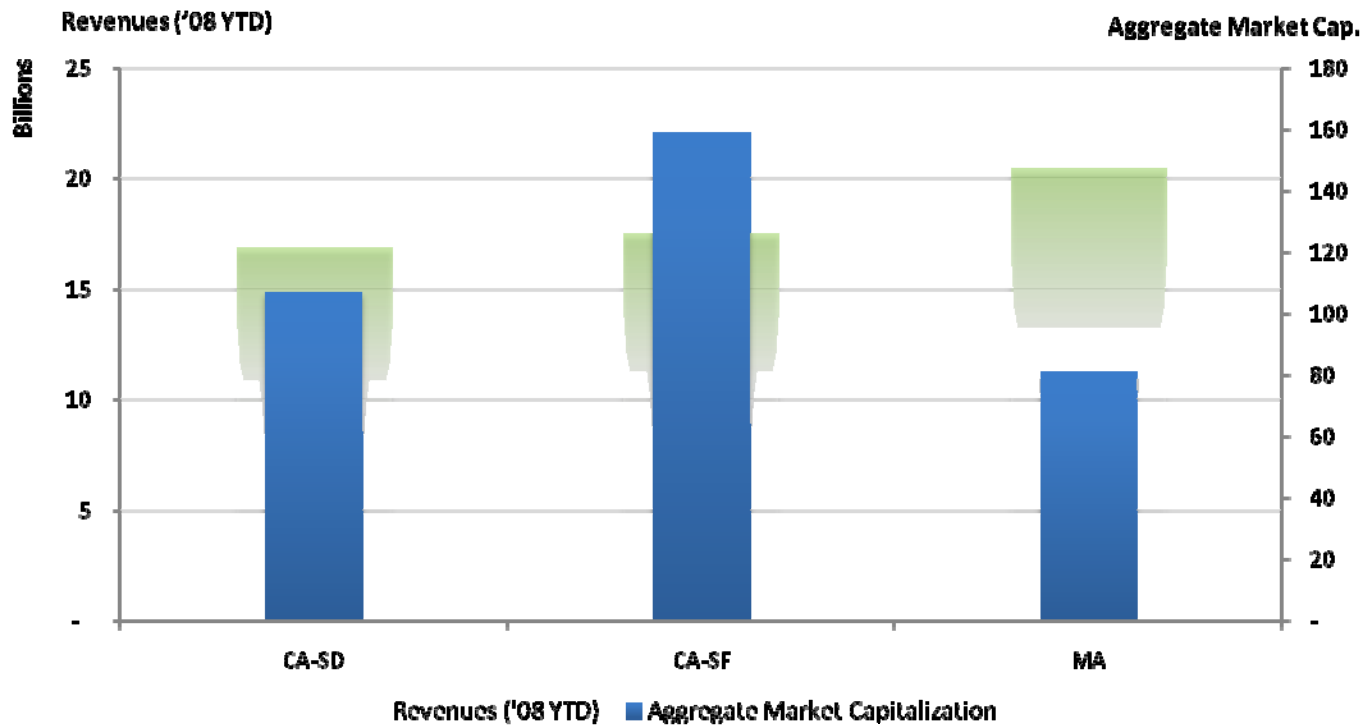
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- Genzyme has the largest cap ~\$17.5 billion



- **Almost fifty percent of companies risk running out of cash by the end of 2009**

## Face of the MA Cluster (5 of 5)

Further, MA has a low market capital to revenue ratio indicating that the market is putting less value on MA companies relative to their revenue generation.



Historically, MA has had an attractive environment for start ups but the cluster may face a struggle to remain competitive as it matures.

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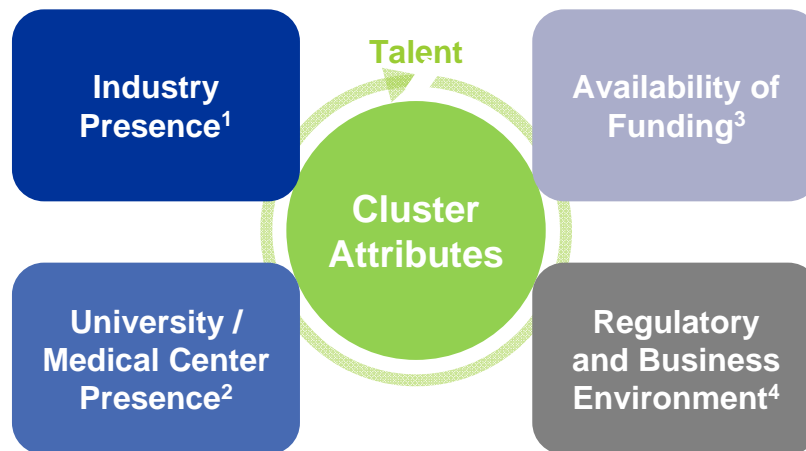
—— **Biotech Cluster Attributes and Analysis** ——

# Biotech Cluster Attributes

Biotech Clusters were evaluated across four key attributes essential to sustaining the full continuum of biotechnology activity.

## Definition of Cluster Attributes

- Presence and nature of biotech companies (e.g., start-up, early stage, late development, mature commercial, enabling service)
- The quantity and diversity of all life sciences stakeholders (e.g., big pharma, mid / large biotech, anchor firms, start-ups, med. Devices, and supporting industries and infrastructure)
- Availability of funding to support early stage company research
- Funding for established biotech companies to invest in additional infrastructure and clinical research to move products into the marketplace



- Strong research universities and academic medical centers, supported by effective technology transfer offices, as a key source of innovation and talent
- Collaborative relationships between research universities and academic medical centers to sustain invention and innovation

- Stable and supportive public policy structure
- Supportive business environment to retain existing companies and / or attract new enterprises (e.g., taxes, permitting, costs, IP protection)

<sup>1</sup> Industry Presence Indicators: Quantity and diversity of life sciences companies; biotech company presence per value chain segment; availability of talent (# and skill level of workforce)

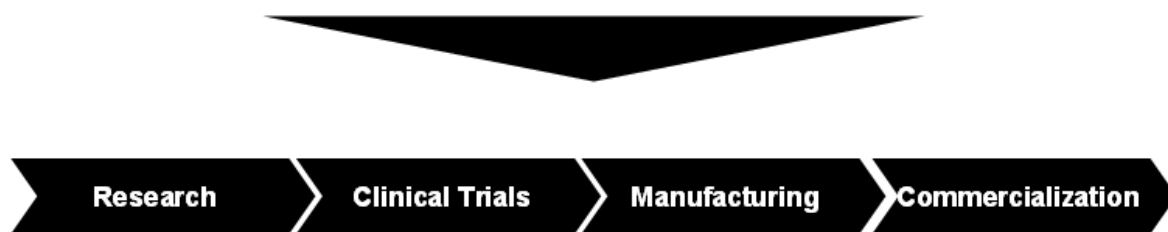
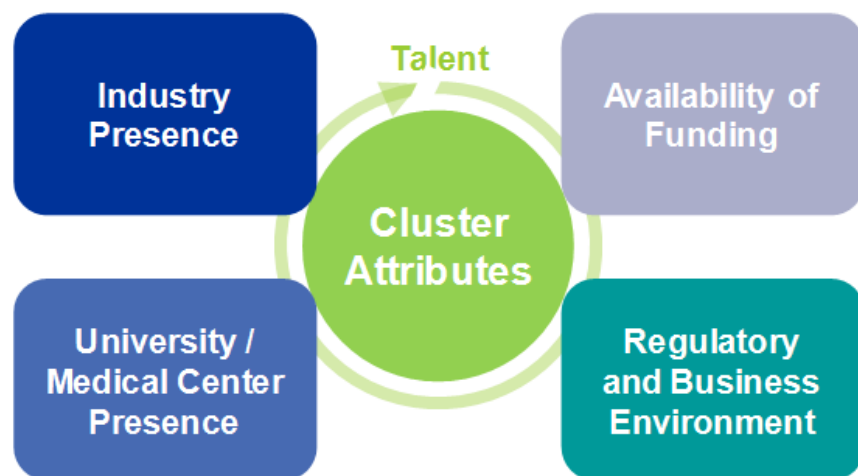
<sup>2</sup> University / Medical Center Presence Indicators: relative # and prestige of research universities and medical centers; level and performance of university / medical center technology transfer activity; life sciences graduates (MD, PhD, scientists, engineers)

<sup>3</sup> Availability of Funding Indicators: relative ease / difficulty in obtaining capital at all stages of company development; monetary amount of and private financing (VC) and government funding (NIH) within cluster

<sup>4</sup> Regulatory / Business Environment Indicators: capital and operating costs (e.g., wages, real estate costs, construction cost indices); strength of IP protection; presence and quality of tax incentives or other economic development incentives (e.g., grants, subsidies)

# Relevance of the Biotechnology Value Chain

These cluster attributes are further tied to the biotechnology value chain, which is the cornerstone of biotechnology companies



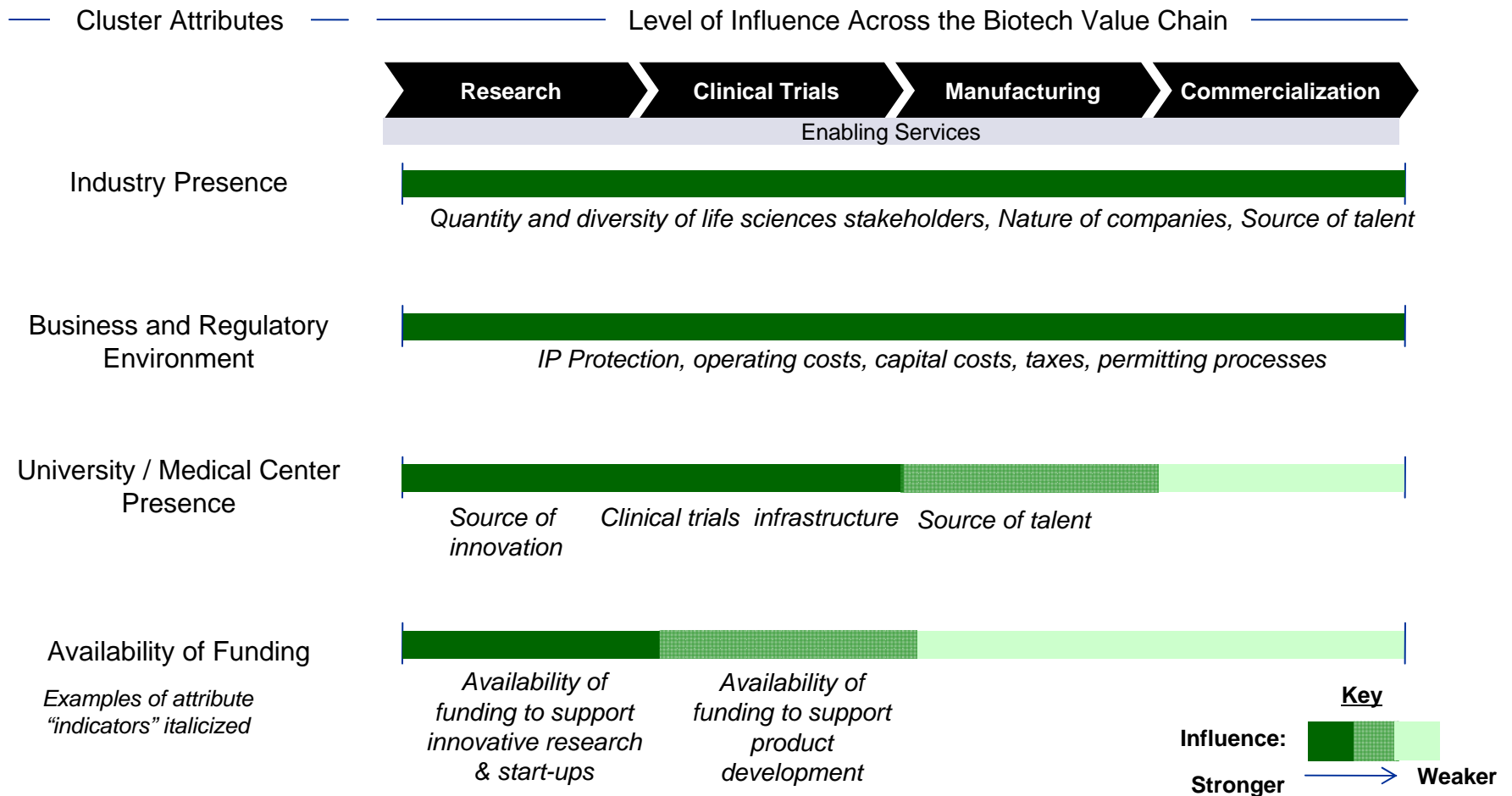
## Relevance of Value Chain

- The value chain represents interrelated, yet distinct core competencies to bring a biotechnology product to market
- The majority of biotech firms are not integrated across the value chain
- Biotech companies typically focus on the early stages of the value chain (e.g., early research focus) and many companies utilize partnerships to manufacture and commercialize their products

*As clusters emerge or evolve, there is further fragmentation across the value chain (e.g., players in specific segments of the value chain rather than across the value chain)*

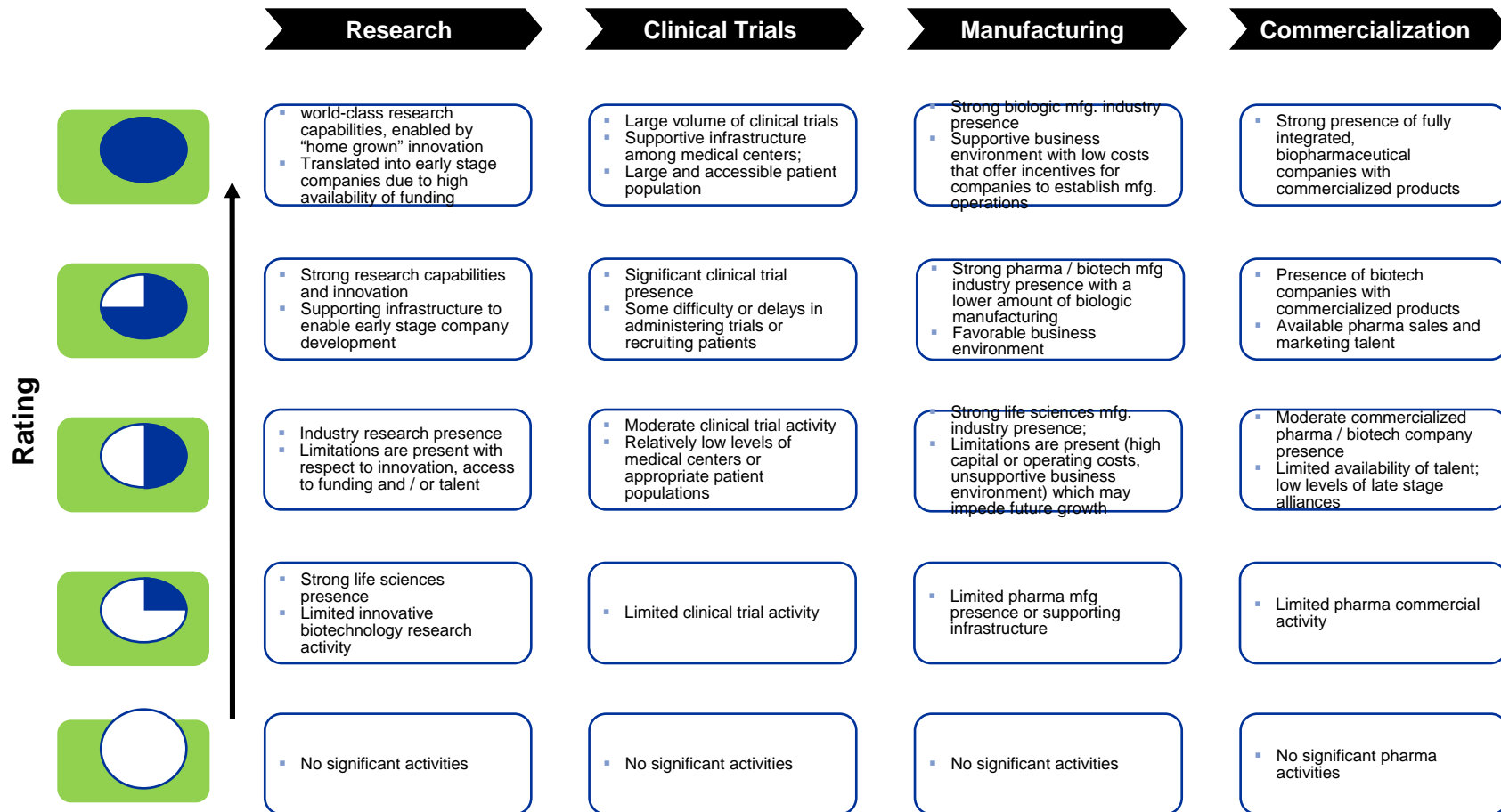
# Relevance of Attributes to Value Chain

Further, cluster attributes have varying levels of influence across the value chain segments.



# Maturity Model Used to Compare the Biotechnology Clusters<sup>1,2</sup>

A qualitative “competitive scoring” was developed for each cluster along the value chain.



<sup>1</sup> Evaluating and comparing clusters using only quantitative data is difficult due to lack of consistent and accurate data; this analysis combined both quantitative and qualitative metrics and defined them along a maturity continuum

<sup>2</sup> While biotechnology can have many applications, the cluster evaluations focused primarily on biotechnology associated with the development and production of human medical therapeutics; we recognize that many clusters have strengths in other forms of biotechnology (e.g., agriculture / plant) and this was incorporate as appropriate in the analysis

# Competitive Analysis Summary: Integrated Clusters

The analysis indicates that MA, SF and SD are the leading clusters across the value chain.

	Research	Clinical Trials	Mfg.	Comm.	Rationale
Massachusetts					<ul style="list-style-type: none"> <li>High concentration of world-class research universities and academic medical centers is a source of scientific innovation and reputed talent</li> <li>Presence of diverse biotech firms across different stages of the value chain and maturity</li> <li>Availability of funding due to high VC presence and top NIH funded hospitals</li> <li>Region's high costs are unattractive for large scale manufacturing operations; cumbersome IRB policies and patient recruitment processes make running clinical trials harder</li> </ul>
San Francisco, CA (Northern CA)					<ul style="list-style-type: none"> <li>Leading VC presence and strong NIH funded research universities and medical centers</li> <li>Large biotech industry presence with fully integrated biopharmaceutical anchor firms with a higher number of products in the market and late stage pipeline</li> <li>Region's high cost also impedes manufacturing investments</li> </ul>
San Diego, CA (Southern CA)					<ul style="list-style-type: none"> <li>Strong research presence and collaborative culture; high concentration of companies in close proximity; significant investments in innovative technologies like stem cell research</li> <li>Larger concentration of end-to-end biotechs as opposed to start-ups</li> <li>Slightly lower but growing VC presence (compared to SF and MA)</li> </ul>
Philadelphia, PA					<ul style="list-style-type: none"> <li>Strong pharma presence in the region</li> <li>Strong academic medical and research centers</li> <li>However, tech transfer limitations and lower VC presence have led to fewer start-ups and difficulty retaining organic talent</li> <li>Supportive government with many initiatives and funding available to support sector growth</li> </ul>
United Kingdom (London / Cambridge)					<ul style="list-style-type: none"> <li>Europe's premier biotech cluster possesses significant talent and history of innovation; however, current barriers regarding costs, funding and clinical trials are limiting the cluster's future potential</li> <li>Largest pipeline in Europe, with 361 products in development, including 155 in phases II / III</li> <li>Access to VC funding has been increasingly difficult for UK companies in recent years, and the current economic crisis is having a more profound effect; the UK biotech industry is currently advocating for a \$770 million "bailout" from the government</li> </ul>
Switzerland					<ul style="list-style-type: none"> <li>Boasts a high concentration and diversity of life sciences companies including large pharma, mid-sized biotechs and start-ups (ranks second in number of phase III products in EU)</li> <li>Strong academic presence with notable eminence and intellectual property developed</li> <li>Strong government support for innovation and tech transfer, enabled by investment in incubators</li> <li>Focused primarily on human therapeutics</li> <li>Strong public market and experienced investor base have created an attractive public and private funding environment</li> </ul>

# Competitive Analysis Summary: Established Specialty Clusters

Several clusters have established themselves with a notable specialty and strength in specific value chain segments.



	Research	Clinical Trials	Mfg.	Comm.	Rationale
RTP, NC					<ul style="list-style-type: none"> <li>Third largest biotechnology state in the U.S. and contains a strong manufacturing and CRO base, but has a limited R&amp;D infrastructure</li> <li>Relatively lower costs have made the region attractive for establishing manufacturing and to a lesser extent R&amp;D centers</li> <li>Supportive government and infrastructure is available to support early stage start-ups</li> </ul>
Baltimore, MD / Washington D.C.					<ul style="list-style-type: none"> <li>Strong presence of government agencies and academic research centers as well as a strong CRO industry presence; however, the cluster lacks a significant network of key biotech stakeholders</li> <li>Region does not attract significant VC funding but state government is planning to address this gap with \$1.1 billion investment over the next 10 years</li> <li>Relatively higher number of clinical trials take place in the region primarily due to NIH</li> <li>Relatively lower number of companies engaging in manufacturing or commercial operations</li> </ul>
Canada (Toronto / Montreal)					<ul style="list-style-type: none"> <li>Significant number of R&amp;D biotech companies specifically in the Montreal and Toronto areas</li> <li>Attractive place to do business due to low taxes and relaxed immigration policies</li> <li>Hosts the second largest number of clinical trials behind the US; however, rising costs are expected to decrease this number going forward</li> <li>Strong “homegrown” public and private biotech presence; approximately half of companies are involved in therapeutics, with a third involved in agriculture and environment related biotech products</li> </ul>
Ireland					<ul style="list-style-type: none"> <li>Historically strong manufacturing presence with big pharma</li> <li>Lower academic research eminence as well as VC presence to support innovative start-ups</li> <li>Ireland has one of the world’s lowest corporation tax rates that supports establishing manufacturing units</li> <li>Poor R&amp;D infrastructure and talent</li> </ul>

# Competitive Analysis Summary: Emerging Clusters

Emerging clusters are taking strides forward with significant government support.

	Research	Clinical Trials	Mfg.	Comm.	Rationale
Madison, WI					<ul style="list-style-type: none"> <li>Nascent industry with a low level of VC funding;</li> <li>Recognized for its leading position in stem cell research and poised for future growth with strong government support</li> </ul>
Singapore <sup>1</sup>					<ul style="list-style-type: none"> <li>Strong investments by government in biotechnology R&amp;D; however, the country's home grown biotech industry is nascent with minimal VC investment</li> <li>Strong footprint by big pharma in Singapore due to attractive business environment, primarily in manufacturing; there is a potential to leverage the country's pharma strength into biologics</li> <li>Big pharma also using Singapore as a clinical trials hub for Asia</li> </ul>
India (Bangalore / Hyderabad) <sup>1</sup>					<ul style="list-style-type: none"> <li>Focused on bio-generics, CRO type activities and manufacturing</li> <li>Clinical trial activity is expected to significantly increase over the next several years</li> <li>Significant government investments in biotechnology research and high-tech parks, but IP protection risks have limited the Indian biotech industry significantly</li> </ul>
China (Shanghai / Beijing) <sup>1</sup>					<ul style="list-style-type: none"> <li>Focusing on the biotechnology industry due to tremendous growth potential and is positioned to become a center for CRO activities ("CRO light")</li> <li>Biotech VC activity is increasing, and government support for local R&amp;D is expected to top US\$14 billion by 2015</li> <li>Potential to emerge as ideal location for global biogenerics manufacturing and continue to attract a growing number of clinical trials</li> </ul>

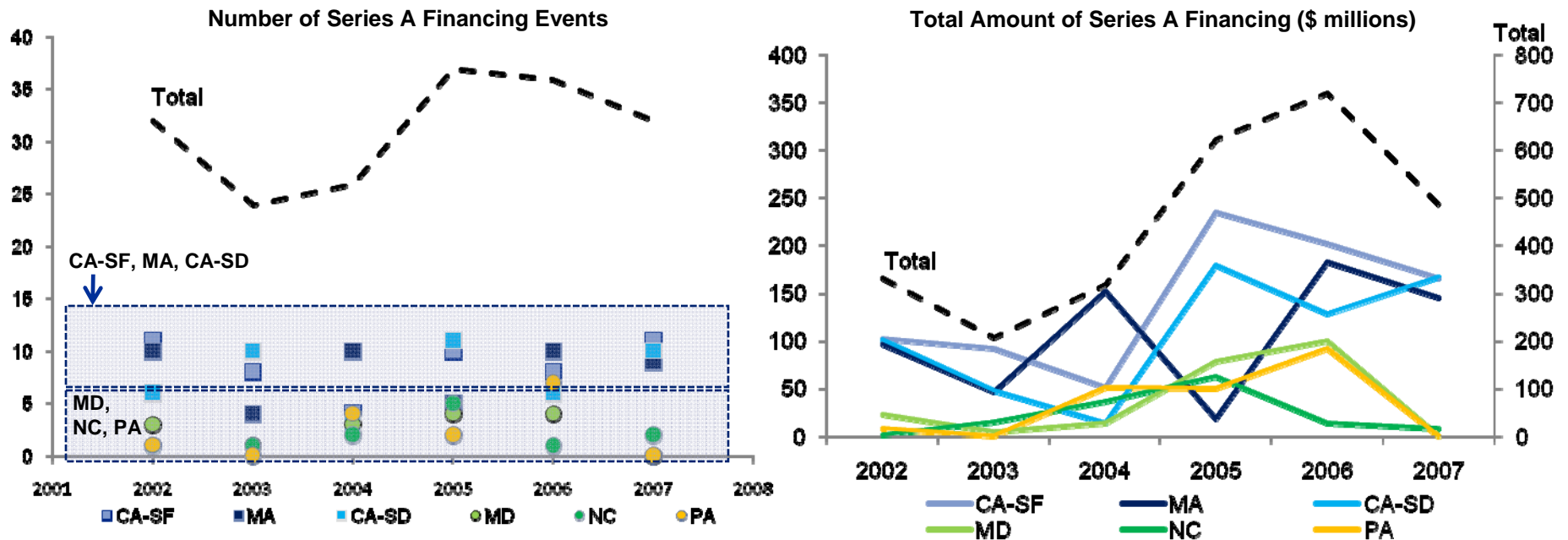
<sup>1</sup> Ratings are not related to cost arbitrage, but to knowledge and skill differentials



————— **Financing the Leading Clusters** —————

## Series A Financing<sup>1</sup>

An analysis of VC activity of the six integrated domestic clusters reveals that SF, MA and SD have historically received more Series A funding that other US clusters, representing the number of new companies being formed



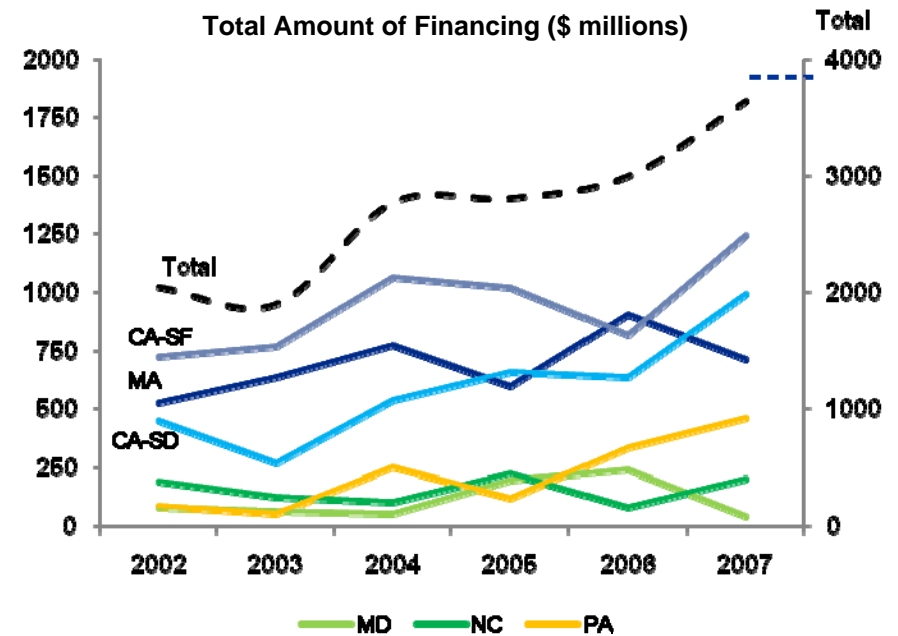
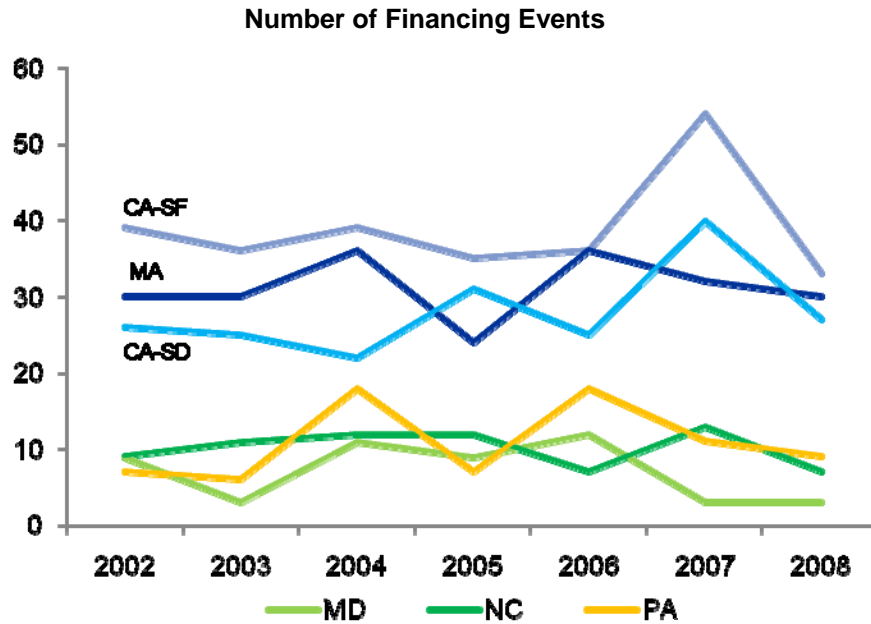
The number and amount of Series A (Start-up) Financing incurs regular cycles; SF, MA, and SD are consistently the leading clusters for new company formation, and in fact, the downtimes of Series A financing appear to have a greater impact on the clusters outside of the “Big 3”

<sup>1</sup> Additional financial details can be found in Appendix B

Source: Deloitte Recap LLC, 2008 data through 2Q08

## Total Amount of VC Financing

As leading clusters, MA, SF and SD also dominate in total number and amount of private company financings.



- Dating back to 2002, VCs have consistently focused on later stage opportunities
- With a robust blend of early to late stage companies, MA, SF, and SD have increased their regional dominance relative to other US clusters during this time period
- Of the Big 3, MA seems to have benefitted least from this financing trend, with fewer late stage investment opportunities to attract investment

## Public Company Cash on Hand

Macroeconomic trends have greatly impacted the financing environment for biotech, and roughly half of the companies in the Industry are in danger of running out of cash in the next year

Percentage of Companies With < X Quarters of Cash On Hand

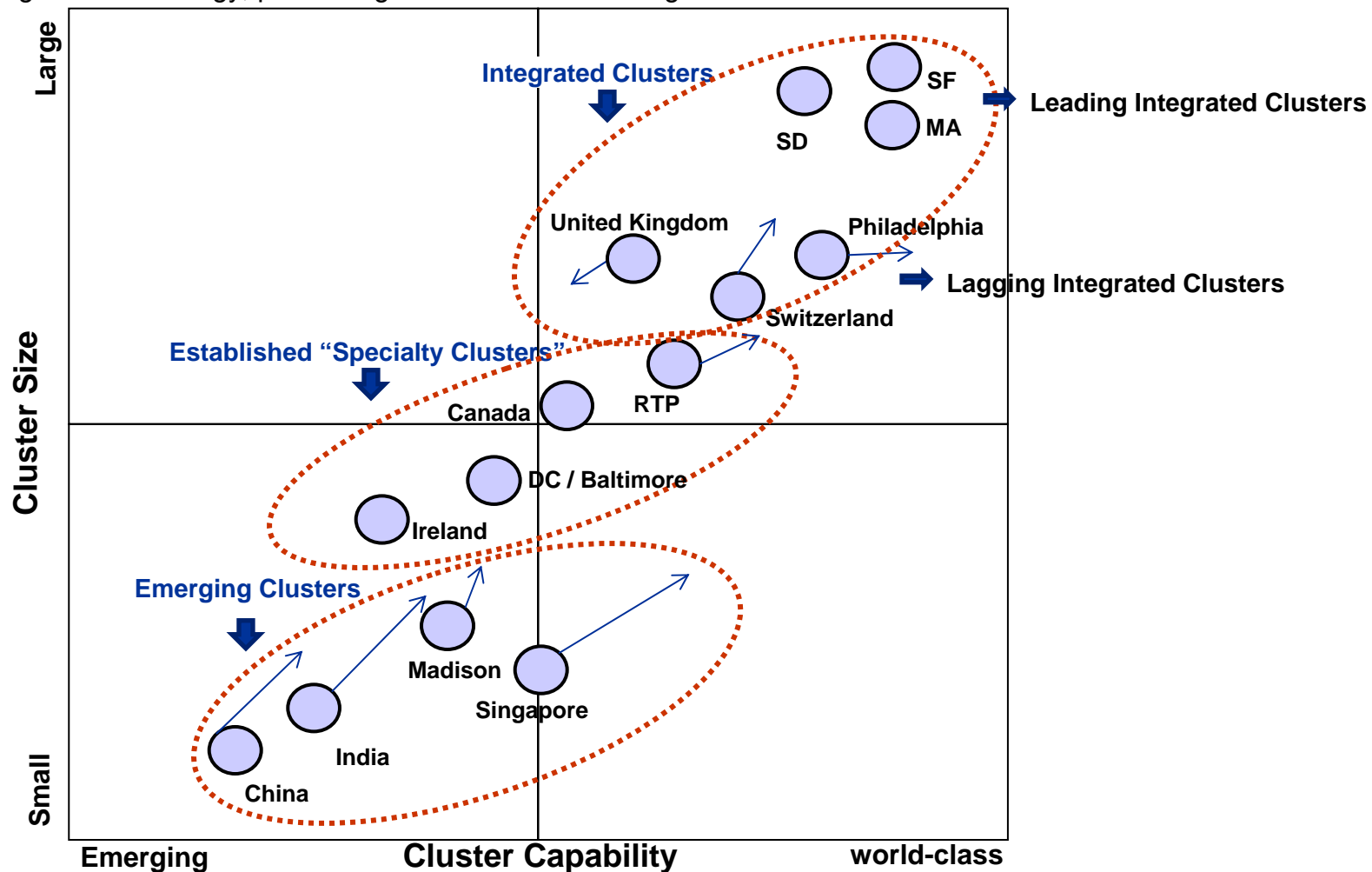
	< 4 Qtrs	< 8 Qtrs
Massachusetts	49%	55%
San Francisco, CA (Northern CA)	51%	56%
San Diego, CA (Southern CA)	46%	57%
Philadelphia, PA	42%	50%
North Carolina	36%	36%
Maryland	71%	76%



**Competitive Analysis Summary**

# Categorization of Clusters

Based on a qualitative and quantitative analysis of select clusters, MA, SD and SF are in a leading position; however, many clusters are investing in biotechnology, positioning themselves for future growth<sup>1</sup>.



## Key Challenges and Barriers

The leading integrated clusters face collective challenges, while many barriers are in place limiting the growth potential of emerging, specialty and lagging integrated clusters.

<i>Leading Integrated</i>	<i>Lagging Integrated</i>	<i>Specialty Cluster</i>	<i>Emerging Cluster</i>
<b>Challenges</b>	<b>Barriers to becoming a Leading Integrated Cluster</b>		
<ul style="list-style-type: none"> <li>▪ <b>High costs</b> - sustaining innovation while balancing cost and value</li> <li>▪ <b>Limited talent</b> pool for less complex but critical activities</li> <li>▪ <b>Collective challenges</b> from emerging and specialized clusters, some of which are focusing on specific functions or types of activities</li> <li>▪ <b>Slow down in VC funding</b></li> <li>▪ <b>Lacks deep commercial talent</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>High costs</b></li> <li>▪ <b>Limited VC funding</b> or non availability of funds</li> <li>▪ Some have <b>clinical trial limitations</b> (Europe based)</li> <li>▪ More mature outlook due to significant influence of big pharma</li> </ul>	<ul style="list-style-type: none"> <li>▪ Focused on <b>one or few functions</b> along the value chain</li> <li>▪ <b>Limited biotech innovative research infrastructure</b> and scale (network is absent)</li> <li>▪ <b>Limited VC funding</b></li> <li>▪ <b>Clinical trial limitations</b></li> <li>▪ <b>Lacks significant network</b> of key biotech stakeholders</li> <li>▪ <b>Limited scientific and commercial talent</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Limited breadth of funding</b>; significant funding for “less complex and more standardized” activities across the value chain or unique platform technologies</li> <li>▪ <b>Reliance on importing innovation</b> due to lack of innovative research infrastructure</li> <li>▪ <b>Innovative business models</b></li> <li>▪ <b>Limited VC funding</b></li> <li>▪ <b>Regulatory uncertainty</b> in India and China</li> </ul>

## Competitive Analysis Summary

While the three leading clusters are in a “class of their own”; MA is a maturing cluster and will need to proactively address its key challenges in order to retain its preeminent position.

- The MA Cluster has key strengths in R&D that if leveraged effectively will help sustain its leadership position
  - MA has an unmatched concentration of world-class research universities and academic medical centers that provide a high level of innovation and a significant homegrown talent source
  - Historically, MA has had a stronghold in start-up and early stage innovative biotech companies; however, VC funding trends indicate a possible downturn in innovation
- The current economic environment is affecting all clusters; according to the analysis of both public and private companies in the US, MA is in no better or worse position to “weather the storm”
- As fragmentation along the value chain continues due to companies striving to reduce costs and become more flexible, specialty and emerging clusters are becoming increasingly attractive for biotech and pharma companies
  - If MA does not strengthen its competitive position, the cluster faces the risk of companies or significant operations of current MA companies shifting or being outsourced to other clusters
- MA has a greater presence of big pharma than SF or SD which contributes to the overall strength of the cluster; however, this may contribute to some cultural and entrepreneurial differences that exist between MA and SD
  - Maturation of MA companies may further contribute to these cultural differences, further increasing the necessity for MA to focus on sustaining its strength in innovation and biotech start-ups

MA is a leader in biotechnology, however its value proposition may be declining if it loses its grip on innovation

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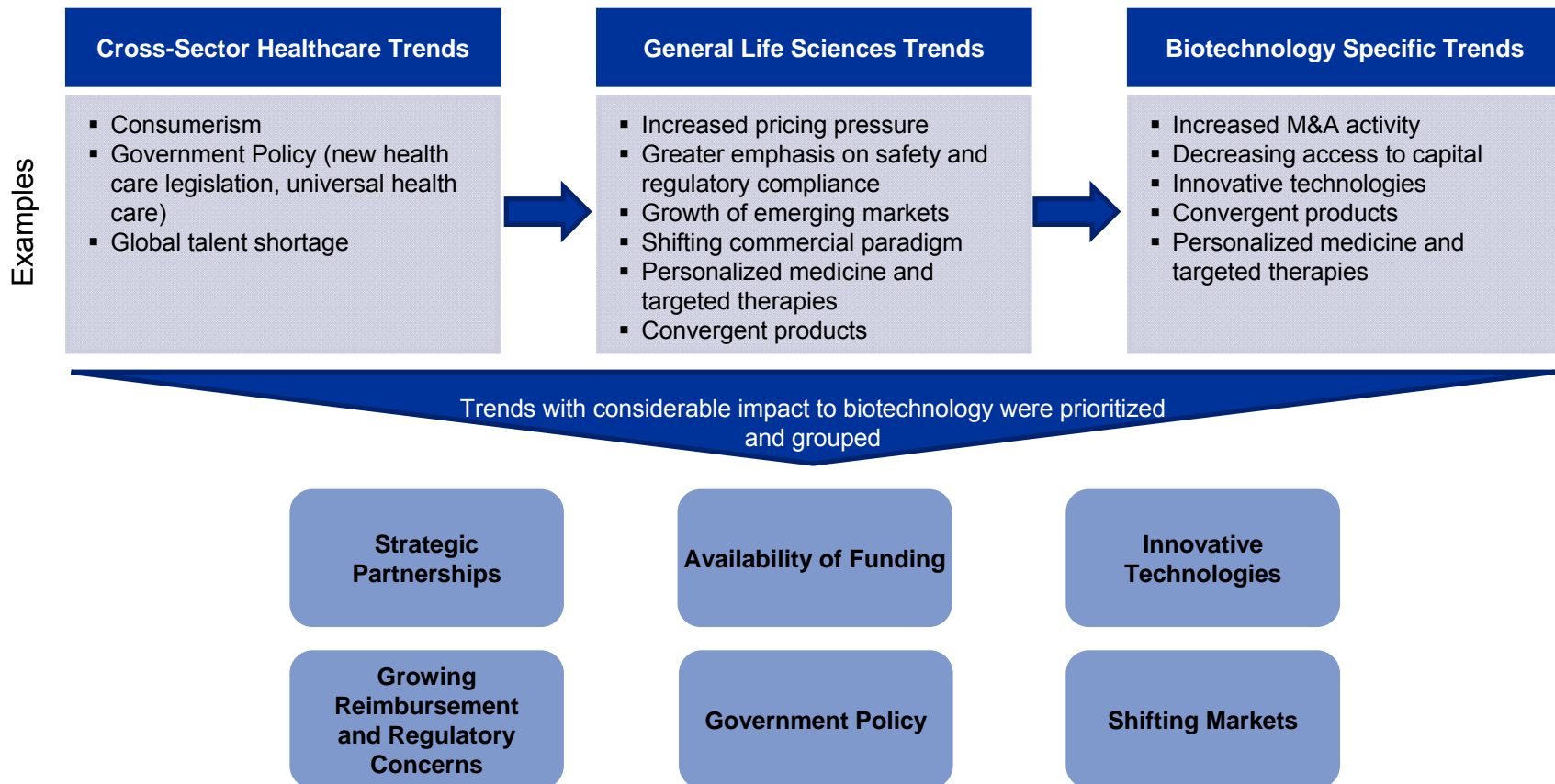
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# Approach

A listing of top trends impacting the biotechnology industry was developed using Deloitte research and subject matter advisors as well as through secondary research (industry overviews and market research).

Trends were compiled by evaluating cross-sector healthcare trends, general life sciences trends and biotechnology specific trends which encompassed scientific, business and policy drivers.



# Key Trend Descriptions

Key trends will shift the overall biotechnology landscape in the next 7 years; some with a greater impact in the near term (1-2 years)

## Strategic Partnerships

- Driven by weak pipelines and decreasing R&D productivity, **big pharma** is becoming increasingly **active in acquisitions and partnerships with biotech companies**

## Availability of Funding

- The **current economic crisis** has resulted in reduced funding for biotech companies
- Many companies are unable to secure funding and are **operating with dangerously low cash levels**
- VCs are **increasingly funding late stage** companies

## Innovative Technologies

- **Personalized medicines and targeted therapies** pose significant opportunities and challenges
- The **combination of drugs, devices, and diagnostics** is leading to innovative health care solutions
- **Novel technologies** such as RNAi, stem cells and MAb continue to provide innovative therapeutic potential

## Growing Reimbursement and Regulatory Concerns

- In an effort to control the rising costs of biologics, payers are beginning to scrutinize treatments, taking into account both **comparative effectiveness and cost-effectiveness**
- **Increasing industry regulation** and litigation are forcing life science companies to be more cautious and **increase their focus** on product quality

## Government Policy

- **Healthcare reform** is a major priority for the incoming president and congress

## Shifting Markets

- External pressures are affecting many healthcare sectors and will impact biotech in various ways
  - These include the growth of **emerging markets, global talent shortage and the shifting drug commercialization paradigm**

## High Impact Trends: Implications for MA

Trends	Impact to Biotech	Implications for MA
<b>Strategic Partnerships</b>	<b>Near Term</b>	<ul style="list-style-type: none"> <li>MA companies would be <b>attractive acquisition</b> targets / strategic partners <b>for big pharma</b></li> <li>MA companies may outsource a growing share of less complex activities to other clusters (e.g., India, China) to enable operational flexibility</li> </ul>
<b>Availability of Funding</b>	<b>Near Term</b>	<ul style="list-style-type: none"> <li>Many <b>smaller MA companies</b> will be <b>forced</b> to find a <b>buyer</b> or <b>discontinue operations</b></li> <li><b>Decreasing NIH funding</b> would impact the number of <b>innovative trials</b> and new molecule discovered</li> <li><b>Cost efficiency plays</b> will drive activities to less costly clusters and MA companies may need to identify other funding mechanisms</li> </ul>
<b>Growing Reimbursement and Regulatory Concerns</b>	<b>Near Term</b>	<ul style="list-style-type: none"> <li>Since MA has a higher percentage of <b>late stage companies</b> they will be significantly impacted by <b>pricing pressures</b></li> <li>Increasing pipeline of biotech drugs and more rigid FDA standards will <b>reduce the availability of patients</b> for clinical trials in MA</li> <li>MA's large presence of early stage companies emphasizes the need for a supportive clinical development environment</li> </ul>

## High Impact Trends: Implications for MA

Trends	Impact to Biotech	Implications for MA
<p><b>Innovative Technologies</b></p>	<p><b>Long Term</b></p>	<ul style="list-style-type: none"> <li>▪ <b>Collaboration</b> among MA's biotech, pharma, device and diagnostics industry may position the cluster as a leader in <b>convergent solutions</b> and <b>personalized medicine</b></li> <li>▪ Investment by other clusters in novel technologies may make it necessary for MA to <b>evaluate</b> what <b>technologies to focus on</b> (e.g., MA may be in a lagging position for stem cell research)</li> </ul>
<p><b>Government Policy</b></p>	<p><b>Long Term</b></p>	<ul style="list-style-type: none"> <li>▪ MA will face the same <b>uncertainties and opportunities</b> as other clusters with respect to <b>new legislation</b> and <b>health care policy</b> reform</li> <li>▪ <b>MA will need</b> to <b>focus public advocacy</b> efforts at both the state and federal level to ensure supportive biotech policies are maintained</li> </ul>
<p><b>Shifting Markets</b></p>	<p><b>Long Term</b></p>	<ul style="list-style-type: none"> <li>▪ <b>Less complex and standardized activities</b> may move to CRO / CMO focused clusters</li> <li>▪ <b>MA companies</b>, research universities and academic medical centers need to <b>focus on growing, developing and retaining talent</b> within the MA cluster</li> </ul>

## Trend: Strategic Partnerships

Biotech M&A deals and strategic partnerships have increased dramatically in recent years and are expected to continue

### Market Trend

- Large pharmaceutical and biotech companies are increasingly pursuing partnership and M&A deals to bolster and diversify their product portfolios in response to weak pipelines
- Biotech and pharma companies continue to look to the convergence of drugs, diagnostics, and medical devices to drive new pipeline development
- In addition, as companies both large and small aim to reduce costs and add flexibility to their operating models, strategic partnerships are increasing along all segments of the value chain

### Market Observations

- Several major transactions occurred recently between big pharma companies with faltering pipelines and smaller biotechs with rich pipeline potential, including:
  - Astra Zeneca's acquisition of MedImmune in April 2007 (\$15.6B)
  - Schering Plough's acquisition of Organon Biosciences in March 2007
  - Japan's Takeda Pharmaceuticals Company Ltd., acquisition of US biotech Millennium Pharmaceuticals Inc. for \$8.8 billion
- Large-cap biotech players are also pursuing aggressive diversification strategies through M&A to boost their growth
  - Amgen entered the diabetes market through its acquisition of Alantox Pharmaceuticals in June 2007
  - Genzyme acquired Bioenvision in May 2007 to bolster its oncology pipeline
  - Other promising biotech companies, such as Biogen-Idec, are actively courting prospective big pharma buyers, such as Pfizer and Bristol-Myers Squibb

# Impact to MA: Strategic Partnerships

## Impact to Biotech

- Biotech companies have more opportunities on the table regarding their expected participation and rate of return due to their pipeline potential
- To achieve success in an era of biotech-pharma convergence, biotech companies need to be nimble about relationship structures and relationships in general, whether at the production, discovery, development or marketing level
- It may well get to the point where the lines between pharma and biotech become completely blurred and production, discovery techniques, and reputation no longer separate
- There will be fragmentation of the value chain, resulting in the emergence of new players, offering enabling solutions for innovative products (e.g., stem cells, genomics) and enabling activities (e.g., animal studies, toxicology studies, market research)



## Implications for MA

- MA companies would be attractive for big pharma to consider as acquisition targets / strategic partners as the region contains a broad array of companies
- The number of independent companies in MA will be reduced
- MA companies may outsource a growing share of less complex activities to other clusters (e.g., India, China)

## Trend: Availability of Funding

The current economic crisis and the resulting decreased access to capital is having significant effects on the biotech industry

- Decreased access to capital is affecting biotech companies of all sizes as public biotech companies have seen their share prices decrease dramatically and many smaller biotech companies are operating with less than a year's worth of cash
- VC, public equity markets and big pharma have increasingly focused on late-stage biotech companies, leaving an even greater early stage funding gap

### Market Trend

- Despite the fact that biotech companies are snagging a growing share of the billions of dollars in venture capital, most of that is going toward late-stage developers who can offer investors a less risky bet at a near-term payback
- Venture capitalists are increasingly favoring investments with more predictable capital needs and exits, investing in business model innovation instead of scientific innovation
- In the U.S., NIH funding increases have slowed dramatically in recent years which has further limited the amount of funding available for academic medical centers

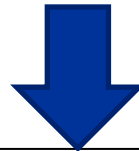
### Market Observations

- So far this year, public and private biotechnology companies have raised \$5.6 billion: only one-third the amount in all of 2007 and likely to be the lowest amount since 2002
- Start-ups are dealing with a challenging funding environment
  - Since 1995, early-stage funding has dropped from 45 percent of deals to 26 percent in 2007
- An analysis of U.S. public biotech companies in six major clusters revealed that approximately 50% of companies are operating with less than a year's worth of cash
- Recently, smaller pharma companies have seen their stock prices decline more on average than larger companies - this may impact biotechs that are holding out for large acquisition offers

## Impact to MA: Availability of Funding

### Impact to Biotech

- Diminished venture capital funding, bank loans and public equity markets are hampering biotech's ability to invest in R&D and commercialization activities
- Strategic buyers (large pharma) may be well-positioned for acquisitions on account of falling biotech share prices and large pharma's historically high levels of cash to finance transactions; without VC financing available, many biotech companies will be more willing to take low offers from cash-rich pharma companies
- Biotech companies may have to develop new financing models aimed at generating revenues from the early stages of product development
- Biotech companies of all sizes are performing unprecedented cost containment efforts and many small companies will be forced to limit the breadth of R&D activities



### Implications for MA

- Many MA companies will be forced to find a buyer or discontinue operations; thus lowering the overall number of companies
- Coupled with the trend towards strategic partnerships, falling biotech share prices and high levels of cash-starved companies will lead to increased M&A activity from big pharma, creating even greater consolidation
- MA companies may need to identify other funding mechanisms in order to continue investment in R&D
- Decreasing NIH funding would impact the number of innovative trials and new molecule discovery; lack of funding may move some innovation to newer clusters that have government funding
- Cost efficiency plays will drive activities to less costly clusters

## Trend: Growing Reimbursement and Regulatory Concerns (Pricing Pressures)

In an effort to control the rising costs associated with therapeutics (including biologics), payers are beginning to scrutinize treatments, taking into account both comparative effectiveness and cost-effectiveness

### Market Trend

- Payer initiatives to reduce costs are challenging biotech drug pricing
- Until recently, payers have generally avoided restrictions on biologics; however, the number of biologics and the rise in expenses associated with them are growing rapidly
- In an effort to curb prescription drug costs, public and private payers are implementing strategies that will impact pricing for biotech companies; such strategies include
  - Restricting formularies
  - Requesting physicians for prior authorizations
  - Raising higher co-payments on costly biotech drugs
  - Promoting the use of lower-cost therapeutic-equivalent drugs

### Market Observations

- In the US, health plans are increasingly assessing the clinical efficacy of a new product versus its cost
- Europe has taken and is likely to continue to take a more visible stance on the issue
  - Recently, the UK's National Institute for Health and Clinical Excellence (NICE) recommended that its National Health Service not pay for six different cancer drugs, including Genentech's Avastin, either for lack of efficacy or for being too expensive versus other options
- Increased competition has also lowered pricing, evidenced by
  - Amgen's introduction of its colorectal cancer drug, Vectibix, at a 20 percent discount to ImClone's Erbitux in September 2006

## Impact to MA: Growing Reimbursement and Regulatory Concerns (Pricing Pressures)

### Impact to Biotech

- The key development milestone is shifting from gaining product approval to securing product reimbursement
- Pricing pressures (e.g., increased payer scrutiny or consumer utilization decisions) result in lower revenues for companies with commercial products in the short term, but ultimately limit the amount of investment in R&D and decrease the incentive for future innovation
- Biotech companies must start building an organizational infrastructure to include pharmaeconomic analysis into their development practices
- Biotech companies must employ similar strategies as big pharma: working more collaboratively with a growing number of external stakeholders to make informed decisions regarding product development



### Implications for MA

- As the MA cluster matures and more companies enter the revenue generating stage, reimbursement challenges will become an item of increasing importance
- The MA cluster will be more significantly impacted by pricing pressures than other clusters with smaller percentages of late stage or commercialized companies

## Trend: Growing Reimbursement and Regulatory Concerns (Regulatory Compliance)

Increasing industry regulation and litigation are forcing life science companies to increase their focus on product quality, more effectively plan for and mitigate adverse events and establish greater credibility with regulatory agencies and consumers

### Market Trend

- Emphasis on safety and regulatory compliance is increasing and as a result FDA requirements are more stringent
- Companies looking to sell products in the U.S., the world's largest drug market, are facing an environment of heightened patient safety concerns
- FDA approval of NMEs have declined significantly and are at their lowest levels since 1983; in addition, some of the industry's most successful products have had serious safety questions emerge post-launch which required a "black box" warning, the strictest label
- Requirements for clinical trials are more stringent in the wake of drug safety issues, resulting in FDA requests for longer and larger clinical trials
- FDA concerns about drug safety led it to delay approvals for several biotechnology therapies, opting instead to issue "approvable letters", which in essence ask manufacturers to provide more information about the product under review before the agency makes a final decision
- The amount and type of information requested by the agency varies, so delays can last for several months to several years

### Market Observations

- In 2007, President Bush signed into law the reauthorization of the Prescription Drug User Fee Act (PDUFA) granting the FDA more post-marketing authority
  - The bill triples post-marketing drug manufacturer fees to enable the FDA to fund drug safety activities
  - The bill also contains clauses addressing drug safety, post market studies on new medications, prescription drug advertisements, clinical trial disclosures, pediatric trials, and conflicts of interest on FDA advisory committees

## Impact to MA: Growing Reimbursement and Regulatory Concerns (Regulatory Compliance)

### Impact to Biotech

- The FDA's conservative position on drug safety and efficacy could drive increased operating costs for biotech companies in the future
- Increased regulatory compliance burdens in areas such as privacy, post-marketing monitoring of drug safety and sales-force compliance poses internal challenges to biotech companies and increases the cost of compliance (potentially diverting funds from R&D activities)
- However, many new biotech drugs are directed at hard-to treat serious illnesses and thus could benefit from some of the FDA's new programs related to broadening access to experimental medicines for these diseases



### Implications for MA

- MA's large presence of early stage companies highlights the importance of a supportive clinical development environment
- Increasing pipeline of biotech drugs and more rigid FDA standards will reduce the availability of patients for clinical trials in MA

## Trend: Innovative Technologies (Personalized Medicine)

Personalized medicines and targeted therapies pose significant opportunities and challenges to the industry

### Market Trend

- Targeted therapies with companion molecular diagnostics have quickly progressed from idea to realization while innovation continues in discovery and development
- Pharma and biotech are more consistently evaluating targeted, smaller market niches
- Targeted therapies are expected to help decrease the number of adverse drug reactions and failed drug trials, the time it takes to get a drug approved, the number of medications patients must take to find an effective therapy, the length of time patients are on medication, the effects of a disease on the body (through early detection)
- A targeted approach to drug treatment will result in trials aimed at pre-selected focus groups, resulting in lower development costs and increased margins; targeting existing drugs to specific populations may be more cost-effective

### Market Observations

- The worldwide market for pharmacogenomics therapies' R&D spending reached \$1.24 billion in 2004 and is projected to rise at an average annual growth rate (AAGR) of 24.5 percent to reach \$3.7 billion by 2009
- Although the revenue potential of any one new therapy or group is as yet unknown, the growth of pharmacogenomic therapies is critical, given the amount of anticipated revenue loss from products going off patent
- New FDA regulations (Risk Evaluation and Mitigation Strategies, or REMS) allow the agency more ways to say "yes" to new drugs by placing extra restrictions that limit the patient population that can access the product
  - In many ways REMS is creating extra incentives for pharma and biotech companies to target specific patient populations which should result in faster and cheaper development times
  - The role of genetic-based diagnostics in the development of personalized medicines has already shortened the R&D cycle for those products

## Impact to MA: Innovative Technologies (Personalized Medicine)

### Impact to Biotech

- A collaborative approach across industry stakeholders is required to drive the implementation of personalized medicine; unique partnerships in the areas of diagnostics, treatments and prevention will be required with providers, health plans and employers as they have the patient data that holds the key to personalized medicine
- Biotech companies that can identify these niche opportunities and choose the less risky development path, may be able to sell the results to larger drug companies or build their own specialist businesses
- Personalized medicine may also help biotech with funding from non-traditional sources such as private foundations and governments



### Implications for MA

- MA's large concentration of stakeholders necessary to drive forward personalized medicine provides the cluster with the potential to take a leadership role in this field

## Trend: Innovative Technologies (Convergent Solutions)

The promise of enhanced therapeutic efficacy has prompted investment in a wide variety of convergent solutions; sectors within the life sciences industry will continue to converge, fostering a greater degree of collaborations among pharma, biotech, medical device and diagnostics companies.

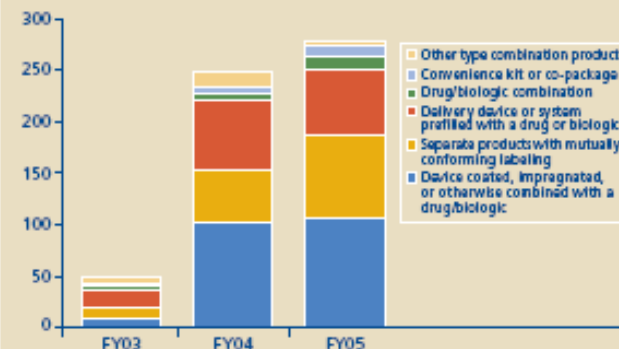
### Market Trend

- The combination of drugs, devices, and diagnostics is leading to innovative health care solutions and new opportunities for growth and differentiation
- The convergence of therapeutics and medical devices, which started in earnest with the drug releasing stent, will continue and become increasingly sophisticated, improving efficacy and reducing the risk profile of many existing therapeutic agents
- Combination products are a trend projected to impact all life science sectors including a pipeline-starved pharmaceutical sector, a funding-strained biotech sector, an innovation-focused device sector, and an emerging diagnostics sector
- Because of their greater resources, experience with partnerships and acquisitions, and ability to realize economies of scale and scope, large pharmaceutical and device companies have the opportunity to drive the trend toward bringing multiple, cross-sector capabilities into a single enterprise

### Market Observations

- Firms like Johnson & Johnson, Boston Scientific, Abbott, and Medtronic are creating integrated solution pipelines and building portfolios of related products through convergence, a trend that may come to characterize the life sciences industries
- The number of combination products under development is rising quickly as developers seek to enhance existing products and introduce fundamentally new health care solutions to the market

Figure 1. Number of applications submitted to the FDA's Office of Combination Products



Sources: U.S. Food and Drug Administration, Office of Combination Products, FY2003 Performance Report to the Congress for the Office of Combination Products and FY2004 Performance Report to the Congress for the Office of Combination Products. Mark D. Kramer, Regulation of Combination Products: ACRP 2006, accessed April 23, 2007 <<http://www.fda.gov/oc/combination/presentations/>>.

## Impact to MA: Innovative Technologies (Convergent Solutions)

### Impact to Biotech

- Through convergence, some biotech firms will be able to secure a stronger position than they might have on their own; licensing and partnering with device and diagnostics companies are viable options, but the risk (or opportunity) of becoming an acquisition target remains strong
- Developing a combination product requires more than the integration of disparate technologies; based on the majority of convergent solutions on the market today, partnerships are necessary to secure capabilities
- Companies will need to develop an effective convergent R&D culture: companies face cultural and organizational issues when building teams comprised of separate drug and device R&D organizations



### Implications for MA

- Collaboration among MA's biotech, pharma, device and diagnostics industry may position the cluster as a leader in convergent solutions

## Trend: Innovative Technologies (Other)

Continued research and development of emerging novel technologies (e.g., RNA Interface (RNAi), Stem Cells, Monoclonal Antibodies (MAB) offers significant therapeutic potential

### Market Trend

- RNA Interference (RNAi) represents a novel paradigm for drug discovery and the treatment of disease by selectively interfering with disease-associated genes
  - Discovery and development of this technology enables rapid validation of potential drug targets, functional genomics research and development of novel therapeutics; however, drug delivery is the single greatest challenge remaining in the development of RNAi as a broad therapeutic platform
- The use of stem cells as therapeutic treatments has made significant progress in recent years; expanded federal support of embryonic stem cell research will likely spur further innovation
- Commercialized MABs have achieved great success in the market place and are poised to continue to do so, supplemented with a strong pipeline of innovative MABs in late stage development
  - MABs have seen a large number of product approvals in recent years; there are presently 20 products in the market and about 200 products under different stages of clinical development

### Market Observations

- The RNAi market is expected to expand 5X between now and 2012 with RNAi therapeutics having the most potential for revenue growth
- The stem cell market has grown from zero to \$87 million in less than three years, and analysts at the year's Stem Cell Summit forecasted its growth to \$8.5 billion over the next decade
- Several large pharmaceutical companies are investing in regenerative medicine technologies
  - Last spring, Pfizer opened a "regenerative medicine unit" in Cambridge, MA and plans to open another similar shop in Cambridge, U.K.,
  - In July, GlaxoSmithKline Plc signed a deal worth more than \$25 million with the Harvard Stem Cell Institute to use stem cell technology for drug development
  - Last year, GlaxoSmithKline, AstraZeneca Plc and Roche launched Stem Cells for Safer Medicines, a collaboration to use stem cells for safety testing of new drugs
  - The monoclonal antibody market has grown rapidly over the last six years consistently registering growth rates exceeding 30%; demand for therapeutic monoclonal antibodies (MABs) is forecasted to reach \$38.0 billion in 2012, making MABs the largest biotech segment

## Impact to MA: Innovative Technologies (Other)

### Impact to Biotech

- Companies will need to rapidly develop, acquire and integrate new technologies and capabilities to extract value from investments and be able to acquire the necessary talent and devote significant resources to R&D in order to bring discoveries towards development and commercialization
- Public and private funding of stem cell research continues to grow and stem cells are one of the most popular areas of current investment; as access to capital is becoming increasingly difficult, investing in stem cell research may prove beneficial for biotech companies
- Explosive growth in the area of therapeutic antibodies in recent years has stimulated new demand for improved production and manufacturing techniques; companies able to capitalize on improved production techniques may be poised for even further growth



### Implications for MA

- The presence of MA companies engaged in innovative technology R&D may provide a foothold for future growth within the cluster
- Competition and investment by other clusters in novel technologies may make it necessary for MA to evaluate what technologies to focus on (e.g., MA may be in a lagging position for stem cell research)

## Trend: US Government Policy

Health care is expected to be one of the top priorities for President Obama and the Democratic Congress –Major items that will likely be addressed include: implementation of a universal health care system, introduction of measures to decrease the price of drugs (negotiated bulk purchases of drugs for Medicare enrollees, re-importation of drugs from overseas, price controls), passage of a regulatory bill that allows abbreviated FDA approval for follow-on biologics, patent reform

### Market Trend

- Policy and industry experts predict that Obama will focus efforts on cutting overall health care costs and that pharma will be a major target
- High on the Democratic agenda are direct government-negotiated pharmaceutical pricing, drug reimportation from Canada, and a new pathway for generic imitations of biologic medicines
- However, that loss could be offset at least partly by the Democratic candidate's efforts to cut the number of uninsured people; if his plans come to fruition, more people will be able to afford prescription drugs to begin with
- Obama's plans include controlling prices on expensive biotech drugs, plans to regulate DTC advertising and a push toward generics
- Positives for the biotech industry include Obama's support of embryonic stem cell research, a move from "ideological to a science-based" policy, and greater funding for the FDA

### Market Observations

- Various bills concerning follow-on biologics (FOB) were considered in 2007/2008 and policy experts predict more FOB activity in 2009
  - FOBS or biogenerics, are a critical issue for the entire biotechnology industry as they represent a potential opportunity for cost savings
  - A key obstacle to bringing copies of biologics to market in the United States is the lack of a regulatory pathway for approval as safety questions remain about the ability to test the bioequivalence of biologics
  - In February 2008, President Bush included the authorization for the FDA to establish a regulatory pathway for biosimilars in his last budget request.
- Pricing pressure legislation (modifications to the Medicare Modernization Act) received increased attention under the Democratic-Led Congress and is expected to continue in the next term
- Patent reform legislation may also have significant implications for biotechnology companies

## Impact to MA: US Government Policy

### Impact to Biotech

- The establishment of a regulatory pathway for FOBs will have a profound impact on the industry and will potentially result in many new entrants focusing on biogenerics (e.g., big pharma, generic manufacturers); companies facing FOB competition could see significant declines in product revenue
- Measures to reduce the price of drugs will result in a downward pressure on reward, and could eventually result in decreased incentive for innovation and investment in R&D; small biotechs with limited commercialized products may also be impacted more directly due to revenue decreases
- Patent reform debate could impact IP protection and raise patent risks



### Implications for MA

- MA will face the same uncertainties, challenges and opportunities as other clusters with respect to new legislation and health care policy reform
- MA will need to combine and focus public advocacy efforts across all key stakeholders at the both the state and federal level to ensure supportive biotech policies are maintained / improved

## Trend: Shifting Markets (Talent Shortage)

The life sciences industry faces a global talent shortage; the demand for skilled-life sciences workers far exceeds their supply, most notably in the US

### Market Trend

- Key talent in emerging scientific areas will be competitively recruited (and poached) not only by the health care and life sciences industries, but also by government, university, and non-traditional but lucrative positions in management consulting and investment banking.
- While there does exist a much richer biotech talent pool outside of the US, the US limits the number of visas it grants to foreign employees
  - In 2007 the federal government had received almost three times as many visa applications as it will approve and biotechs anticipate filing even more applications in coming years

### Market Observations

- In the West, the study of scientific disciplines has declined precipitously in the last 50 years
  - In the United States, only 5 percent of college graduates obtain a science or engineering degree, compared to 50 percent in China
- According to a recent National Science Foundation report, the demand for biotech workers is outpacing the rate at which U.S. universities are churning out graduates
  - Because academic institutions aren't able to satisfy the industry's demand for new PhD graduates, attracting and keeping workers is becoming an increasingly serious problem in the drug development process

## Impact to MA: Shifting Markets (Talent Shortage)

### Impact to Biotech

- The inability to secure the right talent at the right time can be a growth-limiting factor for biotech organizations
- It is critical for biotech companies to hire and retain strong managerial and leadership teams, including alliance managers, M&A specialists, corporate development managers, and intellectual property lawyers; venture capitalists often assess the strength of management before financing these companies
- Biotech has done a historically better job developing and retaining talent than pharma or medical device but are generally heavy on “R” and not “D”; thus, biotechs must have enough resources to hire, develop, and retain their critical workforce segments in manufacturing, sales and marketing, and general management or merge with another company that can



### Implications for MA

- MA companies as well as research universities and academic medical centers need to focus on growing, developing and retaining talent
- MA will need to ensure that its world-class universities and graduate degree / medical programs remain attractive and retain graduate students and PhDs in the MA workforce

## Trend: Shifting Markets (Emerging Markets)

Emerging markets are growing in influence as both consumers and developers

### Market Trend

- The role of emerging markets as developers and consumers across the life science sector is projected to significantly grow in the next decade
- Life science companies are expanding globally to combat declining pipeline productivity, capitalize on emerging health care markets and generate profitable growth
- To improve profitability, life science companies are outsourcing operational activities to lower-cost countries such as India and China
- U.S. life science companies are increasingly targeting emerging markets for future growth
  - Life science companies estimate 25 percent of their revenues to come from emerging markets by 2015
  - Demand for pharmaceutical products in many emerging markets is beginning to mirror demand in the global market, primarily as a result of a shift in disease patterns from acute to chronic disorders

### Market Observations

- Life science companies are expanding current operations and establishing facilities and partnerships in countries and regions including China, India and Eastern Europe.
- The forecasted increase in the number of patients with diseases such as cancer in emerging markets, may lead to fast growth in the size of their markets
- By 2020, industry analysts project the greatest demand for health services will come from Eastern Europe, the Pacific Rim and Africa
- Clinical trials and manufacturing are the two most popular functions outsourced by U.S. life science companies globally
- 72 percent of all global drug companies are considering the outsourcing of clinical trials to emerging markets
- Both India and China offer a cost-effective labor pool and large population for potential customer demand
  - India also has a highly educated, English-speaking, science-driven population, which offers further potential for in-country drug discovery and development

## Impact to MA: Shifting Markets (Emerging Markets)

### Impact to Biotech

- To succeed, companies will need to select the right investment expansion strategy and expand necessary capabilities which include an effective regulatory strategy, M&A experience, alliances, outsourcing, R&D, manufacturing, and sales and marketing
- Companies will need to develop key relationships with foreign governments and build new business models in the form of affiliations with local companies
- The emergence of biotech start-ups in emerging markets may distract the US-based investor community
- Increased use of emerging markets for R&D and manufacturing may pose challenges to regulatory agencies in terms of safety monitoring and approval processes



### Implications for MA

- Some of MA's less complex activities will move to CRO / CMO clusters and other clusters offering innovative business models / enabling development solutions

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## Stakeholders Needs Assessment: Approach

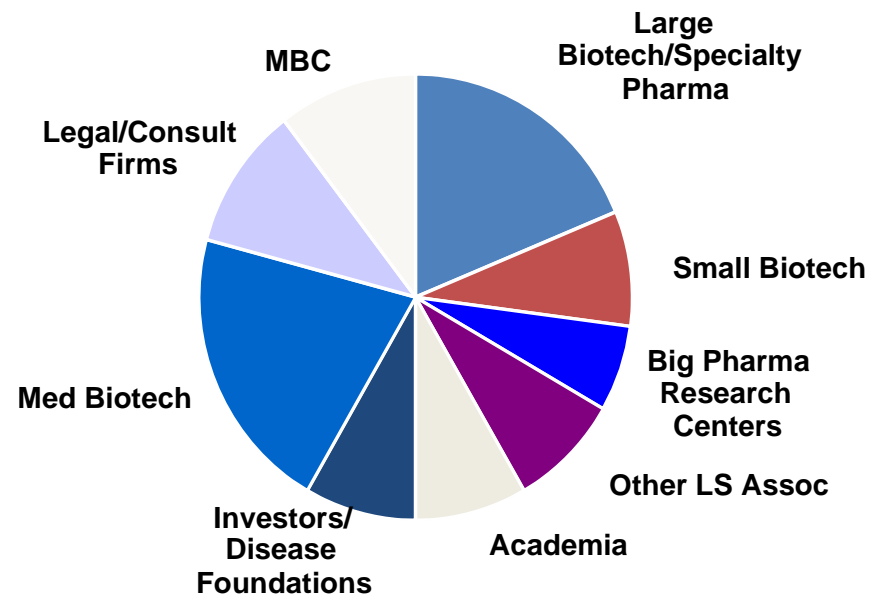
- Stakeholder needs were assessed through one on one interviews and a workshop effort to gather insights on the industry trends, cluster competitiveness, and MBC's role from the perspective of its stakeholders
- We involved 48 stakeholders in interviews and government affairs focus group to explore the following questions:
  - What are the top-of-mind industry trends and what implications do they have for MBC and its stakeholders?  
How should the MA cluster position itself competitively?
  - What are MBC stakeholders' needs and expectations?  
How well do the current offerings from the MBC address those needs?
  - What are the critical and unmet needs of the MBC's key stakeholders, looking out to 2015?  
What capabilities does MBC need to prioritize and develop in order to provide value to its members?

Stakeholder Type	Outputs
MBC Leadership and Staff	<ul style="list-style-type: none"> <li>• Internal perspective on MBC's role, capabilities, successes and opportunities to date</li> <li>• MBC's current vision and objectives looking ahead; possibilities and limitations</li> </ul>
MA Private Sector Executives	<ul style="list-style-type: none"> <li>• Current top-of-mind industry trends and their implications on MBC members</li> <li>• External perspective on MBC's current and future role, capabilities and opportunities</li> </ul>
Academic / Clinical Research Centers	<ul style="list-style-type: none"> <li>• Needs and challenges in maintaining research pipeline (education, funding, etc)</li> <li>• Opportunities with the private sector (e.g., transferring technology to industry)</li> </ul>
Government, Trade and Regulatory	<ul style="list-style-type: none"> <li>• Policy-makers' perspective on the role of biotech in local economy and policy</li> <li>• Current issues under consideration; opportunities for MBC input and participation</li> </ul>
Investors	<ul style="list-style-type: none"> <li>• Current industry trends and their implications on MBC members</li> <li>• Opportunities and challenges related to future financing and investment deals</li> </ul>

## Key Stakeholders – Cross Section of Participants

The interviews and focus group involved a large cross section of MA stakeholders to provide valuable input to the current MA cluster situation, the future opportunities and the role MBC could play.

### Cross Section of Interviewees and Focus Group Participants



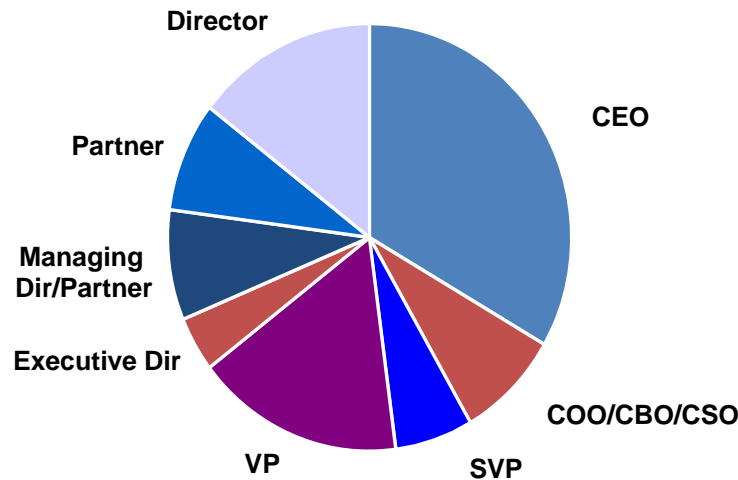
**Note:**

Small biotech = 1-50 WW employees  
Med biotech = 51-500 WW employees  
Large biotech = 500+ WW employees

# Key Stakeholders – Cross Section of Roles

Senior level leadership participation from the stakeholder organizations ensured that the level of input provided represented the highest level of strategic thinking for the MA cluster

## Cross Section of Participant Roles



## Companies

- Alnylam Pharmaceuticals
- Archemix Corporation
- Ariad Pharmaceuticals
- Ascent Therapeutics, Inc.
- Astra-Zeneca R&D Boston
- Aveo Pharmaceuticals
- Beth Israel Deaconess Medical Center
- BIND Biosciences, Inc.
- Biogen Idec Corporation
- Cubist Pharmaceuticals
- Dana Farber
- EMD Serono
- Flagship Ventures
- Foley Hoag
- Genzyme Corporation
- Goodwin Procter LLP
- GTC Biotherapeutics
- Juvenile Diabetes Research Foundation (JDRF)
- LEK Consulting
- Life Science Center
- Mass BioEd
- Mass Technology Collaborative / Mass LS Collaborative
- MassMEDIC
- MaxThera, Inc.
- MBC
- Merck and Co.
- Millenium/Takeda Oncology
- Millipore Corporation
- Momenta Pharmaceuticals
- Nixon Peabody
- Novartis Institutes for Biomedical Research
- Organogenesis Pharmaceuticals
- Oxford Biosciences
- Partners Healthcare
- Sepracor
- Skyline Ventures
- Targanta Therapeutics
- Vertex Pharmaceuticals

## Stakeholder Views of Key Trends

The increasing role of government, economic crisis, changing regulatory landscape, and consolidation within the biotech industry represent the greatest concerns of MBC stakeholders



In light of these trends, stakeholders articulated four areas of needs: policy / regulatory, access to capital; collaboration / partnerships and operations

# Stakeholder Needs – Policy / Regulatory

MBC's stakeholders are "tentative" about the incoming administration and have many concerns related to federal / state policy changes, regulatory pressures, role of government and the overall impact on biotech.

## Med-Large Biotech / Pharma

- IP protection / exclusivity to sustain innovation
- Favorable legislation on bio-generics and drug importation
- Levelling of Federal and State restrictions on Sales and Marketing
- Regulatory pathways to provide personalized medicine / diagnostics to improve targeted treatment
- Updated regulatory policies on drug / device combinations and green technology
- Relaxed / effective regulations for establishing mfg. facilities and expanding R&D capabilities in MA

## Small Biotech

- Advocacy to ensure a portion of the \$1B LSI goes to small biotech in MA
- Increased R&D tax credits to encourage investments in early stage research
- Advocacy for a new suite of tax incentives for non-commercial biotech
- Support for investments in innovative technologies (e.g., stem cells, novel platforms)
- State / Federal advocacy to ensure changes in healthcare policies include small biotech's needs

## Academic Medical Centers

- Increased R&D tax credits to encourage investments in early stage research
- Political outreach to ensure MA is well represented on any changes to PCAST (President's Council of Advisors on Science and Technology)

## Investors

- Regulatory policies and pathways to clear the way for profitable investments in personalized medicine / diagnostics, drug / device combinations, and green technology

"The MA biotech cluster is a fragile supremacy - it depends on NIH innovation as long as innovation is being rewarded"

"We need to talk more about the therapies and the societal burden to pay - shift the discussion from value-based to economic benefit"

"MA biotech should get out in front of the bio-similar debate and help set the regulatory guidelines. Then we should begin developing them here - no one can do it better than us"

## Stakeholder Needs – Access to Capital / Funding

The impact of the current economic crisis affects all stakeholders, however, small biotech and academic medical centers are feeling the largest impact and raising the highest crisis call

“MA biotech is a highly fragile industry. We are in crisis! This is a call to action to MA Legislators”

### Small Biotech

- Immediate access to capital to support organizational survival
- Connections to new sources of funding:
  - Big pharma / large biotech venture funds
  - Disease foundations
  - Non-traditional funding sources (ex-U.S.)
  - Government provided funds and tax credits (e.g., reverse restrictions on SBIR, R&D tax credits for early stage research)

### Academic Medical Centers

- Increased NIH funding (\$s) to continue to foster innovation and support retention of key research personnel
- Access to funding that enables Biotech spin offs: potentially through large pharma / commercial biotech

### Investors

- Current company survival and / or exit / sell opportunities
- Visibility into new potential investment choices and their potential return

“1/3<sup>rd</sup> to 1/2 of small biotech will merge, sell, or close-up shop over the next 9-12 months”

“Access to capital and decreasing NIH funding are the two biggest financial challenges the MA Cluster will face in maintaining its cutting edge science, innovation and competitive positioning”

# Stakeholder Needs – Operational

As one interviewee stated, “once you have talent and money, all other infrastructure will fall into place”. Unfortunately, the MA cluster is experiencing challenges in all 3, many of which can be addressed by MBC.

## Med-Large Biotech/Pharma

- Implement new commercial models to improve operating cost structures and margins
- Explore outsourcing opportunities to reduce expenditures in Research and potentially in Development.
- Improve efficiencies in transferring innovation in from academia
- Identify streamlined processes to expand mfg and R&D infrastructure in MA
- Retain top talent, scientists by providing additional incentives to remain in MA
- Increase interest in science and technology by creating job shadowing / internship opps for H.S. and college students

## Small Biotech

- Expand purchasing consortium offerings, discount / service contracts and outsourcing offerings to gain better cost efficiencies
- Support retention of top talent
- Identify shared research facilities / laboratory space / equipment / personnel to reduce start-up costs, lower need for capital

## Academic Medical Centers

- Accelerate discovery and translational capabilities
- Expedite novel compounds into clinical trials
- Support translational informatics-related processes to enable better technology transfer from academia to industry
- Retention of talent when access / approval of grants are constrained

## Investors

- Transparency into operational efficiencies of invested companies
- Recruit leadership from local talent and / or bring new jobs / talent into MA

“There are many barriers to getting other companies to locate / relocate / expand in MA – land, permits, infrastructure. We’ve got to find a way to make this easier.”

“We’re going to start seeing a reverse brain drain if we don’t pay attention to keeping our talent.”

The GPO / Purchasing Coalition supports small biotech. MBC should expand it to include more discounts / service contracts and outsourcing offerings, and find ways to offer it to other LS organizations.”

## Stakeholder Needs – Collaboration / Partnering

Collaboration was a common theme in over 83% of the interviews; whether for scientific discussion, product development, international partnerships, or access to funding - going it alone is no longer considered optimal

### Med-Large Biotech / Pharma

- Assess opportunities for partnering with universities, amc's, small biotech, and VCs
- Identify opportunities to develop innovative treatments through collaboration with small biotech and AMCs
- Identify virtual R&D opportunities within U.S. or ex-U.S.

### Small Biotech

- Support innovation in stem cells, niche areas and disruptive technologies through collaboration
- View what VCs and angel networks are interested in funding
- Identify opportunities for collaboration with large pharma / biotech
- Identify partnership opportunities for shared R&D, laboratory space, equipment and personnel

### Academic Medical Centers

- Outsource drug discovery capabilities to Big Pharma
- Collaborate with industry to develop personalized medicine / diagnostics for targeted treatment
- Collaborate with industry to conduct stem cell research with clinical potential

### Investors

- Connect with innovations with good potential in academia and biotech
- Support investments in drug / diagnostic / device convergence

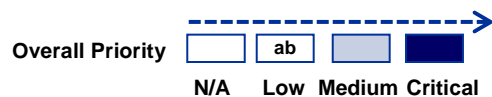
**“We need to play a proactive role in international collaboration. We need to reach out to Global companies for cross-learning and partnership opportunities.”**

**“In the future, Biotech will not build out all components of the value chain – we will have to partner.”**

**“We need to start thinking in terms of “consortiums” for targeted therapeutic area development. Bring together biotech, big pharma, AMCs and Univ. and start the dialogue.”**

# Prioritized Stakeholder Needs

Needs Category	Med-Large Biotech / Pharma	Small Biotech	Academic Medical Centers	Investors
<b>Policy / Regulatory</b>	<ul style="list-style-type: none"> <li>More favorable policies/regulations re: IP protection, bio-generics, importation, reimbursement, sales &amp; marketing regulations and green technology</li> </ul>	<ul style="list-style-type: none"> <li>Secure <b>benefits from LSI funds</b></li> <li><b>Improve access to SBIR funding</b></li> <li><b>R&amp;D tax credits</b> to promote investments in early stage research</li> <li><b>New suite of tax incentives</b> for non-commercial biotech</li> </ul>		<ul style="list-style-type: none"> <li><b>Regulatory policies</b> and pathways to clear the way for profitable investments</li> </ul>
<b>Access to Capital/ Funding</b>		<ul style="list-style-type: none"> <li><b>Immediate access to capital</b> to support survival</li> <li>Connections to <b>new sources of government funds</b> and non-traditional funding sources</li> </ul>	<ul style="list-style-type: none"> <li><b>Increased NIH funding</b> to continue innovation and retention of key research personnel</li> </ul>	<ul style="list-style-type: none"> <li><b>Current company survival and/or exit/sell opportunities</b></li> </ul>
<b>Operational</b>	<ul style="list-style-type: none"> <li>New business models to <b>improve cost structures</b></li> <li>Effective processes for <b>expanding infrastructure</b> in MA</li> <li><b>Retention</b> of top talent and scientists</li> <li><b>Efficiencies</b> in transferring innovation from academia</li> </ul>	<ul style="list-style-type: none"> <li>Gain better <b>cost efficiencies</b> through purchasing consortium/ outsourcing/shared services</li> <li><b>Retention</b> of top talent</li> <li><b>Reduce start-up costs</b>, burn rate, and need for capital</li> </ul>	<ul style="list-style-type: none"> <li><b>Accelerate discovery</b> and translational capabilities</li> <li><b>Expedite novel compounds</b> to clinical trials</li> <li><b>Retention of scientific talent</b> when grants are constrained</li> </ul>	<ul style="list-style-type: none"> <li><b>Transparency into operational efficiencies</b> of invested companies</li> </ul>
<b>Collaboration / Partnering</b>	<ul style="list-style-type: none"> <li><b>Multiple collaboration/partnership opportunities</b> exist across all LS industry sectors</li> <li><b>Virtual R&amp;D</b> opportunities with both U.S. and ex-U.S. companies</li> </ul>	<ul style="list-style-type: none"> <li>Collaborations/partnerships for <b>new innovation and commercialization</b></li> <li><b>Shared operations</b> partnerships</li> </ul>	<ul style="list-style-type: none"> <li><b>Innovation and disruptive technology</b> collaborations for future commercialization</li> <li><b>Collaborations w/Industry</b></li> </ul>	<ul style="list-style-type: none"> <li>Connect with <b>innovations with good potential</b> in academia and other sectors</li> </ul>

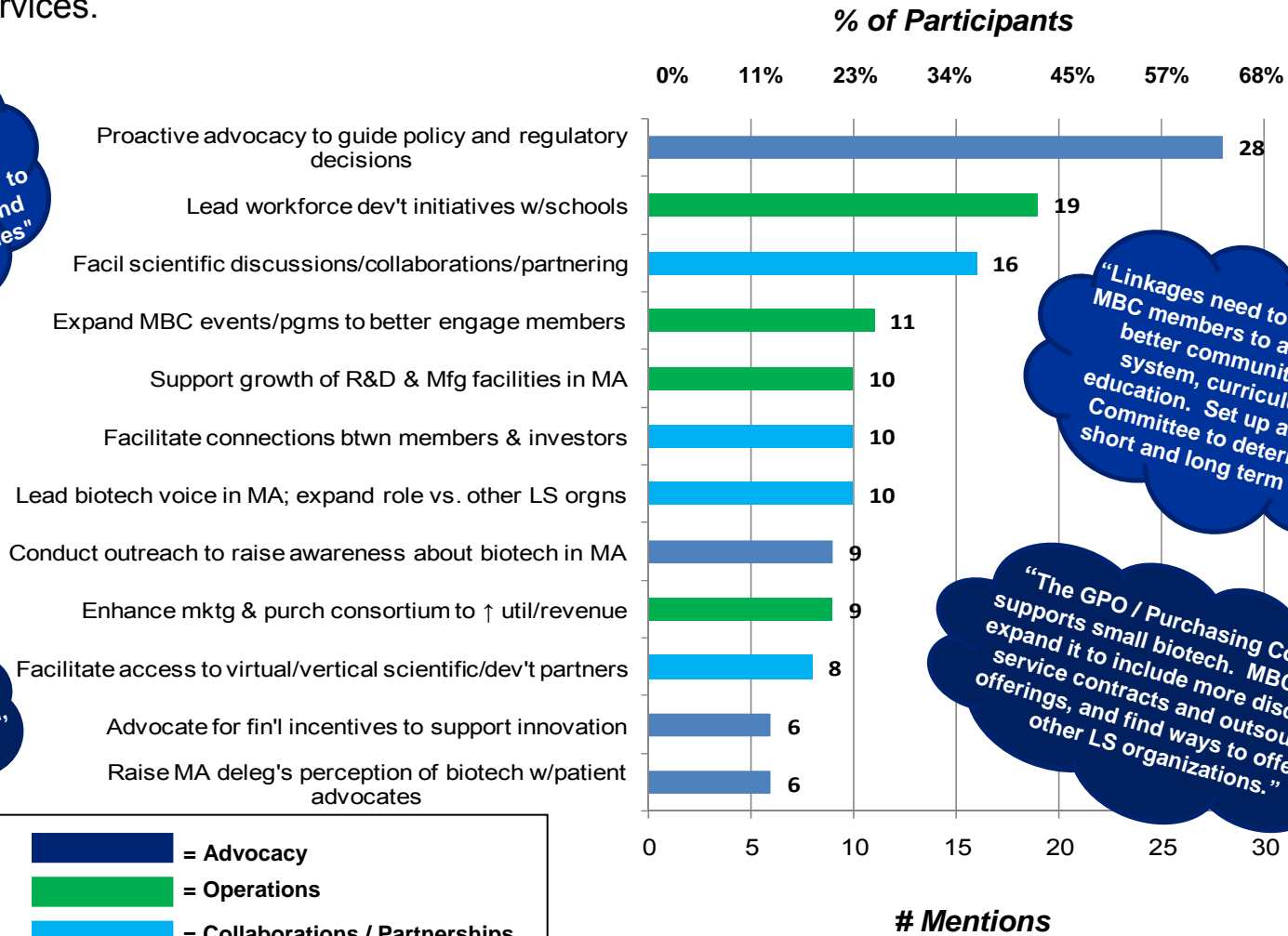


# Opportunities for MBC

Stakeholders identified opportunities for MBC to further support the cluster through advocacy, collaboration and operational services.

"There is a tenuous link between academia and industry – how can we organize more efficiently to accelerate discovery and translational capabilities"

"MBC needs to pick the right issues, create their value proposition, and get on top of policy changes"



"Linkages need to be made with MBC members to advocate for a better community college system, curriculum, and education. Set up an Industry Committee to determine the short and long term needs."

"The GPO / Purchasing Coalition supports small biotech. MBC should expand it to include more discounts / service contracts and outsourcing / offerings, and find ways to offer it to other LS organizations."

# MBC Opportunities by Stakeholder

Needs Category	Med-Large Biotech / Pharma	Small Biotech	Academic Medical Centers	Investors
<b>Advocacy*</b>	<ul style="list-style-type: none"> <li>▪ <b>Elevate / advocate relevant biotech issues</b> to the State and Federal Government (e.g., patent reform, bio-generics, drug importation, price controls, tax code, gift ban, HC reform, FDA / regulatory policies, green tech)</li> <li>▪ Encourage <b>policies that support attracting companies</b> to expand R&amp;D and Mfg facilities in MA</li> <li>▪ Support policy changes for <b>retention of national / international talent</b> in MA</li> <li>▪ Raise <b>awareness</b> on the biotech industry at the state level</li> </ul>	<ul style="list-style-type: none"> <li>▪ Work to improve <b>access to SBIR funding</b></li> <li>▪ Work to <b>secure benefits</b> (\$s) from the LSI</li> <li>▪ Advocate for a new suite of <b>tax incentives</b> for start-ups</li> <li>▪ Advocate for <b>R&amp;D tax credits</b> to promote investments in early stage research</li> </ul>	<ul style="list-style-type: none"> <li>▪ Advocate for <b>increases in NIH funding</b> to support innovation and retention of key research personnel</li> <li>▪ Advocate for <b>R&amp;D tax credits</b> to promote investments in early stage research</li> </ul>	<ul style="list-style-type: none"> <li>▪ Advocate for <b>regulatory policies and pathways</b> that clear the way for profitable investments in <b>innovative and disruptive technology</b> companies (e.g., establish policies for distribution of personalized diagnostics)</li> </ul>
<b>Operations*</b>	<ul style="list-style-type: none"> <li>▪ <b>Accelerate Bio-Ready campaign</b> to support growth of new R&amp;D / mfg facilities</li> <li>▪ Facilitate <b>industry involvement in Mass BioEd</b> initiatives to enhance science programs in high schools and colleges</li> <li>▪ Advocate for Mass BioEd to take leadership role in educational initiatives coming out of the LSI</li> <li>▪ Provide <b>outsourced government affairs</b> function for medium sized biotech</li> </ul>	<ul style="list-style-type: none"> <li>▪ <b>Expand purchasing consortium</b> offerings, service contracts, and outsourcing capabilities to expand membership and increase value</li> <li>▪ Enhance cost efficiencies thru expansion of <b>centralized shared services</b> (e.g., purchasing consortium, government affairs, educational seminars, HR / benefits, job postings, shared laboratory space / equipment)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Develop a COE for clinical trials</li> <li>▪ Establish a "Think Tank" with industry and academia to promote tech transfer and discussions on science and innovation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Improve VC representation on the board</li> </ul>
<b>Collaboration / Partnering*</b>	<ul style="list-style-type: none"> <li>▪ Facilitate opportunities to <b>bring industry and AMCs together</b> to discuss science, research, and clinical development collaborations / partnerships</li> <li>▪ Facilitate <b>introductions for ex-U.S. companies / trade delegations</b> looking to establish presence in U.S.</li> <li>▪ Facilitate introductions to <b>virtual R&amp;D opportunities</b> ex-U.S.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Facilitate opportunities to <b>bring industry and AMCs together</b> to discuss science, research and funding collaborations</li> <li>▪ Facilitate <b>introductions / networking</b> between investors and biotech</li> <li>▪ Facilitate <b>connections to new sources</b> of government funds and non-traditional <b>funding</b> sources</li> <li>▪ Support opportunities for biotech to <b>utilize excess laboratory capacity</b> in member companies</li> </ul>	<ul style="list-style-type: none"> <li>▪ Facilitate opportunities to <b>bring industry and AMCs together</b> to discuss science, research, and clinical dev't collaborations / partnerships</li> <li>▪ Facilitate introductions for ex-U.S. companies looking to <b>outsource its discovery activities</b> to AMCs in U.S.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Facilitate <b>introductions / networking</b> between investors and biotech</li> </ul>

\* Tactical imperatives to support access to capital and funding are contained in all three categories

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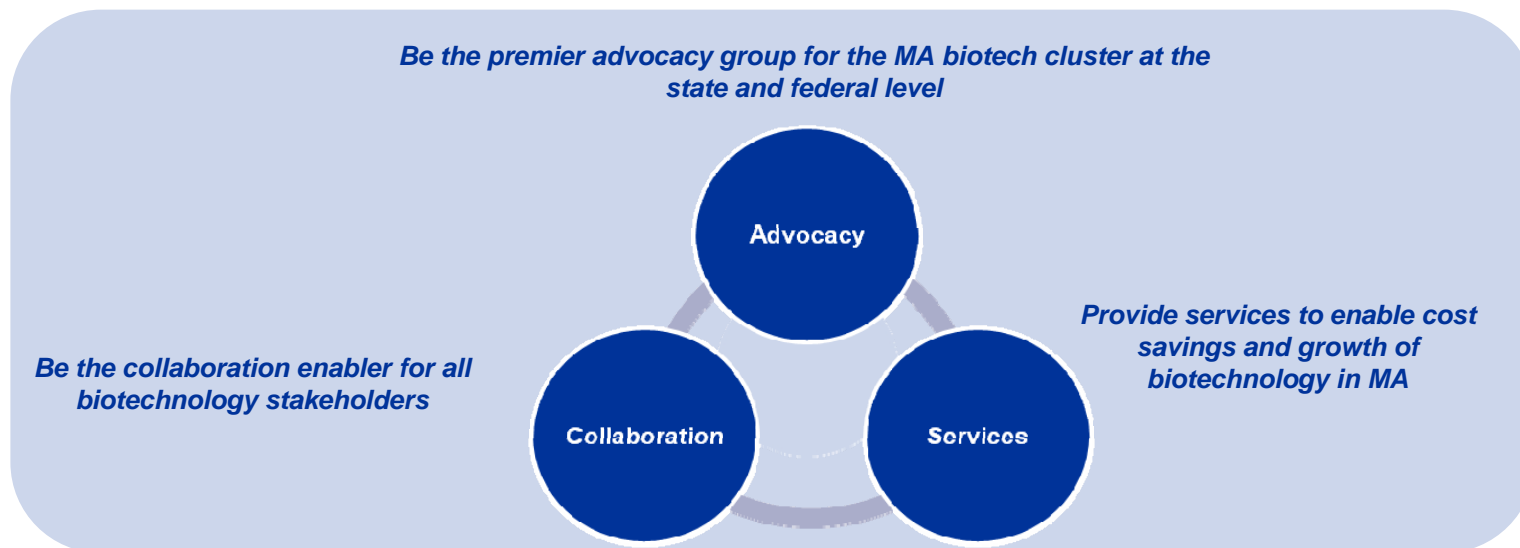
# MBC Vision and Enablers

Based on input from the competitive analysis of biotech clusters, industry trends, and interviews with stakeholders, participants at the visioning workshop developed a vision statement for MBC.

## DRAFT MBC Vision Statement

*MBC will help MA enhance its premier biotech position by strengthening its focus on novel research and development, facilitating scientific and business collaboration, and advocating for supportive public policies, ultimately transforming patient treatment globally while driving the growth of the Massachusetts economy.*

## Levers for MBC to Achieve Vision



***MBC's vision will be enabled by a combination of the organization's key levers: services, advocacy and collaboration***

## MBC Strategic Focus Areas

Strategic focus areas were developed to help MBC realize its vision.

### MBC Strategic Focus Areas

- **Scientific Collaboration and Innovation:** Promote continued innovation and collaboration in research and development so that Massachusetts can retain and enhance its world-class position in this area
- **Capital Formation:** Improve access to capital in the short and long-term by promoting collaborations and enabling access to various funding sources through meaningful events and advocacy
- **Business Services:** Provide services to that help companies increase their operational efficiencies and reduce their burn rate
- **Talent:** Enhance and accelerate efforts to attract, develop and retain biotech thought leaders and talent at all levels
- **Company Retention and Recruitment:** Improve company recruitment and retention efforts through proactive strategies and marketing efforts aligned with initiatives undertaken by the Commonwealth and other economic development partners
- **Industry Representation:** Improve the industry's representation and raise MBC's level of influence through collaborations with other associations and clusters and by raising public awareness of biotech through continued marketing campaigns and advocacy

# MBC Strategy and Supporting Needs: Scientific Collaboration and Innovation

## Strategic Focus

Promote continued innovation and collaboration in research and development so that Massachusetts can retain and enhance its world-class position in this area

## Rationale / Drivers

- MA is a leader in biotechnology, however its value proposition may decline if it loses its grip on innovation
- Interviews revealed the need to better align the academic community with industry to improve the clinical trial environment and technology transfer processes
- Opportunities exist to take advantage of the cluster's strong life sciences industry presence (e.g., biotech, pharma, med device, diagnostics) and concentration of other key stakeholders (e.g., research universities, academic medical centers) through collaboration to position the cluster as a leader in several areas, including convergent solutions, personalized medicine and translational research
- Investment by other clusters in novel technologies may make it necessary for MA to evaluate what technologies to focus on (e.g., MA may be in a lagging position for stem cell research)

## Stakeholder Needs

- Improved interactions between academia and industry to reduce clinical trial barriers (e.g., IRB processes, access to patient populations ) and improve technology transfer processes
- More meaningful collaboration among stakeholders (academia, VC, LS industries) to reduce the reliance on “serendipitous” or “chance” partnerships

# MBC Strategy and Supporting Needs: Capital Formation

## Strategic Focus

Improve access to capital in the short and long-term by promoting collaborations and enabling access to various funding sources through meaningful events and advocacy

## Rationale / Drivers

- Nearly 50% of MA public biotech companies are operating with less than a year's worth of cash and ~40 private MA companies have not received financing since 2006
- Diminished funding is hampering the cluster's ability to invest in R&D; due to the financial health of MA's biotech industry, many companies will be forced to find a buyer or discontinue operations if they are not able to secure funding
- Federal funds are likely to be made available to the life sciences industry through an economic stimulus package, distributed at the state level
- NIH funding increases have slowed dramatically in recent years, putting even more pressure on AMCs and research universities to fund innovative research

## Stakeholder Needs

- New and more effective means to locate alternative sources of funding and connect with appropriate stakeholders (e.g., angel investors, disease foundations, foreign investors) to increase access to capital
- Advocacy for biotech government funding (through economic stimulus package) to ensure beneficial and meaningful provisions are implemented
- Continued advocacy efforts at federal level to increase NIH funding and expand SBIR programs

## MBC Strategy and Supporting Needs: Business Services

### Strategic Focus

Provide services to that help companies increase their operational efficiencies and reduce their burn rate

### Rationale / Drivers

- Enabling the success of start-up and early stage biotech companies is critical in supporting a sustainable and innovative biotech industry presence
- Start-ups and small companies greatly benefit from services / support which provide assistance establishing a company and reducing operating costs
- With the \$1B Life Science Initiative, opportunities are present for MA companies to apply for and receive grants / tax credits; however, many small biotech companies are unaware of these opportunities or lack the expertise / knowhow to navigate application processes for tax credits, grants and other government related processes

### Stakeholder Needs

- Access to discounted or complementary products and services to help reduce both capital and operating costs, thereby increasing a company's "runway"
- Assistance navigating the application processes related to grants / tax credits that are available to companies

# MBC Strategy and Supporting Needs: Talent

## Strategic Focus

Improve company recruitment and retention efforts through proactive strategies and marketing efforts aligned with initiatives undertaken by the Commonwealth and other economic development partners

## Rationale / Drivers

- Talent is the main driver of MA's success as a cluster but availability of qualified scientists, research associates and technicians is becoming increasingly difficult
- Demand for highly qualified biotech talent is growing, both in traditional R&D and in expanding downstream business sectors, such as clinical trials, bio-manufacturing and commercialization
- The quality of the skilled workforce in MA, typically those with advanced graduate degrees and doctorates, is among the finest in the US; however, MA's high cost of living makes MA a less attractive location for retaining talent
- Although the state has many excellent higher education and training programs in life sciences, these programs are not well coordinated and not responsive to the changing needs of the industry

## Stakeholder Needs

- Workforce training programs in life sciences fields that are better coordinated and more responsive to the needs of industry
- Increased availability of scientific talent as well as talent in areas such as management, regulatory affairs, marketing and manufacturing
- Increased pipeline of residents entering both higher education degree programs and life sciences careers
- Training (e.g., professional development course offerings, seminars) tailored to advance the existing workforce and those interested in biotechnology careers
- Additional state level incentives to help companies / universities retain and hire highly skilled talent

# MBC Strategy and Supporting Needs: Company Retention and Recruitment

## Strategic Focus

Improve biotech company retention and recruitment efforts through coordination of proactive strategies and marketing efforts

## Rationale / Drivers

- MA is a strong cluster that can attract a diverse set of biotech companies (e.g., start-up, early stage, late development, mature commercial, enabling service)
- However, MA's biotech economic development efforts are complex and fragmented, requiring coordination among a large variety of state and local organizations
- MA counties / municipalities sometimes pose challenges for companies trying to establish a R&D or manufacturing presence
- MA's notably high costs often detract companies from establishing operations in the state
- The fragmentation of the value chain, coupled with the emergence of new biotech clusters, present both challenges and opportunities for MA as companies will be looking to increase flexibility and reduce costs often through partnerships with companies in other clusters

## Stakeholder Needs

- Elimination of potential harmful legislation in order to improve the general biotech business environment at the state and local level
- Streamlined economic development activities through coordination among key agencies and the development of a clearly defined recruitment / retention strategy
- Continued success and expanded efforts of the BioReady campaign with proactive marketing and targeting efforts
- Increased access and facilitated collaboration with international clusters and companies while also positioning MA as a conduit to US market penetration for international companies

# MBC Strategy and Supporting Needs: Industry Representation

## Strategic Focus

Improve the industry's representation and raise MBC's level of influence through collaborations with other associations and clusters and by raising public awareness of biotech through continued marketing campaigns and advocacy

## Rationale / Drivers

- MA contains numerous industry organizations, government agencies and “think-tanks” devoted to the MA life sciences and / or health care industry, many of which support and work towards similar goals while providing the same services to companies
- Increased awareness of the benefits of biotechnology will help facilitate the creation of a biotechnology friendly environment in MA and contribute to further development of the cluster
- As the lines between pharma and biotech become blurred, biotechnology may need to put more emphasis on distinguishing itself
- Interviews with MBC members suggest MBC improve its level of influence by better demonstrating the value and relevance it provides to its member companies

## Stakeholder Needs

- Improved collaboration and coordination among MA organizations to reduce confusion among the stakeholders, more effectively improve the biotech environment in MA and implement impactful and beneficial programs, initiatives and policies
- Improved understanding of the biotech industry, its economic benefits to MA and the industry's overall impact on promoting better health outcomes
- Meaningful, targeted and relevant events / seminars / forums to discuss specific needs and trends (e.g., CEO summit, scientific roundtables)

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# Current Activities and MBC Strategic Focus Areas

## Strategic Focus

### Capital Formation

- Annual Investor forum
- Disease Foundation Days

### Business Services

- Purchasing consortium expansion and enhanced targeted marketing efforts (e.g., open houses, vendor partnering, weekly sales calls)
- Operational service offerings (e.g., conference room, videoconferencing)
- Career page / job posting functionality

### Talent

- Implementation of the five Life Sciences Talent Report recommendations through MassBioEd and the Education / Industry Advisory Board (e.g., higher education curriculum development, co-op programs / internships)
- BioTeach Program targeting K-12 programs

### Company Retention and Recruitment

- BioReady community campaign and subsequent marketing efforts
- Coordination with state agencies to respond to requests for information / proposals from companies
- MA industry report, industry statistics and MBC BioProfiles publications

### Industry Representation

- Robust Federal and State advocacy agenda and efforts
- Biotech Caucus establishment and ongoing involvement
- Collaboration with BIO on federal issues

### Scientific Collaboration and Innovation

- MBC hosted events (e.g., Pharma Days, Mass Life Sciences Innovation Day, committee led seminars / presentations) and partnerships with other organizations for science related educational / networking events (e.g., Early-Stage Life Sciences Technology Conference with MATT)
- Mass Life Science Start-up Initiative (MALSI)

## Current MBC Activities<sup>1</sup>

<sup>1</sup> Derived from MBC website, MBC business plan dated 1.12.09, and MBC staff input. For additional detail, please refer to Appendix C

# MBC Current State Alignment with 2015 Strategies

Strategic Focus	MBC Current Alignment <sup>1</sup>	Findings
Capital Formation		<ul style="list-style-type: none"> <li>Efforts are primarily focused on Annual Investor Forum</li> <li>Disease foundation days represent first event focused on connecting companies with alternative sources of funding</li> <li>The current environment demands more support connecting companies with funding sources; stakeholders are looking for smaller events amenable to more meaningful interactions with investors</li> </ul>
Business Services		<ul style="list-style-type: none"> <li>The purchasing consortium offers members the opportunity for substantial cost savings</li> <li>Operational services (e.g., conference room videoconferencing) are now being offered</li> <li>The current economic environment is increasing the importance of providing services to companies to help extend their runway; further opportunities to provide advisory services and support are present</li> </ul>
Talent		<ul style="list-style-type: none"> <li>The LSTI report was a noteworthy effort and highlighted key findings and priority recommendations for addressing the talent issue in MA</li> <li>There is an opportunity to leverage the report's findings and LSTI advisory board to provide recommendations on policies to improve talent retention in the state and expand professional development course offerings through MassBioEd</li> </ul>
Company Retention and Recruitment		<ul style="list-style-type: none"> <li>The BioReady community campaign survey has improved the overall attractiveness of retention / recruitment efforts and planned marketing efforts will enhance the campaign</li> <li>MBC plays an active role in state biotech retention and recruitment efforts, but many times these processes are reactive in nature; in general, companies perceive the MA request for information process to be cumbersome and disjointed</li> </ul>
Industry Representation		<ul style="list-style-type: none"> <li>MBC's key strength is its advocacy efforts at both the state and federal level</li> <li>Efforts could be improved through greater, more proactive collaborations with other associations</li> <li>Current biotech public awareness activities show promising potential; however, additional, more formalized efforts could better address the needs of the industry</li> </ul>
Scientific Collaboration and Innovation		<ul style="list-style-type: none"> <li>MBC hosts /co-hosts scientific events / forums; however, stakeholders have articulated the need for more relevant and timely topics for the constituency</li> <li>MBC committees could be better leveraged and coordinated to support the development of pertinent events / seminars</li> </ul>

<sup>1</sup> Ratings based on stakeholder interviews; MBC internal interviews; discussion at the vision workshop and Deloitte observation

## New and Enhancement Initiatives (1 of 2)

<input type="checkbox"/>	Enhancement Initiative
<input type="checkbox"/>	New Initiative

In order for MBC to fully achieve its 2015 strategic objectives, it must supplement its current activities with enhancements and undertake new initiatives over the next several years

Capital Formation		
#	Title	Description
C-1	Increase the frequency and quality of capital formation events	Increase the frequency and quality of capital focused events, as well as facilitate access to various sources of funding (disease foundations, foreign investors, angel investors, etc) through smaller, targeted events (e.g., therapeutic area specific, speed networking for VCs and biotech)
C-2	Advocate for allocation of parts of the MA economic stimulus package to Biotech	Work with state legislators to promote disbursement of potential earmarked economic stimulus funds to the MA biotech industry
Business Services		
B-1	Provide advisory and information services to members	Provide advisory services (e.g., “office hours” for IP, PR, government affairs) and information services (e.g., access to industry reports / databases) to member companies
B-2	Connect buyers and providers of “bio” services	Establish and maintain a web based tool to connect potential buyers and users of “bio support services”, to be provided by member companies (e.g., excess lab capacity, high-throughput testing services)
B-3	Evaluate opportunity for the establishment of a public – private biotech center / incubator	Evaluate opportunities for a public-private MA biotech center to promote new start-up companies and transfer academic innovations to industry
B-4	Provide support to companies with government program applications	Provide support to companies with applications for available tax incentives, grant programs and other government related application processes (e.g., LSI grants)
Talent		
T-1	Advocate for incentives to retain talent	Advocate for additional government incentives (e.g., loan forgiveness; training bonuses, payroll tax credits) to retain MA educated and trained talent in state
T-2	Enhance professional development course offerings through MassBioEd	Expand availability of professional development efforts through MassBioEd to increase the depth and breadth of the talent pool in MA

## New and Enhancement Initiatives (2 of 2)

<input type="checkbox"/>	Enhancement Initiative
<input type="checkbox"/>	New Initiative

Company Retention and Recruitment		
#	Title	Description
R-1	Develop and implement a proactive company retention / recruitment strategy	Facilitate the development of a proactive company recruitment and retention strategy by further defining MA target company profiles and developing specific value propositions; implement strategy by streamlining MA economic development activities and advocating for necessary policies
R-2	Establish MA as an international gateway	Identify, evaluate and facilitate opportunities to create a higher level of collaboration and “open doors” with select international biotech clusters and companies
Industry Representation		
I-1	Collaborate with other associations	Identify opportunities to collaborate with other national, regional and MA based organizations to clarify priorities, assign leadership role for specific initiatives and establish MBC as the premier advocate, voice and source for biotechnology issues in MA
I-2	Increase awareness of biotech in MA	Develop and implement a MA focused biotech public awareness campaign, targeting legislators and the general public
I-3	Increase CEO engagement in MBC	Increase CEO engagement through participation in MBC events (e.g., CEO Summits, roundtables) and by leading implementation of specific 2015 strategic initiatives
Scientific Collaboration and Innovation		
CI-1	Increase the frequency and relevancy of scientific events / forums	Increase the frequency and quality of science related events / forums to address challenges and opportunities related to key trends and to facilitate networking / collaboration among stakeholders; identify and enable mechanism to obtain insights on relevant event topics of high interest and value
CI-2	Create a partnership with MA hospital trade associations to address clinical development issues in MA	Improve the clinical trial infrastructure in MA through collaboration with MA Hospital trade associations (e.g., MHA, Council of Boston Teaching Hospitals) to bring together key stakeholders (industry and AMCs, community hospitals) and gain consensus on how to address challenges and opportunities (e.g., IRB issues, access to patient populations, access to community hospitals)

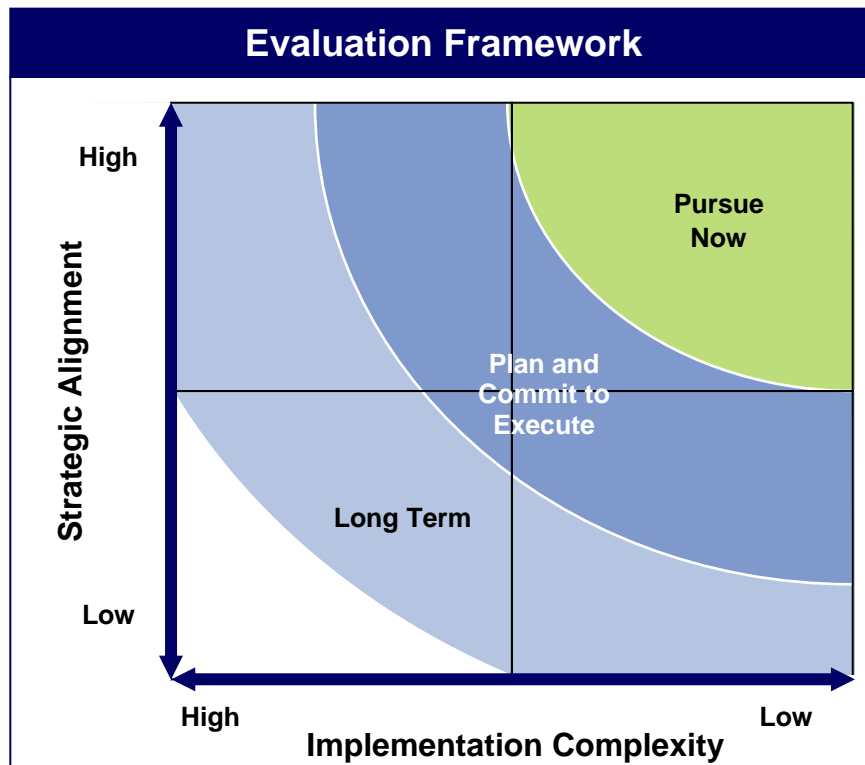
# Initiatives and MBC Enablers

Strategy	#	Recommended Initiatives	MBC Enablers		
			Advocacy	Collaboration	Services
Capital Formation	C-1	Increase the frequency and quality of capital formation events			
	C-2	Advocate for allocation of parts of the MA economic stimulus package to Biotech			
Business Services	B-1	Provide advisory and information services to members			
	B-2	Connect buyers and providers of "bio" services			
	B-3	Evaluate opportunity for the establishment of a public – private biotech center / incubator			
	B-4	Provide support to companies with government program applications			
Talent	T-1	Advocate for incentives to retain talent			
	T-2	Enhance professional development course offerings through MassBioEd			
Company Retention and Recruitment	R-1	Develop and implement a proactive company retention / recruitment strategy			
	R-2	Establish MA as an international gateway			
Industry Representation	I-1	Collaborate with other associations			
	I-2	Increase awareness of biotech in MA			
	I-3	Increase CEO engagement in MBC			
Scientific Collaboration and Innovation	CI-1	Increase the frequency and relevancy of scientific events / forums			
	CI-2	Create a partnership with MA hospital trade associations to address clinical development issues in MA			

Level of Effort  Strong  
Weak

# Prioritization Methodology

The initiatives will be evaluated along dimensions of **Strategic Alignment** and **Implementation Complexity**



## Strategic Alignment




Measure of the initiatives ability to address both short and long term needs, drive value for MBC members, and increase the relevance and value proposition of MBC to the cluster

## Implementation Complexity



Measure of the capability gaps, risks and other challenges that MBC must address to successfully implement the initiative

# Prioritization Methodology

Each initiative was rated based on its expected financial impact, strategic alignment, and ease of implementation and prioritized based on these factors

Criteria for Initiative Prioritization				
Criteria	Attributes			
Strategic Alignment	<ul style="list-style-type: none"> <li>▪ <b>Benefits Created</b> – Assessment of benefits initiative brings to MBC; benefits include qualitative and quantitative drivers                             <ul style="list-style-type: none"> <li>▪ Increase revenue through new membership dues</li> <li>▪ Increases revenue through new service offerings</li> <li>▪ Increase retention of member companies</li> <li>▪ Increase notoriety / relevancy of MBC</li> <li>▪ Optimizes MBC resources</li> </ul> </li> </ul>	Low	Medium	High
	<ul style="list-style-type: none"> <li>▪ <b>Cluster Impact</b> – Level of depth and breadth of impact on cluster stakeholders</li> </ul>	Low	Medium	High
	<ul style="list-style-type: none"> <li>▪ <b>Short Term Alignment</b> – Criticality of initiative in addressing short term needs (i.e., initiative has short “window of opportunity”) or is a key “foundation builder” for future initiatives</li> </ul>	Low	Medium	High
Financial Impact	<ul style="list-style-type: none"> <li>▪ <b>Investment Costs</b> – level of incremental investment (resource driven based on estimated incremental resource needs and assumption of \$75/hour)</li> </ul>	<\$10K	\$10-20K	>\$20K
Implementation Complexity	<ul style="list-style-type: none"> <li>▪ <b>Duration</b> – expected time to implement (strategy development and planning phases)</li> </ul>	<12 wks	12-20 wks	>20 wks
	<ul style="list-style-type: none"> <li>▪ <b>MBC Business Impact</b> –                             <ul style="list-style-type: none"> <li>▪ Degree of change required from existing activities, processes, interfaces with members and other stakeholders</li> <li>▪ Degree of training / acquisition of new skills required</li> <li>▪ Degree of change in current resource structure</li> </ul> </li> </ul>	Low	Medium	High
	<ul style="list-style-type: none"> <li>▪ <b>Collaboration Impact</b> – Quantity and diversity of stakeholders required for involvement with implementation</li> </ul>	Low	Medium	High

# Initiative Prioritization

 Enhancement Initiative  
 New Initiative

ID	Title	Strategic Alignment			Financial Impact	Implementation Complexity			Priority
		MBC Benefits	Cluster Impact	ST Alignment	Investment Costs	Duration	Business Impact	Collab. Impact	
C-1	Increase the frequency and quality of capital formation events	●	●	●	◐	○	◐	◐	1
C-2	Advocate for allocation of MA economic stimulus package to biotech	●	●	●	○	◐	◐	◐	1
B-1	Provide advisory and information services to members	●	◐	●	●	◐	◐	◐	1
B-2	Connect buyers and providers of “bio” services	◐	◐	◐	●	●	●	●	3
B-3	Evaluate opportunity for the establishment of a public – private biotech center / incubator	○	◐	◐	●	●	◐	●	3
B-4	Provide support to companies with government program applications	◐	◐	●	◐	○	○	◐	1
T-1	Advocate for incentives to retain talent	○	◐	◐	◐	●	○	◐	2
T-2	Enhance professional development course offerings through MassBioEd	◐	◐	◐	●	●	◐	◐	2
R-1	Develop and implement a proactive company retention / recruitment strategy	◐	●	◐	●	●	◐	●	2
R-2	Establish MA as an international gateway	◐	◐	◐	◐	◐	◐	●	2
I-1	Collaborate with other associations	●	●	●	○	◐	○	●	1
I-2	Increase awareness of biotech in MA	●	●	●	◐	◐	◐	◐	1
I-3	Increase CEO engagement in MBC	●	●	●	◐	◐	◐	○	1
CI-1	Increase the frequency and relevancy of scientific events / forums	◐	◐	◐	◐	◐	●	◐	2
CI-2	Create a partnership with MA hospital trade associations to address clinical development issues in MA	○	◐	◐	○	●	◐	●	2

    
 Low High

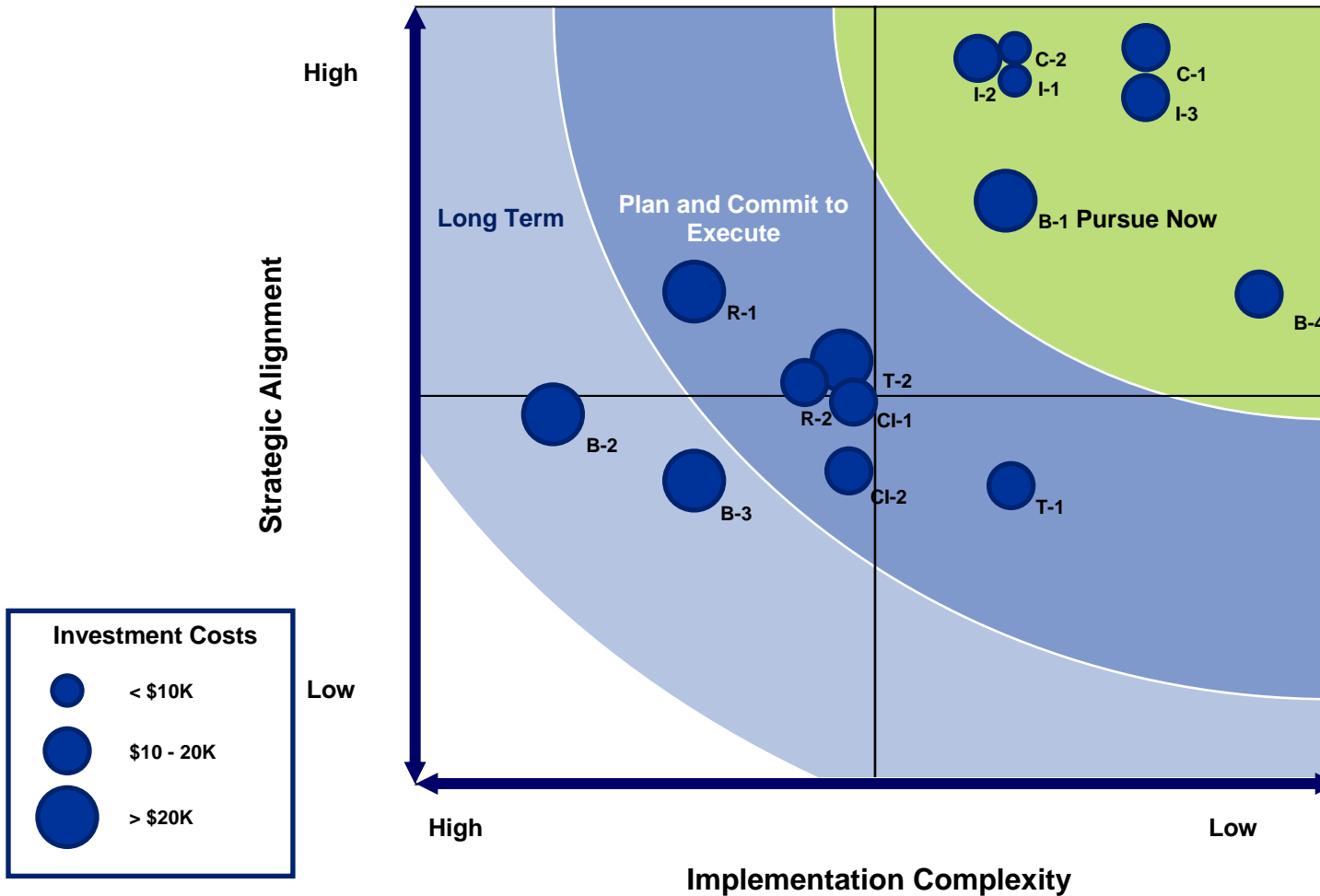
1 High Priority 
 2 Medium Priority 
 3 Lower Priority

**MBC**

Massachusetts Biotechnology Council

# Initiative Prioritization

Initiatives were grouped into three primary classifications



# Initiative Roadmap

Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3 & Q4 2010	2011 and on
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## Milestones

- Annual Mtg.
- Investors Forum
- New web / database

### Capital Formation

- Increase the frequency and quality of capital formation events
- Advocate for allocation of parts of the MA economic stimulus package to Biotech



### Business Services

- Provide advisory and information services to members
- Connect buyers and providers of "bio" services
- Evaluate opportunity for the establishment of a public – private biotech center / incubator
- Provide support to companies with government program applications



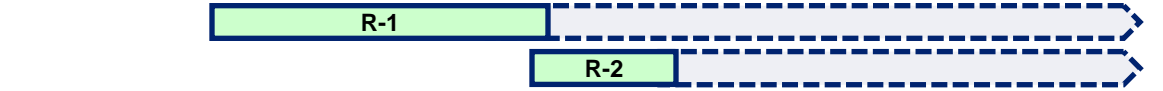
### Talent

- Advocate for incentives to retain talent
- Enhance professional development course offerings through MassBioEd



### Company Retention and Recruitment

- Develop and implement a proactive company retention / recruitment strategy
- Establish MA as an international gateway



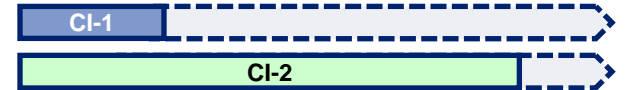
### Industry Representation

- Collaborate with other associations
- Increase awareness of biotech in MA
- Increase CEO engagement in MBC



### Scientific Collaboration and Innovation

- Increase the frequency and relevancy of scientific events / forums
- Create a partnership with MA hospital trade associations to address clinical development issues



# Resource Allocation Summary

Strategy	Recommended Initiatives	Q1 2009*	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3&4 2010	2011 and on
<b>Capital Formation</b>	Increase the frequency and quality of capital formation events	0.57	0.30	0.08	0.08	0.08	0.08	0.08	0.08
	Advocate for allocation of parts of the MA economic stimulus package to Biotech	0.20	0.14						
<b>Business Services</b>	Provide advisory and information services to members			0.42	0.29	0.10	0.10	0.10	0.10
	Connect buyers and providers of "bio" services						0.8	0.14	0.05
	Evaluate opportunity for the establishment of a public – private biotech center / incubator							0.74	
	Provide support to companies with government program applications		0.33	0.10	0.10	0.10	0.10	0.10	0.10
<b>Talent</b>	Advocate for incentives to retain talent			0.03	0.20	0.03	0.03	0.03	
	Enhance professional development course offerings through MassBioEd				0.50	0.37	0.08	0.08	0.08
<b>Company Retention and Recruitment</b>	Develop and implement a proactive company retention / recruitment strategy		0.06	0.40	0.22	0.05	0.05	0.05	0.05
	Establish MA as an international gateway					0.37	0.06	0.06	0.06
<b>Industry Representation</b>	Collaborate with other associations	0.19	0.15	0.05	0.05	0.05	0.05	0.05	0.05
	Increase awareness of biotech in MA			0.28	0.22	0.10	0.10	0.10	0.10
	Increase CEO engagement in MBC		0.38	0.08	0.08	0.08	0.08	0.08	0.08
<b>Scientific Collaboration and Innovation</b>	Increase the frequency and relevancy of scientific events / forums					0.38	0.08	0.08	0.08
	Create a partnership with MA hospital trade associations to address clinical development issues in MA					0.09	0.05	0.05	0.03
<b>Average Resource Allocation (FTE Equivalence)</b>		<b>0.96</b>	<b>1.36</b>	<b>1.43</b>	<b>1.73</b>	<b>1.80</b>	<b>1.66</b>	<b>1.74</b>	<b>0.86</b>

\* Q1 average assumes 7 remaining "working weeks" for the implementation of initiatives during this time period

## Recommendations – Summary for 2009

- Based on **estimated level of effort** for each initiative, we estimate that 2009 initiatives require an incremental workload of about 1.4 FTEs for 2009
- The **estimated investment** associated with implementing the 2009 initiatives is \$271,300\*
  - Initial cost (one-time): \$177,600
  - Running cost (yearly): \$93,700
- While it is difficult to accurately quantify benefits to MBC based on recommended initiatives, **anticipated benefits** to MBC include
  - Sustaining and increasing revenue:
    - Directly through:
      - Recruitment of new membership
      - Increased sponsorship opportunity
      - Increased event participation
      - Minimized membership losses
      - Increased service offerings
    - Indirectly through:
      - Increased visibility
      - Increased relevancy of MBC offerings
      - Increased involvement/ engagement of members
  - Reducing costs through optimized use of MBC resources towards activities and initiatives of highest value

Recommended initiatives are aligned to address the needs of the MA biotech cluster and to provide tangible and sustainable benefits to MBC

\* Estimates of investment needed to implement initiative based on incremental level of effort; assumes \$65/hour employee cost

## Financial Overview for 2009 Initiatives

#	2009 Initiatives	Costs			Anticipated Benefits <sup>4</sup>	
		2009 Investment <sup>1</sup>	2009 Ongoing <sup>2</sup>	2010+ Ongoing <sup>3</sup>	Direct	Indirect
C-1	Increase the frequency and quality of capital formation events	\$18,720	\$7,280	\$10,816	<ul style="list-style-type: none"> <li>▪ Increased event participation</li> <li>▪ Retain / Recruit members</li> <li>▪ Increased sponsorship opportunities</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased visibility</li> <li>▪ Increased relevancy</li> </ul>
C-2	Advocate for allocation of parts of the MA economic stimulus package to Biotech	\$8,320				<ul style="list-style-type: none"> <li>▪ Increased visibility</li> <li>▪ Increased relevancy</li> </ul>
B-1	Provide advisory and information services to members	\$21,840	\$2,080	\$13,520	<ul style="list-style-type: none"> <li>▪ Increased service offering</li> <li>▪ Retain / Recruit members</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased involvement / engagement of members</li> </ul>
B-4	Provide support to companies with government program applications	\$10,400	\$7,540	\$13,520	<ul style="list-style-type: none"> <li>▪ Retain / Recruit members</li> <li>▪ Increased event participation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased visibility</li> </ul>
T-1	Advocate for incentives to retain talent	\$7,800				<ul style="list-style-type: none"> <li>▪ Increased visibility</li> </ul>
T-2	Enhance professional development course offerings through MassBioEd	\$16,900			<ul style="list-style-type: none"> <li>▪ Increased revenue through course fees</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased visibility</li> <li>▪ Increased relevancy</li> </ul>
R-1	Develop and implement a proactive company retention / recruitment strategy	\$22,800		\$6,760	<ul style="list-style-type: none"> <li>▪ Retain / Recruit membership</li> </ul>	<ul style="list-style-type: none"> <li>▪ Optimized MBC resource use (streamlined process)</li> </ul>
I-1	Collaborate with other associations	\$8,320	\$3,770	\$6,760	<ul style="list-style-type: none"> <li>▪ Optimized MBC resource use</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased relevance and value of MBC</li> </ul>
I-2	Increase awareness of biotech in MA	\$14,560	\$2,080	13,520		<ul style="list-style-type: none"> <li>▪ Increased visibility and recognition</li> </ul>
I-3	Increase CEO engagement in MBC	\$12,480	\$5,616	\$10,816	<ul style="list-style-type: none"> <li>▪ Increased sponsorship opportunity</li> <li>▪ Increased event participation</li> </ul>	<ul style="list-style-type: none"> <li>▪ Increased CEO involvement &amp; commitment to MBC</li> <li>▪ Increase visibility</li> </ul>
<b>TOTAL</b>		<b>\$142,220</b>	<b>\$28,366</b>	<b>\$75,712</b>		

<sup>1</sup> For initiatives that span into 2010, only costs in 2009 are included

<sup>2</sup> Includes ongoing costs of initiatives for 2009 only

<sup>3</sup> Yearly, costs for ongoing initiative activity for 2010+

<sup>4</sup> For detailed benefits per initiative, refer to Appendix D

# Financial Overview for 2010 Initiatives

#	2010 Initiatives	Costs			Anticipated Benefits	
		Investment <sup>1</sup>	2010 Ongoing	2011+ Ongoing	Direct	Indirect
B-2	Connect buyers and providers of "bio" services	\$33,280	\$2,990	\$6,760	<ul style="list-style-type: none"> <li>Increased sponsorship opportunity</li> </ul>	<ul style="list-style-type: none"> <li>Increased visibility</li> </ul>
B-3	Evaluate opportunity for the establishment of a public – private biotech center / incubator	\$49,920			<ul style="list-style-type: none"> <li>Recruit members</li> </ul>	<ul style="list-style-type: none"> <li>Increased visibility</li> </ul>
T-1	Advocate for incentives to retain talent	\$4,056				<ul style="list-style-type: none"> <li>Increased visibility</li> <li>Increased relevancy</li> </ul>
T-2	Enhance professional development course offerings through MassBioEd	\$11,700	\$8,944	\$10,816	<ul style="list-style-type: none"> <li>Increased service offering</li> </ul>	<ul style="list-style-type: none"> <li>Increased visibility</li> <li>Increased relevancy</li> </ul>
R-2	Establish MA as an international gateway	\$12,480	\$6,240	\$8,112	<ul style="list-style-type: none"> <li>Retain / Recruit members</li> <li>Increased sponsorship opportunity</li> <li>Increased event participation</li> </ul>	<ul style="list-style-type: none"> <li>Increased visibility</li> <li>Increased relevancy</li> </ul>
CI-1	Increase the frequency and relevancy of scientific events / forums	12,480	8,320	\$10,816	<ul style="list-style-type: none"> <li>Increased event participation</li> <li>Retain / Recruit members</li> <li>Increased sponsorship opportunities</li> </ul>	<ul style="list-style-type: none"> <li>Increased visibility and recognition for MBC</li> <li>Increased relevancy</li> </ul>
CI-2	Create a partnership with MA hospital trade associations to address clinical development issues in MA	\$8,060		\$4,056		<ul style="list-style-type: none"> <li>Increased visibility and recognition for MBC</li> <li>Increased relevancy</li> </ul>
<b>TOTAL</b>		<b>\$131,976</b>	<b>\$26,494</b>	<b>\$40,560</b>		

<sup>1</sup> For initiatives that span into 2011, only costs in 2010 are included

<sup>2</sup> Includes ongoing costs of initiatives for 2010 only

<sup>3</sup> Yearly, costs for ongoing initiative activity for 2011+

<sup>4</sup> For detailed benefits per initiative, refer to Appendix D

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Appendix

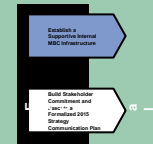
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# Internal and External Success Factors

It will be necessary to manage / address both internal and external success factors in order to realize the maximum benefits of the 2015 strategy and corresponding initiatives.

	<u>Critical Success Factors</u>	<u>Description</u>
<b>Internal</b>	<b>Establish a Supportive Internal MBC Infrastructure</b>	<ul style="list-style-type: none"><li>▪ Improve program management and governance processes</li><li>▪ Improve overall communication and engagement strategy</li><li>▪ Continue investment in information technology (e.g., website and database capabilities)</li><li>▪ Streamline and enhance committee structure and content to support 2015 objectives</li></ul>
<b>External</b>	<b>Build Stakeholder Commitment and Execute a Formalized 2015 Strategy Communication Plan</b>	<ul style="list-style-type: none"><li>▪ Distribute 2015 Strategy materials through a combination of member communications and events<ul style="list-style-type: none"><li>▪ Incorporate 2015 Strategy into annual communication / member engagement plan</li><li>▪ Identify other forums to raise awareness of 2015 findings and recommendations</li></ul></li><li>▪ Identify industry leaders to “champion” 2015 initiatives<ul style="list-style-type: none"><li>▪ Have “champion’s” support efforts to build cluster consensus / buy-in and contribute to initiative implementation</li></ul></li></ul>

# Establish a Supportive Internal MBC Infrastructure (1 of 2)



Improvements to MBC's program management capability and communications strategy will be essential for successful implementation of initiatives and enable a sustainable organizational infrastructure to position MBC for future growth.

## Improve Program Management and Governance Processes

### Key Activities

- Leverage biweekly staff / leadership meetings to oversee the delivery of 2015 initiatives
- Monitor initiative progress on a regular basis, including an update on achievements, issues and next steps
- Develop an internal process for
  - Approval of or modifications to new initiatives / activities / programs
  - Assessment of new services/ offerings for 2015 alignment

### Benefits

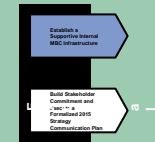
- Ensures resources and efforts are optimally aligned to support both short term and long term objectives
- Improves organizational efficiencies through the establishment of clearly defined roles and responsibilities, accountability and communications for each initiative

## Improve Member Communication and Engagement Strategy

- Continue efforts to develop / improve communication strategy with consistent and targeted messaging for various stakeholder groups
- Plan targeted communication efforts aimed at various company employee level and function (e.g., targeted materials and invites for CEOs, scientists, sales and marketing staff)
- Balance relevancy and frequency of regular member touch points (e.g., newsletters, website postings) to keep membership informed of current MBC activities and events

- Increases MBC's visibility and relevancy to each membership segment
- Raises level of awareness to membership on the breadth and depth of activities / services MBC is involved in to support the MA cluster
  - As indicated in the E&Y survey, there is a major gap among members in the awareness and usage of MBC services
- Provides visibility and introduction to new services and events, which is critical to the success of many 2015 Strategy initiatives

# Establish a Supportive Internal MBC Infrastructure (2 of 2)



IT investments will be a critical to enabling MBC's communication strategy, while a streamlined committee structure and content will further enhance efforts for successful initiative implementation.

## Key Activities

### Continue Investments in Information Technology

- Continue moving forward with web-site / intranet enhancements
- Continue efforts to update database capabilities and link with member profiles
- Expand website content to include searchable member listings and detailed member profiles

### Streamline and Enhance Committee Structure and Content to Support 2015 Objectives

- Evaluate opportunities to streamline / improve committee structure to increase value / interest in committee meetings
  - Investigate topic-based approach to enable collaboration and boost attendance across functional groups and committees
- Explore opportunities to leverage committees where appropriate to support MBC 2015 strategic objectives
  - Leverage quarterly committee chair meetings to support the 2015 strategy and initiatives

## Benefits

- Allows for the collection of necessary information to enable targeted communication efforts
- Enhanced IT infrastructure will help MBC understand their constituency better and enable the distribution of the “right information, to the right people, at the right time”; this capability is an essential foundation for the improved communication strategy
- Increases consistency of committee activities
- Enables a greater degree of collaboration among stakeholder groups and increases the relevancy / value of committee meetings
- As committee participation represents a strong proportion of member attendance / involvement, incorporating 2015 strategy initiatives into committee structure supports efforts to build stakeholder commitment and buy-in

# Formalize Communication Plan and Build Stakeholder Commitment



Effective communication of the 2015 Strategy report and key stakeholder contributions are essential to increasing the visibility of MBC and successful implementation of initiatives.

## Formalize 2015 Strategy Communication Plan

### Key Activities

- Leverage Annual Meeting to “kick-off” implementation of key 2015 Strategy initiatives and to gather support and participation
  - Consider “working sessions” during meeting to actively gain buy-in and recruit individuals to support efforts
- Engage key industry leaders and organizations directly to discuss findings and recommendations
- Finalize communication plan that identifies specific action items per MBC stakeholder groups and socializes the report’s findings

### Benefits

- Increases the visibility of MBC
- Generates awareness of key trends and issues facing the MA biotech cluster
- Facilitates buy-in from cluster constituents
- Supports efforts for greater member engagement and involvement in MBC to support implementation of initiatives

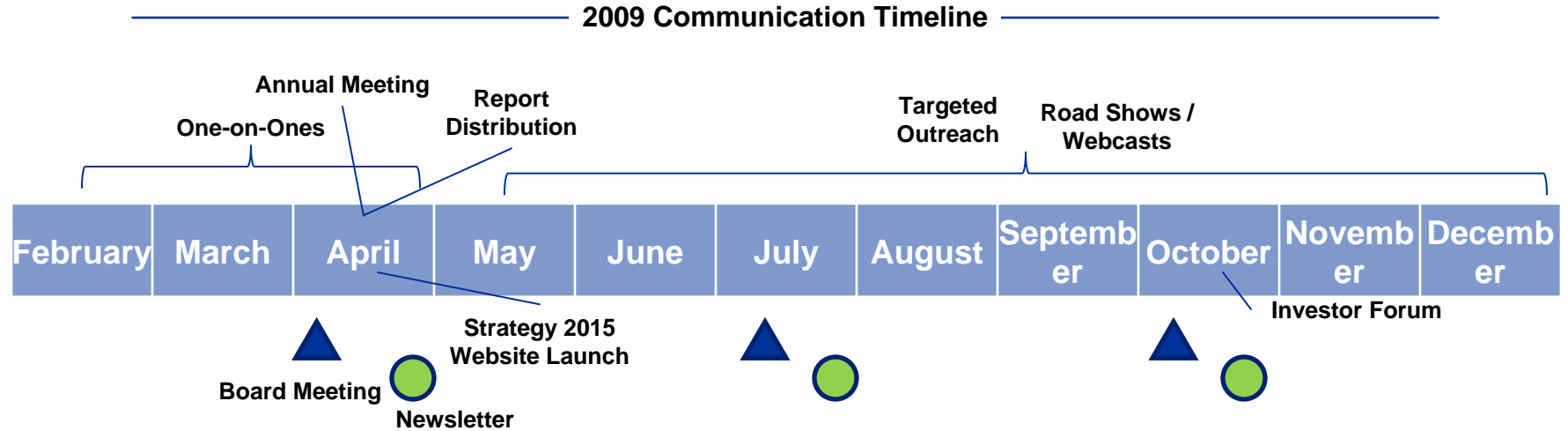
## Build Stakeholder Commitment

- Appoint a MBC board member or other industry leader as an external champion for each initiative
  - Champions should help drive the implementation of recommendations in order to help maximize results
  - Execute upon detailed and targeted communication plan

- Increases the exposure and awareness of 2015 strategies and enables the “cascade” effect by getting the most influential people “on board”
- Supports the uptake and success of each initiative by increasing member involvement in MBC

# 2015 Strategy Communication Plan: Timeline

A communication plan will facilitate leadership alignment, stakeholder engagement, and awareness and understanding by key cluster constituents.



## Guiding Principles

- Consistent and coordinated communications externally and internally are critical to the success of 2015 Strategy
- Communications are not only meant to inform people, but to align efforts in a common direction, build momentum and generate enthusiasm
  - Leverage board members and key industry leaders to present strategy highlights
  - Highlight achievements early and frequently
  - Leverage existing events to promote 2015 Strategy Report
- Provide a forum for two-way communication and feedback; gauge the level of stakeholder buy-in and feedback to alter communication strategy appropriately or to modify initiatives

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## **Appendix A: Competitive Analysis Cluster Profiles**

# Cluster Profile: San Francisco, CA

## Overview

The SF Bay Area is the birthplace of the biotech industry and boasts the largest concentration and diversity of life sciences companies

Reported LS Companies <sup>1</sup>	1,377	<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Strong academic research and medical center presence</li> <li>▪ Global leader in VC presence and investment</li> <li>▪ Large concentration of biotechnology companies, including fully integrated, large-scale biopharmaceutical companies</li> </ul>
Reported LS Employees <sup>1</sup>	90,000	
Biotech Companies <sup>2</sup>	120 (Private) 93 (Public)	<p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>▪ High capital and operating costs</li> <li>▪ Lacks true cluster – biotech presence is broadly distributed across bay area</li> </ul>
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$1,023 M	
NIH Funding (2006)	\$ 2,260 M	

### Industry Presence

- The SF bay area has the largest concentration of life sciences companies and fully integrated biopharmaceutical companies
  - There are an estimated 1,377 life sciences companies in the bay area
  - The cluster as a whole is relatively 'mature'; companies in the region have 449 products on the market and 492 products in Phase II / III
  - Manufacturing presence is primarily through established companies; new manufacturing growth has been limited
- Large pharma has historically been absent from the region, but companies are now establishing a presence in the area (e.g., Pfizer, Takeda)

### Availability of Funding

- Northern California is now home to 34 percent of active US venture capital firms and this regional concentration has existed since the 1980s.
- The San Francisco region received \$1.24 B of biotech VC investment in 2007, the largest amount among clusters
- Northern California received \$2.26 billion in National Institutes of Health (NIH) research grants in 2006, more than any other region in the US

### University / Medical Center Presence

- The region has a wealth of first-tier life science research and medical care institutions, including five major research universities and three medical schools
- Northern California is home to four major research universities with over \$500 million in research funding: University of California at Davis, University of California at San Francisco (UCSF), University of California at Berkeley, Stanford University
- Envidable track record—more than 50 percent of all companies spun out from universities in California have come from Northern California institutions

### Business and Regulatory Environment

- California's net operating loss tax policy trails many states
  - The tax policy allows companies to write off losses for 10 years, compared to the 20-year policy 28 other states and the Federal government allow
- CA ranks 48 among states for cost of doing business; high costs pose challenges for companies looking to expand, especially as California's biotech industry has a promising late stage pipeline
- BayBio, the regions life sciences member association, plays an active role in advocacy at the federal, state and local level

<sup>1</sup> BayBio

<sup>2</sup> Deloitte Recao LLC (Biotech companies developing human therapeutics only; private companies consist of companies that have received VC funding)

# Cluster Profile: San Diego, CA

## Overview

San Diego is home to the third largest concentration of biotech companies behind SF and MA and consists primarily of smaller, integrated biotech companies

Reported LS Companies <sup>1</sup>	700	<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>Seamless collaboration among public, private and academic institutions; true “cluster” environment - high concentration of companies in close proximity</li> <li>Positioned to take advantage of close proximity to growing Asian biotech industries</li> </ul> <p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>Lower level of VC presence than MA or SF</li> <li>High capital and operating costs</li> </ul>
Reported LS Employees <sup>1</sup>	40,000	
Biotech Companies <sup>2</sup>	83 (Private) 90 (Public)	
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$ 658 M	
NIH Funding (2007)	\$1,790 M	

### Industry Presence

- SD contains the third largest concentration of biotech companies behind SF and MA but has a limited big pharma presence
  - An estimated 700 life sciences companies are present
  - Industry began nearly 30 years ago with the growth of Hybritech; many of the original founders and entrepreneurs have since founded an estimated 40 biotech companies in the cluster<sup>1</sup>
  - SD does not contain the same level of biotech start-ups as SF or MA and instead consists mostly of fully integrated biotech companies
  - Close proximity to a large medical device cluster in Orange County

### Availability of Funding

- The San Diego cluster received nearly \$1 B in biotech VC funding in 2007
- In 2007, Southern California received more than \$1.79 billion in research funding from the National Institute of Health.
- Compared to other top biotech locations (e.g., MA and SF), San Diego has a relatively low level of VC firms and institutional banks present which can lead to a decrease in capital flows

### University / Medical Center Presence

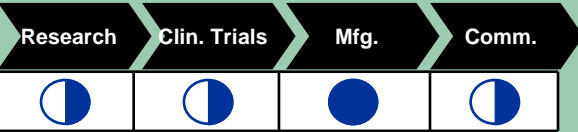
- There are four major academic institutions (UCSD, Scripps, Salk, Burnham) and many smaller ones in San Diego County
- In late 2006, leading research facilities in the area teamed up to create the San Diego Consortium for Regenerative Medicine to provide a haven for stem cell research free of any restrictions attached to federal funding
  - The joint venture aims to take advantage of California's \$3 billion appropriation for stem cell research
  - The funding has already lured scientists from other states looking to expand their work without facing federal limitations

### Business and Regulatory Environment

- California's Net operating loss tax policy trails many states
  - The tax policy allows companies to write off losses for 10 years, compared to the 20-year policy 28 other states and the Federal government allow
- CA ranks 48 among states for cost of doing business; high costs pose challenges for companies looking to expand, especially as California's biotech industry has a promising late stage pipeline
- Through BIOCUM, the regions Biotech member trade association, the industry enjoys a strong policy presence at the local, state and federal level

<sup>1</sup> BIOCUM

<sup>2</sup> Deloitte Reaco LLC (Biotech companies developing human therapeutics only; private companies consist of companies that have received VC funding)



# Cluster Profile: RTP, NC

## Overview

NC is the third largest biotechnology state in the U.S. and contains a strong manufacturing and CRO base, but has a limited R&D infrastructure

Reported LS Companies <sup>1</sup>	450
Reported LS Employees <sup>1</sup>	55,000
Biotech Companies <sup>2</sup>	34 (Private) 12 (Public)
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$ 154 M
NIH Funding (2007)	\$ 931 M

<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Strong manufacturing and CRO presence</li> <li>▪ Region has significantly lower costs than competing clusters (i.e., CA and MA)</li> </ul> <p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>▪ Innovative research lacks other clusters (ranked 20<sup>th</sup> among all states in bioscience patent activity since 2002)</li> <li>▪ Low level of VC presence and investment</li> <li>▪ Limited commercial talent</li> </ul>
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### Industry Presence

- North Carolina is the third leading state in the nation for biotechnology with an estimated 450 companies
- The state has a large and specialized manufacturing sector and contract research organization presence (CRO); 91 contract research, / testing companies are located in the state
- Biotech companies located in NC are mostly smaller in size and scale than in other clusters
- The agricultural feedstock and chemicals subsector has a large presence in NC; 30 agricultural biotechnology companies are present
- Among the ten largest bioscience employer states, NC's 18.5 percent job growth since 2001 has been the fastest

### University / Medical Center Presence

- Strong academic bioscience research presence; North Carolina had a total of \$1.3 billion in academic life sciences research expenditures<sup>1</sup>
- NC has a high concentration of nationally ranked medical schools
- Two North Carolina universities are in the upper echelon of research institutions in terms of overall research expenditures—Duke University (\$590 million) and UNC, Chapel Hill (\$584 million)
  - North Carolina's universities have a mixed record in tech transfer
  - Per \$10 million research dollars, both Duke and UC Chapel Hill lag to some extent in patents issued and license income

### Availability of Funding

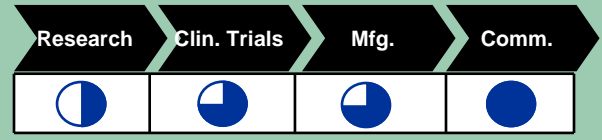
- North Carolina has raised the fifth highest amount of VC funding since 1999, behind CA, MA, PA and NJ
- In November, biotech industry executives from NC proposed to the governor a public-private entity to provide up to \$200 million to fund the state's biotech industry, as many companies are at risk of bankruptcy

### Business and Regulatory Environment

- Among states with a large biotech concentration, North Carolina offers the lowest cost business environment
  - Average rents in Raleigh, NC are roughly half of rents in Boston
  - NC is ranked 22th in the US cost of doing business rankings, compared to 41 and 49 for MA and California respectively
- The state legislature is supportive of the industry and has funneled more than \$1B over the past 10 years
- The state and regional associations have supported growth through incubators and the establishment of bio-ready sties

<sup>1</sup> North Carolina Biotech Center

<sup>2</sup> Deloitte Recap LLC. (State level data; represents biotech companies developing human therapeutics; private companies are estimates based on VC financing data)



# Cluster Profile: Philadelphia, PA

## Overview

Philadelphia has a strong pharma presence and is strong in manufacturing and CRO services; while the cluster has a strong academic medical center and university research presence, innovative biotech research and start-up development is limited

Reported LS Companies <sup>1</sup>	703	<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>▪ Strong pharma presence that is becoming increasingly connected with biotechnology</li> <li>▪ Well-funded, world-class academic research institutions and medical centers</li> <li>▪ Supportive state government policies</li> </ul> <p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>▪ Limited biotech research infrastructure and innovation; research is more conducive to pharma</li> <li>▪ Challenging VC funding environment</li> </ul>
Reported LS Employees <sup>1</sup>	53,000	
Biotech Companies <sup>2</sup>	42 (Private) 10 (Public)	
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$ 279 M	
NIH Funding (2007)	\$1,400 M	

### Industry Presence

- Strong presence of big pharma that is becoming increasingly biotech focused (e.g., AstraZeneca, GSK, Wyeth, Merck)
- The strength of the biosciences industry and state policy commitments to promote growth have ushered investment by several companies in PA
  - GSK acquired a manufacturing plant in Marietta in 2005
  - MEDRAD expansion of mfg facility into Allegheny county in 2005
  - ITSB built new R&D facility in 2006
  - Shire re-located corporate HQ to Chesterbrook in 2005
- PA faces significant challenges with retaining locally developed human capital due to draws from other locations

### Availability of Funding

- Pennsylvania is a major hub for NIH funding, with two academic institutions ranking consistently among the top ten recipients of funding annually
  - NIH funding in 2007 exceeded \$1.4 B
- Creative state funding includes proposed Jonas Salk Legacy Fund utilizing tobacco-settlement to finance \$1B facilities investments at PA universities
- Biotech venture capital investments have increased steadily since 2005 and average value per financing round has increased as well; biotech accounts for a majority of all VC investments in the state

### University / Medical Center Presence

- Pennsylvania has strong academic/research institutions that receive substantial NIH annual funding
  - The University of Pennsylvania and the University of Pittsburgh are in the top 10 universities for receipt of NIH research funding
  - Pennsylvania ranks 4th among states in bioscience academic R&D expenditures

### Business and Regulatory Environment

- Pennsylvania implemented several programs to foster development in the biosciences
  - Provided continued annual allocation to bioscience research and commercialization initiatives through the Commonwealth Universal Research Enhancement (CURE) program
  - Developing 29 Key Innovation Zones (KIZ) with incentives to higher education institutions to improve technology commercialization programs

<sup>1</sup> Philadelphia Bio

<sup>2</sup> Deloitte Recap LLC. (State level data; represents biotech companies developing human therapeutics; private companies are estimates based on VC financing data)



# Cluster Profile: Baltimore, MD / Washington D.C.

## Overview

The Baltimore / D.C. metro area has a strong presence of government agencies and academic research centers as well as a strong CRO industry presence; however, the cluster lacks a significant network of key biotech stakeholders

Reported LS Companies <sup>1</sup>	360	<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>Strong academic research and federal R&amp;D presence</li> <li>Strong government funding support and incubator infrastructure</li> </ul>
Reported LS Employees <sup>1</sup>	23,200	
Biotech Companies <sup>2</sup>	25 (Private) 18 (Public)	<p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>No significant network of biotech industry stakeholders; limited research scale</li> <li>Restricted availability of entrepreneurs / management teams</li> <li>Low level of VC presence and investment</li> </ul>
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$ 136 M	
NIH Funding (2007)	\$ 977 M	

### Industry Presence

- Of MD's estimated 360 biotech companies, 180 are developing human therapeutics, 90 provide biotech services, 72 develop research tools and diagnostics and 18 are involved in agbio / nutrition
  - MD is home to 18 publicly traded companies, along with more than 20 companies conducting clinical trials for new biotherapeutics
  - 67 Contract Research Organizations are present in MD
- The top 5 products (by revenue) developed by public bioscience companies headquartered in MD produced an aggregate \$1,376MM in 2005
- Private and federal industry presence as well as workforce initiatives have provided MD with an robust and talented workforce; the state is ranked second in concentration of doctoral scientists and engineers

### University / Medical Center Presence

- Home to more than 50 life science research-intensive federal institutions, several world-class academic institutions, an ever-expanding number of private research facilities
- Maryland's leading R&D facilities in bioscience include federal powerhouses such as NIH, FDA, Beltsville Agricultural Research Center, National Institute of Standards and Technology, J. Craig Venter Institute
- Prominent MD institution also include the Johns Hopkins University's Applied Physics Laboratory, the Science Technology Park at Johns Hopkins, Center for Environmental Energy at the University of Maryland, University of Maryland Biotechnology Institute (UMBI), UMB BioPark

### Availability of Funding

- The cluster has struggled with relatively low levels of VC funding; a survey by MDBIo revealed that 162 of 360 companies were funded through friends and family, as opposed to 61 by venture capital
- To address the limited amount of risk financing, the State emphasized public-private coordination to support formation and growth of biotech companies through the Maryland Venture Fund and the Technology Development Corporation (TEDCO)
- The University of Maryland in College Park and Baltimore created a Seed Grant Program in 2006 to encourage collaborative research and NIH grants

### Business and Regulatory Environment

- Maryland companies benefit from the state's commitment to incubators, partnerships and alliances aimed at helping businesses thrive
  - Maryland has 20 business incubators supporting the development of biosciences companies
- The MD government committed to the BIO 2020 initiative, promising over \$1.1B to the MD bioscience industry over the next 10 years
- The governor passed legislation in 2007 to found the Maryland Life Sciences Advisory Board to address issues of communication and coordination among constituents

<sup>1</sup> Bioscience in Maryland, Taking Care of Business; 2007; by Tech Council MD  
<sup>2</sup> Deloitte Recap LLC (State level data; represents biotech companies developing human therapeutics; private companies are estimates based on VC financing data)



# Cluster Profile: Madison, WI

## Overview

Madison hosts a young but growing biotech sector which is enabled by a strong research university, tech. transfer expertise and biotech start-up support; however, the region lacks the necessary network of key biotech stakeholders and VC investment

Reported LS Companies <sup>1</sup>	350
Reported LS Employees <sup>1</sup>	27,000
Biotech Companies <sup>2</sup>	5 (Private) 1 (Public)
VC Funding (Avg./ Yr 5-yr) <sup>2</sup>	\$19 M
NIH Funding (2007)	\$ 370 M

- Key Strengths**
- Young, expanding industry with supportive legislature and government desire for expansion
  - Strong academic research institutions with notable expertise in stem cell research and tech transfer
- Key Weaknesses**
- Immature cluster that lacks a network of key biotech stakeholders, most notably VC presence
  - No fully developed capabilities across value chain

### Industry Presence

- The industry in WI is relatively young, with 2/3 of companies less than 15 years old
- Wisconsin has industry strengths in biomedical engineering – specifically in the area of medical imaging and diagnostic equipment manufacturing, agricultural biosciences, and biological reagents
- University Research Park, built near UW Madison, houses over 100 companies

### Availability of Funding

- WI lags in venture capital investment, but has an impressive angel investor network
- Currently, only 4 bioscience VC funds operate in WI

### University / Medical Center Presence

- WI biosciences industry includes strong academic research institutions which spent over \$675MM on bioscience R&D in 2006<sup>2</sup>
- The UW-Madison is one of the largest bioscience research institutions in the nation, ranking in the top 20 of all research institutions worldwide for NIH funded biomedical research
- More than 80% of bioscience start-ups in the state over the past two decades have evolved from R&D programs initiated at Wisconsin research institutions
- The Wisconsin Alumni Research Foundation (WARF) has licensed more than 3000 technologies from campus discoveries in its 80 years of existence

### Business and Regulatory Environment

- Wisconsin has an active member association that is dedicated to the biotech and medical device industry and the association has been instrumental in spurring the growth of the biotech sector in WI
- In 2008, the WI governor proposed two initiatives to spur biotech growth and investment
  - Innovate Wisconsin - a new R&D tax credit and exemption of R&D equipment from State sales and personal-property tax
  - Accelerate Wisconsin - expansions to existing angel-investor and venture-capital tax credits, an exclusion from taxation of capital gains reinvested in qualifying in-state businesses, and a direct grant and loan program for start-up companies

<sup>1</sup> 2008 Wisconsin Biotechnology and Medical Device Business directory

<sup>2</sup> Deloitte Recap LLC (State level data; represents biotech companies developing human therapeutics; private companies are estimates based on VC financing data)

# Cluster Profile: United Kingdom (Cambridge / London)



## Overview

The UK is Europe's premier biotech cluster and possesses significant talent and history of innovation; however, current barriers regarding costs, funding and clinical trials are limiting the cluster's future potential

Reported Biotech Companies <sup>1</sup>	400
Reported Biotech Employees <sup>1</sup>	25,000
VC Funding	

### Key Strengths

- World renowned universities and research facilities
- Strong access to talent

### Key Weaknesses

- Decreasing access to VC funding, accelerated by current economic crisis
- Lacks adequate infrastructure and support for clinical trials

### Industry Presence

- The UK biotech sub-sector, as defined by Ernst & Young, includes over 400 companies, employing over 25,000 people, and generating revenues of £3 billion<sup>5</sup>
  - The majority of companies are less than 15 years old, and only 8% are publicly traded
  - The cluster contains the largest pipeline in Europe, with 361 products in development, including 155 in phases II / III
- The current financial crisis is shrinking the UK biotech presence as many private biotech companies are being bought by pharma companies, most of which are based abroad

### University / Medical Center Presence

- The UK contains world renowned academic institutions (e.g., University of Cambridge, Oxford University) and has a history of producing a high percentage of Nobel prize winners
- The NHS, UK's main provider of healthcare, offers a gateway to a large patient population which can be used for administering efficient clinical trials; however, the UK currently lacks the adequate infrastructure, cultural support and funding to capitalize on its clinical trial potential
  - The Financial Times reported in June that Pfizer, Roche and Merck Serono have all decided to cut back on clinical research in the UK due to difficulty recruiting patients

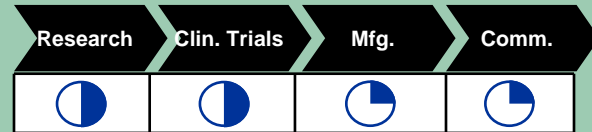
### Availability of Funding

- The availability of funding, from both private and public sources, has decreased over the past several years and the current economic crisis has created a dire situation for the industry
  - The UK's public markets are less welcoming to the risks and rewards of the industry, which has lowered the level of VC investment
  - In 2007, VCs invested in only 36 start-ups in the UK, the lowest level since 1999
  - Companies in early phases of clinical development are relying on alliances and licensing arrangements to fund later stage development
  - Due to current economic crises, the industry is advocating for a "bail out" by the government to inject £550 million into companies struggling to receive funding

### Business and Regulatory Environment

- The NHS has been traditionally less collaborative with the biotech industry, making it more difficult to establish supportive policies and encourage innovative research
- Ability to gain reimbursement approval from NICE is challenging; similar to other biotech clusters in Europe, the primary market for therapeutics remain in the U.S..
  - R&D tax credits are available but are considered to be ineffective
  - London and Cambridge have reasonably high costs of doing business

<sup>1</sup> E&Y Beyond Borders: Global Biotechnology Report 2008;



# Cluster Profile: Canada (Toronto / Montreal)

## Overview

The Canadian biotech sector has a strong public and private biotech presence; however, current funding concerns raise questions about the sustainment of the sector as more companies move to the U.S or enter alliances / partnerships

Reported Biotech Companies <sup>1</sup>	404	<p><b>Key Strengths</b></p> <ul style="list-style-type: none"> <li>Relaxed immigration policies to retain key talent</li> <li>Access to US talent, markets and infrastructure</li> </ul> <p><b>Key Weaknesses</b></p> <ul style="list-style-type: none"> <li>Lack of public and private funding</li> <li>Limited commercial presence and manufacturing infrastructure</li> <li>Ability to attract and retain scientific talent</li> </ul>
Reported Biotech Employees <sup>1</sup>	7,326	
VC Funding (2007) <sup>1</sup>	\$ 353 M	

### Industry Presence

- Canada has a reasonably diverse mix of biotech companies, large pharma, bio-informatics and other sectors; most multi national companies have operations here
  - Approximately half of companies are involved in therapeutics, with a third involved in agriculture, aquatics, biomaterials, and environment related biotech products
- A new report from BioTalent Canada found that the country is having trouble attracting and retaining biotech workers

### Availability of Funding

- Canada lacks a strong public market ready to invest in biotech stocks and IPOs and venture capital funding is limited to a few successful private companies
- M&A, alliances and other partnerships are critical funding sources for many Canadian biotech companies, which has resulted in consolidation in the industry and has reduced the ability of Canadian biotech companies to grow in scale and commercialize products independently
- Lack of funding often forces companies to enter alliances or partnerships prematurely for less than optimal values

### University / Medical Center Presence

- Canada hosts the second largest number of clinical trials behind the US; however, rising costs are expected to decrease this number going forward
- Canada contains several research centers supported by government funding and several institutions like Population Health research institute provide ability to conduct and manage multi-country clinical trials
- Academic institutions such as University of Montreal and McGill University perform respected biotech research and contribute to the overall high level of education among Canada's workforce; 51% of Canadians have at least a tertiary education

### Business and Regulatory Environment

- Canada boasts the third largest R&D tax credit in the world; however, tax regulations are still considered more stringent and recently companies have moved to US locations due to these regulations
- Canada has a lower cost of doing business than the US (leads in all G7 countries)
- Tax implications of cross-border VC investments are reducing the level of US investment in Canadian companies
- Immigration policies support international skilled labor access; IP laws are in alignment with the US and proximity to the U.S. provides access to US markets, infrastructure and talent

<sup>1</sup> E&Y Beyond Borders: Global Biotechnology Report, 2008

## Cluster Profile: Switzerland

### Overview

Switzerland has a significant concentration of key stakeholders, including strong universities and a pharma and biotech presence which has fueled considerable convergence

Reported Biotech Companies<sup>1</sup> 220

Reported Biotech Employees<sup>1</sup> 7,000

VC Funding

#### Key Strengths

- Strong infrastructure with world-class universities, quality of life and economic growth
- Strong government support for innovation and tech transfer initiatives
- Significant availability of trained talent (notably pharma talent)

#### Key Weaknesses

- Primary market for products remains the U.S. due to EU reimbursement challenges
- Limited manufacturing presence, potentially attributed to cost of doing business

#### Industry Presence

- With 148 biotech companies and 72 biotech suppliers, Switzerland boasts the world's highest per capita biotech density
- Switzerland has a strong pharma presence with companies such as Novartis and Roche
  - The presence of large pharmaceutical companies has resulted in a relatively large number of companies created through corporate spinoffs, rather than the more traditional start-up route
- Ranks second in Europe in the number of phase three products with 22
- More than 80% of the Swiss biotechnology R&D activities are performed in one of the country's three main biotechnology/life sciences clusters: Basel, Zurich and Lake Geneva

#### Availability of Funding

- Successful IPOs at the SWX Swiss Exchange, combined with the longstanding interaction between the life sciences and financial industries, have created an attractive atmosphere for private and public funding
  - About 40 VC firms and other private equity firms provide support for incubating research, including 10 of Europe's top 25 biotech funds
  - Investors in the Swiss market are experienced and well funded
- Public funding from research university grants are available to encourage start up biotech companies
- Federal and canton funding supports more than 70% of graduate R&D investments

#### University / Medical Center Presence

- Switzerland contains prominent universities such as the University of Zurich and University of Basel as well as two federal universities, 10 cantonal universities and 7 universities of applied science
- A high degree of collaboration and knowledge exchange among institutes, universities and private companies exists
  - Numerous organizations manage tech transfer including the Swiss Technology Transfer Association and Swiss Institute for Innovation
  - 14% of all European biotech products in the pipeline come from Switzerland, where more than 70% of all scientific contributions originate in academia

#### Business and Regulatory Environment

- Switzerland offers very favorable tax environment
  - The maximum corporate tax rate in 2007 was 21%, one of the lowest in Europe
  - The administrative and regulatory framework encourages new business with low payroll taxes, short product registration cycles, strong IP protection and easy access to markets
- Tax credits and presence of leading financial institutions provides foundational support to encourage biotechnology presence

<sup>1</sup> Swiss Biotechnology Report, 2008



# Cluster Profile: Ireland

## Overview

Ireland has a significant pharma presence for manufacturing operations but has a limited infrastructure and talent base for innovative biotech R&D

Reported Biotech Companies<sup>1</sup> 170  
 Reported Biotech Employees<sup>1</sup> 35,000  
 VC Funding

### Key Strengths

- Significant manufacturing operations presence of large pharma / biotech
- Favorable tax and infrastructure support to establish operations

### Key Weaknesses

- Limited VC presence to support innovation and R&D
- Limited clinical trial infrastructure and access to appropriate patient populations
- Limited scientific talent and academic eminence to transfer new discoveries as spin offs

### Industry Presence

- Nine of the world's top 10 pharmaceutical companies have operations in Ireland
  - Industry leaders such as Pfizer, Amgen, GlaxoSmithKline, Merck, Genzyme, Boston Scientific and Abbott each have substantial operations, most notably in manufacturing
  - Ireland boasts 32 manufacturing plants which are approved by the US FDA, producing six of the 10 best-selling drugs in the world
- There is no significant presence of homegrown Irish companies, instead, R&D is performed mostly through collaborations with larger multinationals
- Ireland lags among European countries in the number of products in development; Irish companies have 27 products in development and only 2 in phase III

### Availability of Funding

- VC investment in Ireland is minimal
- Many recent investments are from leading pharma / biotech companies expanding manufacturing operations in Ireland
- The Irish government has committed to spending \$1.3 B in bio-sciences

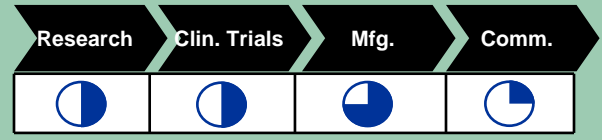
### University / Medical Center Presence

- Ireland contains a limited amount of university and medical centers engaged in and contributing significantly to the country's biotech industry
- Ireland has not been an attractive destination for clinical trials, largely due to the limited infrastructure of physicians and access to patient populations
- Notable recent developments include:
  - The National Bio-processing research, education and training facility was approved in 2005; with an investment of \$80M it is focused on collaborating with academia to produce skilled labor in bio-processing technologies
  - A bio-pharma campus is planned to be built in Galway, Ireland

### Business and Regulatory Environment

- Ireland's business environment is a primary driver of the country's strong manufacturing presence
  - Ireland has one of the world's lowest rates of corporation tax with the maximum rate for trading profits being 12.5 percent
  - Easy access to the EU market
- Economic incentives for intellectual property (IP) which is developed and licensed from the country include a patent royalty exemption, stamp duty exemption, and a research and development tax credit

<sup>1</sup> Next Generation Pharmaceutical, Biotechnology in Ireland



# Cluster Profile: Singapore

## Overview

Historically, a low cost manufacturing hub, Singapore is aiming to move up the value chain and position itself as a world-class center for R&D through significant government investment; however, the cluster has yet to develop a “home-grown” biotech industry

Reported Biotech Companies <sup>1</sup>	100
Reported Biotech Employees <sup>1</sup>	11,517
VC Funding	

### Key Strengths

- Educated and skilled workforce
- Supportive government, business and regulatory environment
- Government supported research institutes

### Key Weaknesses

- Relatively low levels of biotech company presence and “network” effect
- Challenging VC funding environment

### Industry Presence

- Pharmaceutical and biologics manufacturing has emerged as a key component of Singapore’s manufacturing sector in recent years; six of the world’s top 10 pharmaceutical companies have located their manufacturing facilities in the country
  - Singapore is planning to leverage its historical pharmaceutical manufacturing strength to emerge as a leading center for biologics manufacturing
- Singapore is investing heavily in public biotech research centers to enable a platform of innovation and attract / grow talent; however, the homegrown biotech presence is still nascent
- An increasing number of pharma and biotech companies are beginning to leverage Singapore for clinical trials and establishing regional centers

### Availability of Funding

- Singapore has not yet become a major hub for venture capital and investment companies primarily due to lack of strong public market that could provide a reasonable exit strategy
  - Although seed money is available, later phase funding is difficult to attain and companies have to look for investors overseas
  - The recent awareness of the developments in Asia in the western world promises a more positive outlook for young entities in the region
- Singapore’s Ministry of Trade and Industry plans to commit \$7.5 billion during the next five years to sustain innovation-driven growth through R&D that supports its key industry clusters, including biomedical sciences

### University / Medical Center Presence

- Singapore is leveraging public research institutes as a means to build a sustainable biotech R&D platform
  - The Biomedical Research Council (BMRC) oversees the public biomedical sciences research in Singapore through seven institutes, each with its own scientific focus
  - The research institutes continue to publish in high impact scientific journals and Singapore trails only the US in patents per capita
  - Singapore has established a leading presence in stem cell research through the Singapore Stem Cell Consortium
- BMRC also provides grants to universities, hospitals and disease centers

### Business and Regulatory Environment

- Singapore is an attractive choice as an integrated business hub
  - Operational costs in Singapore are significantly lower than in Western countries), but perhaps equally important is a work environment that makes the pace of work speedier and more efficient.
- Strong patent protection and regulatory framework, ease of research on animals, and good work ethic are important attractions
  - Singapore allows work to be done on the use of stem cells for therapeutic purposes

<sup>1</sup> BioSpectrum Asia, defined as “core life science companies”



## Cluster Profile: India (Bangalore / Hyderabad)

Historically focused on CRO type activities, manufacturing and bio-generics, India is currently developing strategies to support innovative research and is poised to continue growth in manufacturing and clinical trials

Reported Biotech Companies <sup>1</sup>	340	<p><b><u>Key Strengths</u></b></p> <ul style="list-style-type: none"> <li>Attractive outsourcing destination: low costs and availability of well-educated resources</li> <li>Public support through research funds and large local market for commercialization</li> </ul> <p><b><u>Key Weaknesses</u></b></p> <ul style="list-style-type: none"> <li>Lacks innovative research infrastructure</li> <li>Weak intellectual property regulation and protection</li> <li>Challenging public and private funding environment</li> </ul>
Reported Biotech Employees <sup>1</sup>	16,000	
VC Funding		

### Industry Presence

- Over 300 biotech firms are operating in India; a small minority of firms are looking at innovative R&D, but the vast majority are involved in biogenerics
- The numbers of players is expected to double by 2010, but consolidation is also anticipated
- Bangalore is home to 200 diverse companies and is the leading cluster in India; other cities like Hyderabad, Chennai, Pune and Mumbai also have emerged as preferred destinations to set up a biotech facility
- India is an emerging preferred hub for contract research organizations and contract manufacturing organizations
- India has about 75 US FDA approved plants, which is the highest number of FDA approved plants outside the US

### University / Medical Center Presence

- Clinical trials conducted in India cost up to a third less than in the US or Europe and the country boasts a large pool of well-educated, English-speaking personnel
- India is becoming increasingly attractive as a destination for clinical trials and has the potential to emerge as the foremost destination for outsourcing clinical trials; however, concerns are present regarding India's infrastructure and availability of talent for the clinical trial influx
- A large number of programs/universities offer generic science/engineering degrees, but limited number of advanced programs on biotechnology

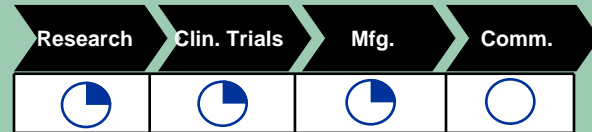
### Availability of Funding

- Securing private and public funding despite risk aversion among VCs is a major challenge for the Indian biotech industry
- Investment in the sector is dominated by public sector financial institutions and early stage research are primarily supported by public sources and grants

### Business and Regulatory Environment

- The government is supportive of biotech growth and is committed to the construction of multiple biotech research parks; public centers provide incubation and infrastructure support for newly formed bio-tech companies
- Intellectual property rights are poorly protected in India; India is one of 15 countries on the 'priority watch list' compiled by the Office of the US Trade Representative
- The industry is lobbying for the need to improve the regulatory infrastructure, bio-manufacturing standards, clinical development capabilities, R&D collaborations with US / EU firms and acceptance of Indian clinical data by the FDA and the European agency for Evaluation of Medicinal Products of Europe

<sup>1</sup> Biotech Boom: Gathering steam. India Now - A Perspective Vol 4 Issue 3



# Cluster Profile: China (Shanghai / Beijing)

## Overview

Similar to India, China's biotech strength is in CRO-type activities; however, with strong government support the biotech sector is poised for rapid growth in all aspects of the value chain

Reported Biotech Companies<sup>1</sup>      500

Reported Biotech Employees

VC Funding

### Key Strengths

- Attractive outsourcing destination
- Government funding and support

### Key Weaknesses

- Uncertainty about IP laws and government regulations
- Research infrastructure: limited ability to promote innovation & transfer tech effectively from universities

### Industry Presence

- China has approximately 200 state-run biomedical facilities and more than 500 biotechnology firms
  - Many of the 500 biotech companies perform CRO-type services; firms that are pursuing innovative R&D have incorporated hybrid business models that dilute resources to include contract services or non-innovative products, to first fund the firm's survival and then fund R&D activities
  - Given that China's biopharmaceutical market is primarily generic, most companies developing therapeutics are smaller domestic companies that compete primarily on price
- A total of 18 bio-pharmaceutical products have been commercialized by Chinese companies, 30 products are in clinical trials

### Availability of Funding

- While VC investment in Chinese biotech companies are increasing, and more western VC funds are establishing a presence in China, funding limitations exist for early-stage companies
  - Venture capital investment in China tends to favor lower-risk investments in revenue-generating companies
- The Chinese government is actively investing in biotechnology ; the government is estimated to spend more than \$600 M on biotech R&D annually with in excess of 60 local companies receiving state support
  - By 2015, government support for local R&D is expected to top \$14 B
  - Continued regulatory reforms are likely to boost foreign investor confidence which could pave the way for even more future growth

### University / Medical Center Presence

- China is becoming an increasingly attractive location for clinical trials due to low costs and ease of patient recruitment.; the FDA has established a presence in China and the country has also joined the WHO trial registry
- The Chinese government is encouraging technology transfer and start-up formation through the New Drug R&D Coordinating and Leading Group, a project in which universities and research centers will list technologies for commercialization
- China has an available talent pool with technical expertise and the country is poised to benefit significantly from a "reverse migration" of U.S.-trained Chinese scientists now setting up biotech start-ups, contract-research companies, and university labs in mainland China

### Business and Regulatory Environment

- The rapid growth of the biotech industry over the past several years was facilitated by significant regulatory reform, including:
  - Accession to WTO which led to revised and improved IP regulations
  - Full compliance mandate of good manufacturing practice (GMP) regulations
- The main barriers to faster growth in biotech include continued concerns over lax IP rights, language barriers and quality issues
- The government has sought to improve the situation through the construction of a number of US FDA-standard biotech parks

<sup>1</sup> China Pharmaceuticals & Healthcare Report Q1 2008, Business Monitor International

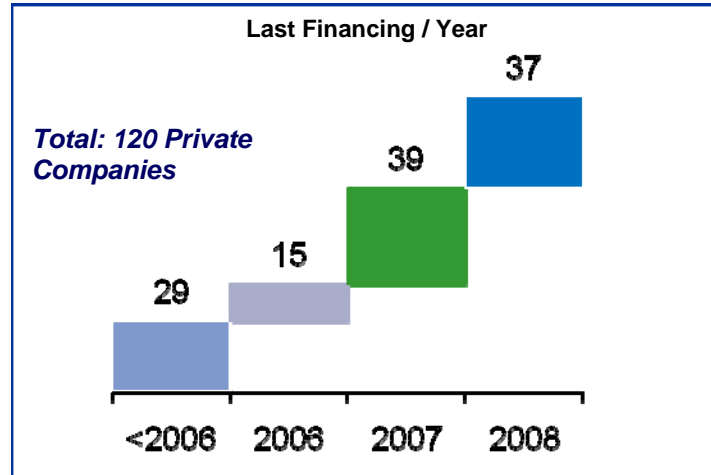
— **Appendix B: Additional Detail on Cluster Financials** —

## Cluster Financing: San Francisco

### Private Companies

Since 1999, 325 recorded rounds of VC financing raising \$7.49 billion

- 181 companies have raised VC Funding since 1999
- 47 companies completed IPO, Reverse Merger, or Trade Sale
- 14 companies liquidated or closed
- **120 Current Active SF Private Companies**

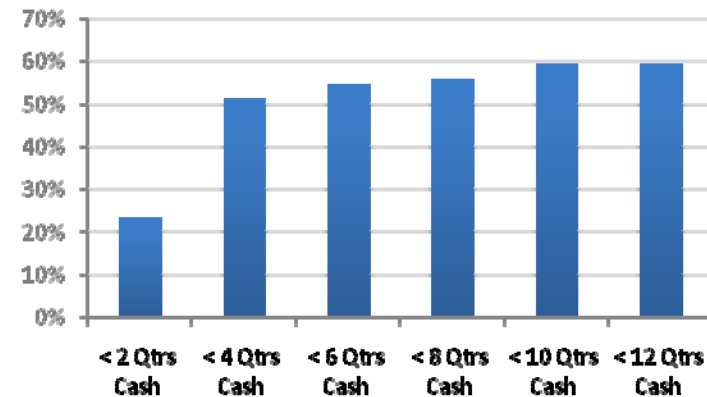


- **Over 1/3 of SF's private companies have not received financing since 2006**

### Public Companies

~93 public companies - Market cap of ~\$159 billion

- 49 companies have market cap <\$100 million
- 83 companies have market cap <\$1 billion
- Genentech has the largest cap ~\$81.8 billion



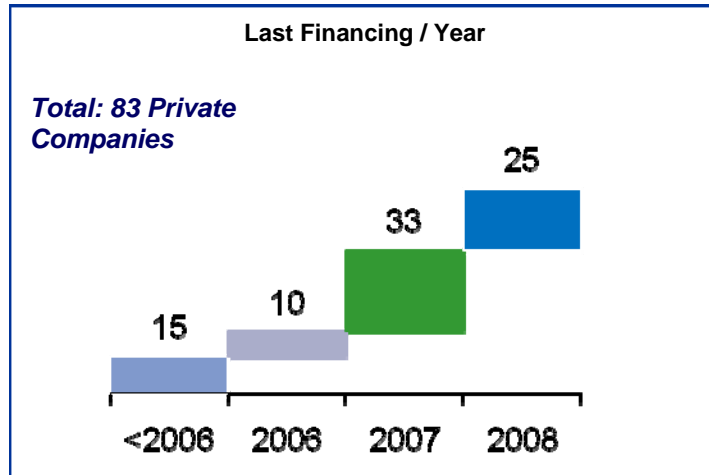
- **Fifty percent of companies risk running out of cash by the end of 2009**

## Cluster Financing: San Diego

### Private Companies

Since 1999, 252 recorded rounds of VC financing raising \$4.74 billion

- 144 companies have raised VC Funding since 1999
- 42 companies completed IPO, Reverse Merger, or Trade Sale
- 19 companies liquidated or closed
- **83 Current Active SF Private Companies**

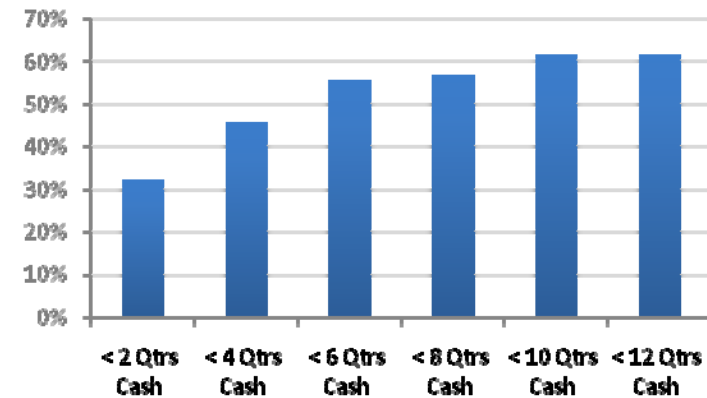


- **30% of SD's private companies have not received financing since 2006**

### Public Companies

~90 public companies - Market cap of ~\$107 billion

- 52 companies have market cap <\$100 million
- 74 companies have market cap <\$1 billion
- Amgen has the largest cap ~\$60.7 billion

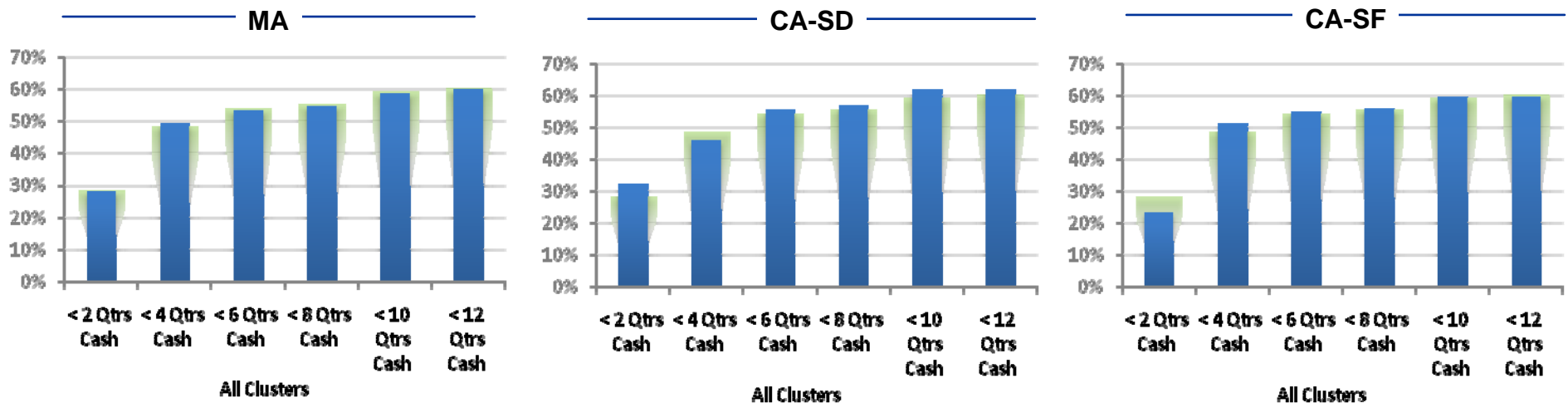
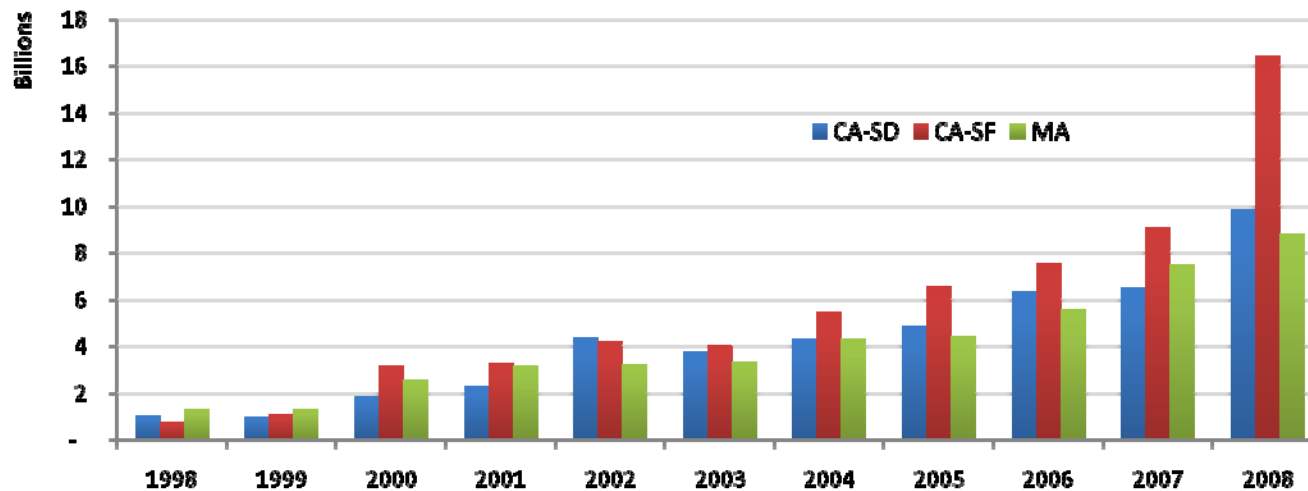


- **Roughly 45% percent of companies risk running out of cash by the end of 2009**

## Cash on Hand

The credit crisis has had major effects on the biotech financing environment with the greatest impact on early and mid stage companies; approximately 50% of public companies in the “big 3” clusters have less than a year’s worth of cash on hand.

Cash on Hand

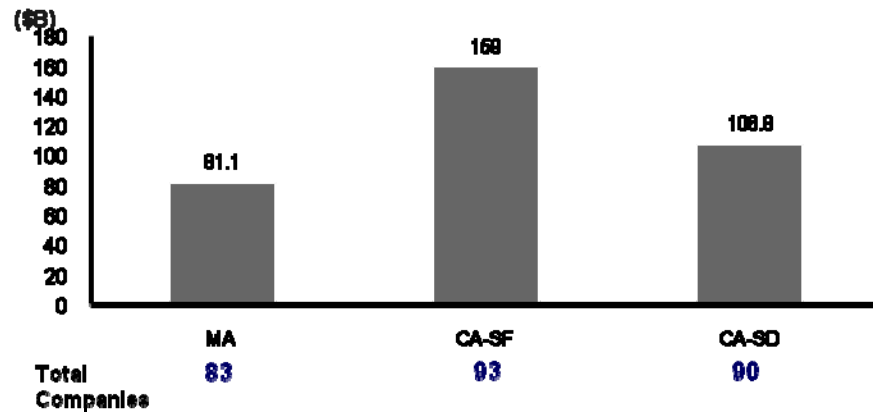


Source: Deloitte Recap LLC, 2008 data through 2Q08

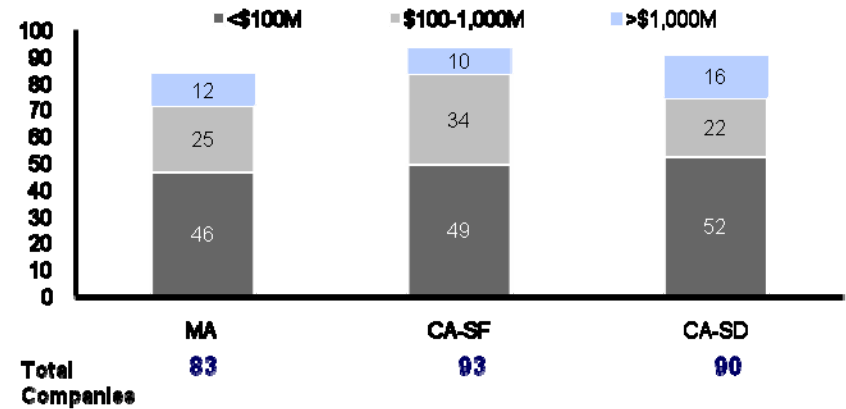
# Market Capitalization and VC Funding

The Big 3 clusters have similar numbers of private and public companies, although the SF and SD clusters each have a single large stakeholder (Genentech and Amgen) that impacts the overall cluster valuation.

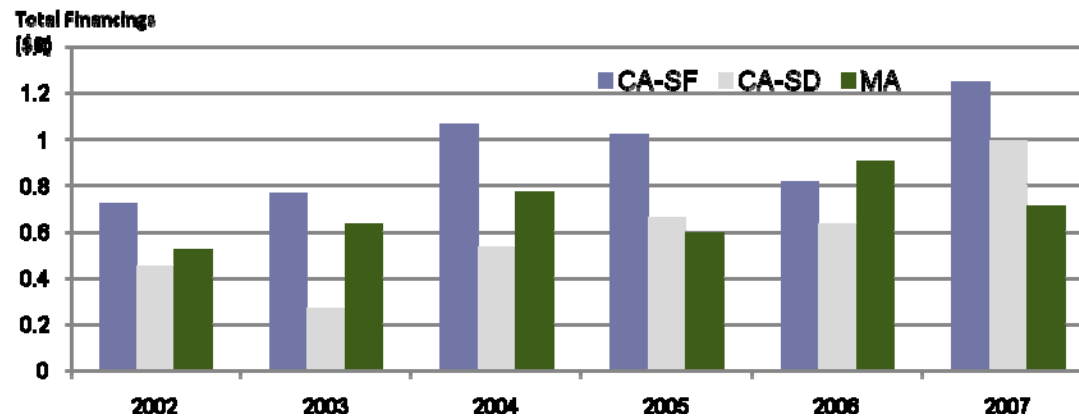
Market Capitalization



Market Capitalization Distribution



Total Amount of VC Financings

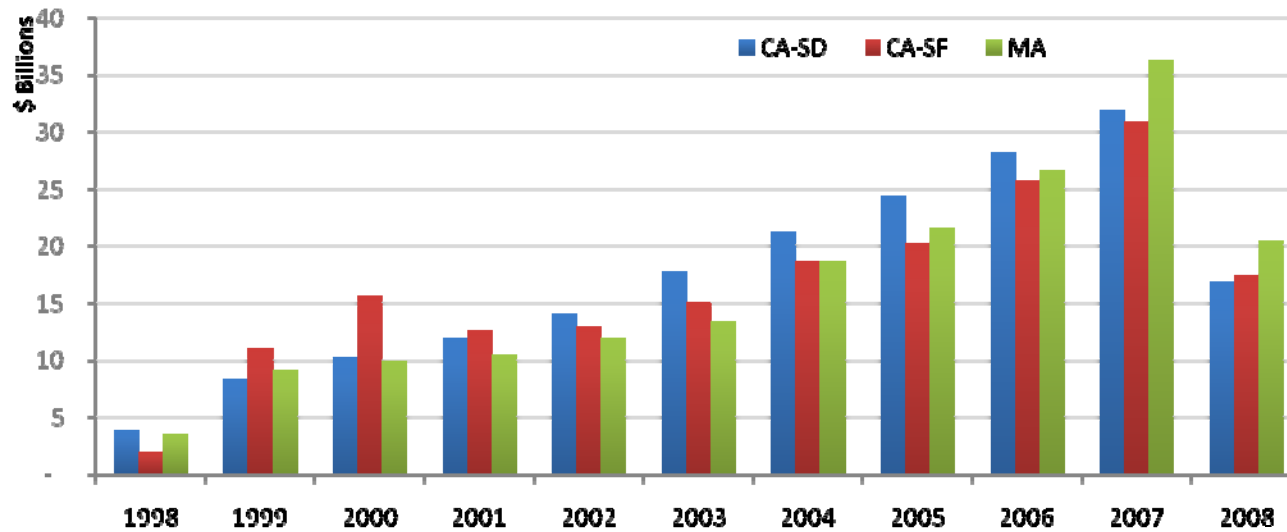


These successful clusters have a robust blend of early to late stage investment opportunities to attract capital

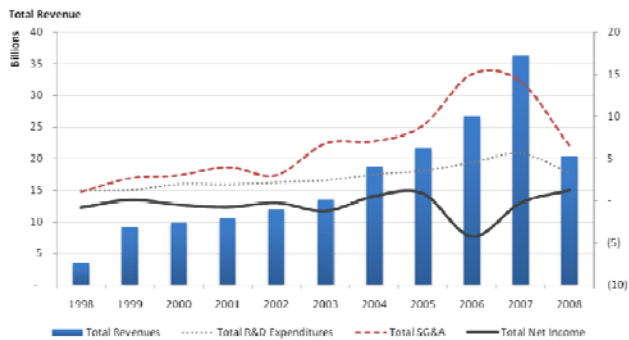
# Cluster Revenue Analysis

MA took the lead in revenues for the first time in 2007, primarily due to revenue growth among its medical device and instrumentation companies.

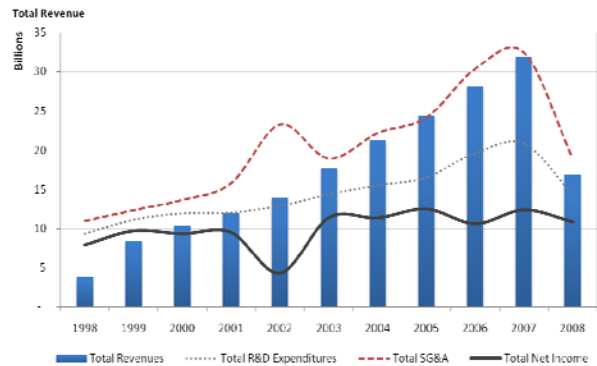
## Revenue



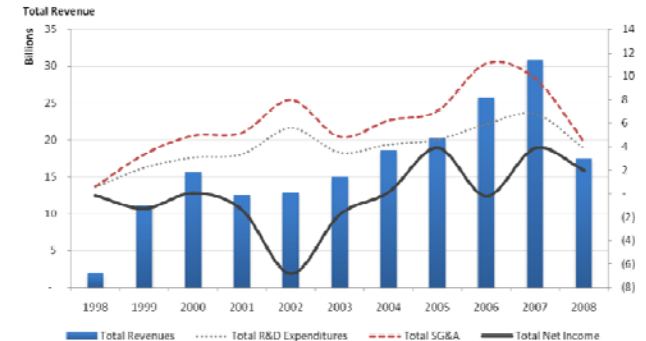
### MA



### CA-SD



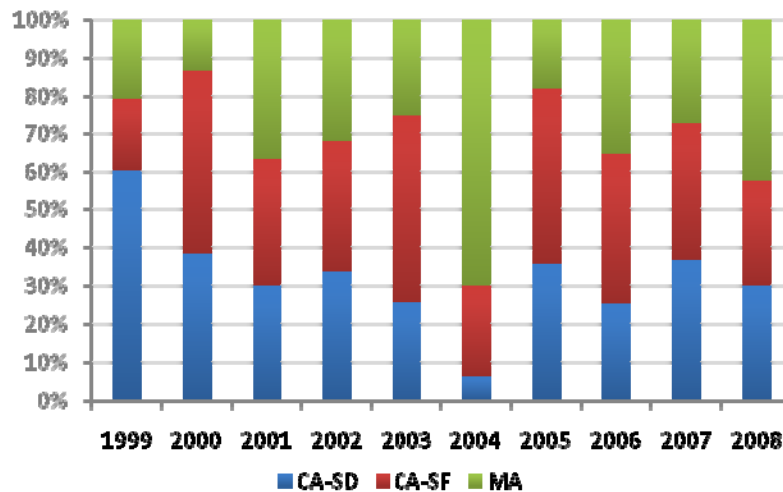
### CA-SF



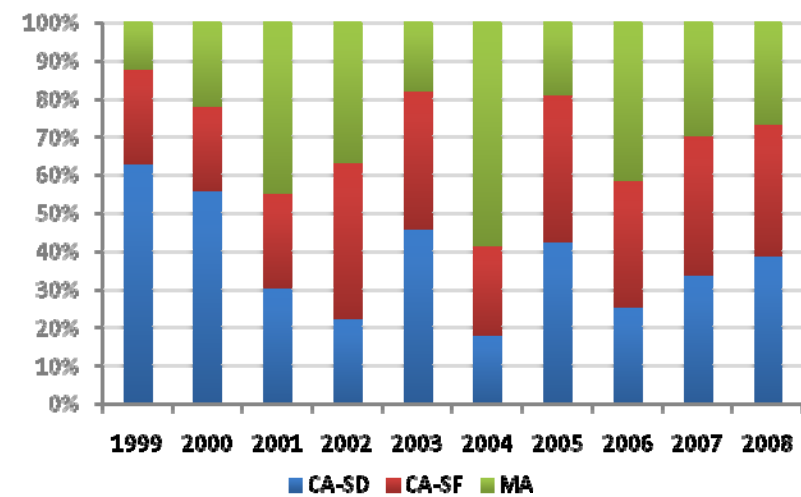
## Series A Financings

However, MA may be losing ground from an innovation perspective as indicated by the distribution of Series A financing events

Value Share of Series A Financings



Volume Share of Series A Financings



- SF and SD growing stronger in Series A financing frequency and amounts
- SF has become the preferred location for early stage, high risk start-ups
- SD attracts later stage, product focused start-ups
- MA's recent trend has been that a small number of companies are attracting larger average financings