



# **A Critical Alliance: The Biotechnology & Pharmaceutical Industries in Massachusetts**

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**Eric Nakajima  
Senior Research Manager**

**Rebecca Loveland  
Research Manager**

**With  
Alexandra Proshina  
Research Analyst**

**William Proulx  
Research Assistant**



# Contents

**List of Figures ..... II**

**Introduction ..... 3**

**Executive Summary ..... 5**

**Section I. Bio-Pharma Trends: Massachusetts & Its Competitor States..... 8**

**Section II. Bio-Pharma Alliances & Industry Growth in Massachusetts ..... 15**

Industry Background ..... 15

Research and Development Alliances ..... 21

Conclusion ..... 27

**Section III. Business Conditions and Opportunities in Massachusetts..... 28**

The Competitive Position of Massachusetts for Biopharmaceutical Investment ..... 28

The Comparative Strengths and Weaknesses of Massachusetts ..... 30

The Policy Challenges Confronting Bio-Pharma in Massachusetts ..... 30

**Methodology ..... 34**

## List of Figures

Table 1. Top Ten Competitor States in Biopharmaceuticals, 1998 and 2004 .....	9
Table 2. Wages per Worker in Biopharmaceutical Industry .....	10
Table 3. Top Ten Competitor States in Biotechnology Venture Capital, 1998 & 2005 .....	11
Table 4. Biotechnology Venture Capital per Bio-pharma Employee .....	12
Table 5. Top Ten States Ranked by NIH Awarded Medical Research Funds .....	13
Table 6. NIH Funds per Bi-pharmaceutical Employee .....	13
Figure 1: Bio-pharma Development Lifecycle: Phases and Institutional Players .....	18
Figure 2: Bio-pharma Discovery Process: Sources of Funding by Stage .....	20
Table 7: Thirteen Company Survey, Summary of Alliances and Values, 2000-2006 .....	23
Figure 3: Massachusetts Bio-pharma Alliances by Type, 2000-2006 .....	24
Table 8: Alliances by Alliance Category .....	24
Table 9: Alliances by Stage of Drug Discovery .....	26

## Introduction

The Massachusetts pharmaceutical and biotechnology industries are widely recognized as pillars of the Commonwealth's knowledge economy. While these two industries are clearly interconnected in a number of important ways, the specific ways in which they interact and support each others growth and development are not well understood.

The Bay State is undeniably a world leader in the research and development of biological and pharmaceutical products and treatments. However, although Massachusetts is home to some of the leading pharmaceutical firms in the world, to date the Commonwealth has not been as successful in attracting bio-pharma manufacturing activities, even of those bio-medical innovations developed by home-grown Massachusetts firms.

This report is intended to provide industry leaders and the Commonwealth's elected officials, public policymakers and opinion leaders with insight into the ways in which these two important industries interact and specific information regarding the specific obstacles to growth faced by the pharmaceutical and biotechnology industries in the state.

The report is organized into three main sections:

**Section I.** Provides a snapshot of the Commonwealth's competitive position compared to the leading bio-pharmaceutical states in the nation. The report benchmarks Massachusetts in terms of employment, wages, venture capital investments and National Institutes of Health (NIH) awards. This data provides a framework for understanding the broader context of the competitive position of Massachusetts' biotechnology and pharmaceutical firms.

**Section II.** Describes the financial and business relationships between Massachusetts biotechnology and pharmaceuticals firms and analyzes the robust pattern of collaboration and investment in this sector. The UMass Donahue Institute documented the extensive alliances and investments in the bio-pharmaceuticals sector in Massachusetts through use of a life sciences-specific financial services

database that carefully compiles a full record of corporate filings, announcements and contracts. The database was supplemented with interviews with leading figures in the bio-pharmaceuticals industry in Massachusetts and a full review of recent literature in the field.

**Section III.** As this report will show, the larger biotechnology and pharmaceuticals companies in Massachusetts underwrite a significant amount of basic research and drug discovery activity in the bio-pharmaceuticals sector in the state. The report concludes with a discussion of the barriers to expansion and development of the bio-pharmaceuticals sector from the perspective of many of the leading bio-pharma companies in Massachusetts. The opportunities and barriers to expansion were identified through a series of interviews with industry leaders and a representative survey of the leading bio-pharma companies in the state.

## Executive Summary

Massachusetts is home to leading life sciences companies and institutions that make it, along with California, the leading center for biopharmaceutical research and development in the world. Over the past ten years, Massachusetts' competitor states have made significant strides increasing their share of biopharmaceutical investment, employment and support for basic research. However, a close look at the state's performance shows that despite lagging job growth as compared to its peers, Massachusetts continues to outperform other states in attracting highly-paid, high value-added employment in the cluster's leading companies.

The UMass Donahue Institute found:

- In Massachusetts, bio-pharmaceutical employment grew by 44 percent from 1998 to 2004, but the state fell from fifth to seventh in the nation in total bio-pharma employment.
- Massachusetts is home to the highest average wages in the biopharmaceutical industry, with an average wage in 2004 of \$98,595.
- Massachusetts and California have – by far – the highest levels of venture capital and National Institutes of Health (NIH) investment of any states.
- Massachusetts has the highest level of venture capital and NIH funding per bio-pharma worker of any state in the nation.

### **Alliances are Critical to the Bio-Pharma Sector in Massachusetts**

The UMass Donahue Institute conducted a thorough study of the challenges that biotechnology companies confront in funding drug and therapeutic research and development. Research and development is very expensive – by some estimates up to \$900 million per drug from discovery to approvals – and there is a high failure rate for any given discovery. Given the risk involved, funding can be scarce for research, preclinical testing and clinical trials. Into this funding gap, there has grown a robust set of relationships between biotechnology companies and pharmaceutical companies. These

alliances take the form of licensing agreements, equity investments and full collaborations to co-develop drug discoveries and therapies. At a national level, bio-pharmaceutical alliances are worth \$10 to \$16 billion per year – by far in excess of the amount of biotechnology venture capital invested in the field. The importance of alliances at a national level is equally true in Massachusetts.

To document the importance of bio-pharma collaboration in Massachusetts, the UMass Donahue Institute investigated investment records and announcements from 13 major pharmaceutical and biotechnology companies in the state. The 357 alliances documented in this report were worth a total of \$13.4 billion and supported drug discovery and product development at key stages of the product development life cycle in which resources can be most scarce. The alliance activity further documents a key insight into private sector investment in Massachusetts: the leading biotechnology and pharmaceuticals companies in the world want to invest in Massachusetts during the early, high value-added-high-risk stages of product research and development.

### **Business Conditions and Policy Challenges Facing the Bio-pharma Sector in Massachusetts**

The biotechnology and pharmaceutical industries are major employers in Massachusetts and comprise a cornerstone sector in the state's high value-added, knowledge economy. In addition to documenting the robust partnership between pharmaceutical and biotechnology companies in the state, this report seeks to present the competitive strengths and weaknesses of Massachusetts as a location for bio-pharmaceutical businesses.

To better understand the competitive and policy challenges facing bio-pharma companies in the state, the UMass Donahue Institute interviewed and surveyed leading figures at half of the approximately two-dozen largest biotechnology and pharmaceutical companies in Massachusetts. The eleven companies that participated in this project report over 16,000 total employees in Massachusetts and more than 500,000 employees worldwide. These leading bio-pharma companies employ over one third of all bio-pharmaceutical workers in Massachusetts.

## **Highlights from the Company Survey and Interview Include:**

### **The Comparative Strengths and Weaknesses of Massachusetts**

#### **Key Strengths**

- Availability of skilled workers in Massachusetts;
- Proximity to world-class research partners.

#### **Key Weaknesses**

- Business regulations and permitting;
- The effectiveness of state government in meeting business needs.

### **The Core Policy Challenges Confronting Bio-Pharma in Massachusetts**

#### **Business Conditions**

- Improve the pipeline of science, technology, engineering and math (STEM) workers;
- Need for more affordable workforce housing;

#### **Effectiveness of State Government**

- Reduce the cost of doing business;
- Streamline the real estate permitting process;
- Respond in a time-sensitive fashion to business needs and concerns;
- Support land assembly and infrastructure for bio-pharma manufacturing in Massachusetts.

#### **Federal Policies and Programs**

- Advocate for increased federal funding for biomedical research;
- Advocate for the industry in Washington, D.C.;
- Oppose federal efforts to impose drug price controls or enable drug re-importation programs.

## Section I. Bio-Pharma Trends: Massachusetts & Its Competitor States

Massachusetts is home to leading life sciences companies and institutions that make it, along with California, the leading center for biopharmaceutical research and development in the world. Over the past ten years, Massachusetts' competitor states have made significant strides increasing their share of biopharmaceutical investment, employment and support for basic research. However, a close look at the state's performance shows that despite lagging job growth as compared to its peers, Massachusetts continues to outperform other states in attracting highly-paid, high value-added employment in the cluster's leading companies.

The purpose of this section is to provide readers with a brief update of Massachusetts competitive position in the biotechnology and pharmaceuticals industries. The biopharmaceuticals industry sector is defined to include three areas: pharmaceutical manufacturing, life sciences research and development (R&D), and medical laboratory services. In the tables presented in this section, Massachusetts is compared to its competitor states along the following dimensions: total bio-pharmaceutical employment, total dollar value of venture capital invested in biotechnology companies, and total dollar value of National Institutes of Health (NIH) awards. Massachusetts is ranked by absolute performance (total employment or dollars) and by measures that document the high value-added nature of the biopharmaceuticals sector in Massachusetts.

We present the following rankings: average wages in the biopharmaceuticals industry by state, venture capital investment per biopharmaceutical employee, and NIH awards per biopharmaceutical employee. These tables demonstrate that Massachusetts and California are far-and-away the leading centers of high value-added production in the bio-pharma sector in the United States.

## Total Employment by State

Table 1: Top Ten Competitor States in Bio-pharmaceuticals, 1998 and 2004

1998			2004			1998-2004
Rank	State	Employment	Rank	State	Employment	Employment % Change
1	California	110,169	1	California	177,034	61%
2	New York	60,107	2	New York	92,221	53%
3	New Jersey	51,066	3	New Jersey	84,943	66%
4	Illinois	35,953	4	Michigan	55,987	239%
5	<b>Massachusetts</b>	<b>33,618</b>	5	Pennsylvania	55,899	71%
6	Pennsylvania	32,762	6	Illinois	48,496	35%
7	Texas	32,037	7	<b>Massachusetts</b>	<b>48,242</b>	<b>44%</b>
8	Maryland	26,072	8	North Carolina	47,796	92%
9	Virginia	25,440	9	Virginia	43,465	71%
10	North Carolina	24,928	10	Maryland	39,031	50%
	All States	662,635		All States	1,041,604	57%

Source: County Business Patterns, 2006; Non-Employer Series, 2006

As shown in Table 1, biopharmaceutical employment growth in Massachusetts lagged competitor states. In 1998, Massachusetts was fifth overall in bio-pharma employment behind California, New York, New Jersey and Illinois. By 2004, Massachusetts had slipped to seventh place behind Pennsylvania, Michigan and all of the 1998 leaders. North Carolina's bio-pharma employment grew from 1998 to 2004 by 92 percent and is ranked eighth in employment less than 1,000 jobs behind Massachusetts. Though Massachusetts bio-pharma employment has grown more slowly than its competitors, it should be noted that the industry employment grew a substantial 44 percent from 1998 to 2004. And the aggregate employment figures for the biopharmaceuticals sector mask a key distinction between the quality of the jobs in different states. Massachusetts is very strong in some sub-sectors, such as research and development, and less competitive in others, such as manufacturing. Massachusetts tends to attract investment and employment among high-skilled and highly-compensated occupations in the industry.

Table 2 shows that Massachusetts has the highest average wages in the United States in the bio-pharmaceuticals sector. From 1998 to 2004, Massachusetts passed New Jersey to have the highest average wages in the bio-pharma sector of any state in the nation. In 2004, Massachusetts had average bio-pharmaceutical wages of \$98,595 or more than \$26,907 above the national average wages in the sector. In 2004, the average bio-pharma wage in Massachusetts was \$32,258 higher than in North Carolina. Massachusetts may have slower overall job growth than other states but the quality of the jobs that the state does possess is on average the highest in the nation.

**Table 2: Wages per Worker in Bio-pharmaceutical Industry**

Rank	State	1998	Rank	State	2004
1	New Jersey	\$67,016	<b>1</b>	<b>Massachusetts</b>	<b>\$98,595</b>
<b>2</b>	<b>Massachusetts</b>	<b>\$60,577</b>	2	New Jersey	\$90,203
3	Virginia	\$57,073	3	California	\$84,455
4	California	\$55,899	4	Michigan	\$81,755
5	Illinois	\$55,689	5	Virginia	\$75,339
6	Pennsylvania	\$52,708	6	Illinois	\$74,819
7	Maryland	\$48,782	7	Pennsylvania	\$73,151
8	Michigan	\$46,867	8	North Carolina	\$66,337
9	North Carolina	\$43,174	9	Maryland	\$63,606
10	New York	\$41,683	10	New York	\$54,825
	USA	\$51,344		USA	\$71,688

Source: County Business Patterns, 2006; Non-Employer Series, 2006.

### Venture Capital Investment by State

As section two of this report will show, venture capital investment is not the only or even the most significant source of capital for firms developing bio-pharma products and bringing them to market. However, the total volume of biotechnology venture capital invested in firms by state remains an excellent indicator of how investors view the states as locations for research and development. As shown in Table 3, Massachusetts and California are – by far – the premier locations for biotechnology venture capital investment in the United States. In fact, Massachusetts received more than twice as much venture capital investment in its biotechnology companies in 2005 than the next highest recipient, New Jersey. In 2005, Massachusetts received nearly three-times the biotechnology venture capital as North Carolina. If you eliminate California’s venture capital from consideration, Massachusetts received 27 percent of all remaining biotechnology venture capital invested in the United States in 2005. The relative strength of Massachusetts as an investment location is even clearer when the venture capital is presented per biopharmaceutical worker, as in Table 4.

**Table 3: Top Ten Competitor States in Biotechnology Venture Capital, 1998 & 2005**

1998			2005			1998-2005
Rank	State	Venture Capital	Rank	State	Venture Capital	Venture Capital % Change
1	California	\$608,002,200	1	California	\$1,819,071,900	199%
2	<b>Massachusetts</b>	<b>\$279,367,500</b>	2	<b>Massachusetts</b>	<b>\$561,724,900</b>	101%
3	New Jersey	\$105,132,600	3	New Jersey	\$191,642,600	82%
4	Pennsylvania	\$77,045,100	4	North Carolina	\$190,907,700	304%
5	Texas	\$68,073,400	5	Maryland	\$147,560,200	808%
6	Washington	\$54,067,500	6	Pennsylvania	\$133,025,200	73%
7	North Carolina	\$47,236,100	7	Washington	\$131,444,900	143%
8	New York	\$41,750,000	8	Connecticut	\$56,555,000	195%
9	Michigan	\$34,500,000	9	Texas	\$53,368,000	-22%
10	Connecticut	\$19,159,000	10	Michigan	\$30,599,700	-11%
	USA	\$1,560,396,300		USA	\$3,907,359,500	150%

Note: Data is for the biotech industry only; VC data is for 2005; employment data is for 2004.

Source: PriceWaterhouse Coopers, Money Tree Survey; County Business Patterns; Non-Employer Series, 2006.

As Table 4 demonstrates, Massachusetts receives an intensive amount of biotechnology venture capital per worker. In 1998 and 2005, Massachusetts companies received more biotech venture capital per worker than any other state in the nation, including California. Massachusetts companies had nearly three times the VC invested per worker than North Carolina and more than three times the national average. The data confirms information gathered from the Donahue Institute's interviews with leading bio-pharma company executives who reported that venture capital funds almost exclusively look to Massachusetts and California as the ideal locations to develop successful products.

**Table 4: Biotechnology Venture Capital per Bio-pharma Employee**

Rank	State	1998	Rank	State	2005
1	Massachusetts	\$8,310	1	Massachusetts	\$11,644
2	California	\$5,519	2	California	\$10,275
3	Pennsylvania	\$2,352	3	North Carolina	\$3,994
4	Michigan	\$2,088	4	Maryland	\$3,781
5	New Jersey	\$2,059	5	Pennsylvania	\$2,380
6	North Carolina	\$1,895	6	New Jersey	\$2,256
7	Virginia	\$1,184	7	Michigan	\$547
8	New York	\$695	8	Illinois	\$258
9	Maryland	\$623	9	Virginia	\$211
10	Illinois	\$471	10	New York	\$67
	USA	\$2,362		USA	\$3,648

Note: Data is for the biotech industry only; VC data is for 2005; employment data is for 2004.

Source: PriceWaterhouse Coopers, Money Tree Survey; County Business Patterns, 2006; Non-Employer Series, 2006.

### National Institutes of Health Awards by State

The receipt of National Institutes of Health (NIH) research dollars has long been regarded as an indicator of a state's research strength and innovative capacity. Basic life sciences research, as reflected in NIH awards, is far more evenly distributed among states than venture capital or wages. Still, Massachusetts can be seen as a national leader in basic biomedical research, as shown in Table 5. From 1998 to 2005, Massachusetts has consistently followed California as the leading location for NIH awards. In 1998, Massachusetts institutions and companies were awarded nearly 11 percent of all NIH dollars. In 2004, Massachusetts received just under 10 percent of all NIH awards by dollar value.

**Table 5: Top Ten States Ranked by NIH Awarded Medical Research Funds**

1998			2005		
Rank	State	Dollars Awarded	Rank	State	Dollars Awarded
1	California	\$1,662,020,713	1	California	\$3,311,231,100
2	<b>Massachusetts</b>	<b>\$1,176,783,188</b>	2	<b>Massachusetts</b>	<b>\$2,272,675,609</b>
3	New York	\$1,122,769,429	3	New York	\$2,021,127,717
4	Pennsylvania	\$740,589,474	4	Maryland	\$1,764,278,447
5	Maryland	\$683,944,010	5	Pennsylvania	\$1,448,431,995
6	Texas	\$551,476,356	6	Texas	\$1,149,983,026
7	North Carolina	\$440,724,292	7	North Carolina	\$1,078,384,691
8	Washington	\$396,973,011	8	Washington	\$812,696,664
9	Illinois	\$348,051,863	9	Illinois	\$733,395,959
10	Ohio	\$338,974,477	10	Ohio	\$721,105,224
	<b>USA</b>	<b>\$11,135,995,226</b>		<b>USA</b>	<b>\$23,116,571,209</b>

Source: National Institutes of Health, Office of Extramural Research, 2006.

As with venture capital, Massachusetts receives the most NIH funds per biopharmaceutical worker of any state in the nation. As shown in Table 6, Massachusetts firms and institutions were awarded more than 2 ½ times more NIH dollars per biopharmaceutical worker than California. Maryland closely follows Massachusetts in the receipt of NIH awards, but it should be noted that Maryland has fewer biopharma employees, lower average wages and receives approximately one-quarter the biotechnology venture capital than Massachusetts.

**Table 6: NIH Funds per Biopharmaceutical Employee**

Rank	State	1998	Rank	State	2005
1	<b>Massachusetts</b>	<b>\$35,005</b>	1	<b>Massachusetts</b>	<b>\$47,112</b>
2	Maryland	\$26,233	2	Maryland	\$45,202
3	Pennsylvania	\$22,605	3	Pennsylvania	\$25,980
4	Michigan	\$19,521	4	North Carolina	\$22,562
5	New York	\$18,680	5	New York	\$21,913
6	North Carolina	\$17,680	6	California	\$18,647
7	California	\$15,086	7	Illinois	\$15,133
8	Illinois	\$9,681	8	Virginia	\$10,399
9	Virginia	\$6,809	9	Michigan	\$10,080
10	New Jersey	\$2,609	10	New Jersey	\$3,455
	USA	\$16,806		USA	\$22,171

Source: National Institutes of Health, Office of Extramural Research, 2006.

## Conclusion

The purpose of this section has been to provide a brief snapshot of Massachusetts competitive position in the bio-pharmaceutical sector. As the data shows, Massachusetts is an international leader in bio-pharmaceuticals and is a robust center for research and development in the sector. Massachusetts has lagged its competitor states in overall employment growth but exceeds every other state in average wages and investment per worker. The health of the industry from a policymaking standpoint depends on how one measures success. For policymakers interested in expanding the number of manufacturing jobs, call center jobs and other occupations with a low barrier of entry for moderately-skilled workers, the report is mixed. At present, Massachusetts is a less-competitive location for lower-skilled tasks as reflected in the lower overall employment levels compared to its competitor states.

However, Massachusetts is clearly a dominant location for the research and development of bio-pharmaceutical products and processes. As industry leaders interviewed for this study mentioned repeatedly, there are really only two places in the world that seriously compete in the areas of drug discovery and development: California and Massachusetts. The role that pharmaceutical and biotechnology companies play in fostering the state's dominance in research and development is the subject of the next section.

## Section II. Bio-Pharma Alliances & Industry Growth in Massachusetts

### Industry Background

Massachusetts has established itself as a central hub of bio-pharmaceutical research and product development. Within the state, major pharmaceutical and biotechnology firms and important research institutions are particularly dense in the Boston and Northeast regions and around the City of Worcester. Due to the strength and diversity of the bio-pharma sector, Massachusetts is home to the professional and technical expertise to support the entire spectrum of biopharmaceutical product development. The bio-pharma sector in Massachusetts is home to the full range of institutions involved in the development process: established pharma and biotech companies, biotech start-ups and other small companies, and world-class research groups in universities and research hospitals.

Large pharmaceutical companies remain some of the most powerful industry players in terms of the scale of their operations, their expertise and their revenue stream. Many of these big pharma companies maintain significant biotechnology research and development programs and are actively involved in developing bio-pharmaceuticals. Notable pharmaceutical firms in Massachusetts, include: Wyeth, Pfizer, Merck, AstraZeneca, Novartis, Abbott and soon, Bristol-Myers Squibb.

As with big pharma, large biotechnology companies are a powerful agent for the development of the entire bio-pharmaceutical sector in Massachusetts. A large number of major competitors are located in Massachusetts including: Amgen, Biogen Idec, Genzyme, Cubist, Serono, Millenium Pharmaceuticals, Sepracor and Vertex Pharmaceuticals. In addition, many smaller, specialized biotechnology companies are located in the state. These small companies act on their own or in alliance with the larger companies in the development of new drugs and therapeutics.

### **Product development alliances: complexity and risk inspire partnerships**

The development of a bio-pharmaceutical product is a complex, expensive and time consuming process. Successful projects require a high level of scientific and organizational capacity rarely found in one company alone. In fact, a variety of firms and institutions are typically involved over the fourteen or

more years it takes to develop an approved drug. A recent study suggests that nearly one third of new pharmaceutical products are developed through alliances.<sup>1</sup>

During the discovery and development process, a firm often relies on a combination of established in-house resources (organizational and scientific), combined with strategic partnerships to tap specific resources offered by other companies or research institutions. These trends have created an increasing web of investment and interaction among firms and between firms and research hospitals. This dynamic, in fact, provides critical momentum for the firms and institutions involved in the development of new bio-pharma products.

Within the sector, the smaller companies and independent research groups provide important resources and services to the larger companies. As costs and risks related to earlier stages of drug development have increased, many large companies have limited their internal research and development efforts in favor of outsourcing early-stage research and development activities to smaller biotechnology companies. Research and development collaborations with university-based research institutes and for-profit clinical research organizations have also increased. The smaller biotechnology firms and research hospitals offer access to a wide pool of new products including: new chemical entities or biologically-based products; scientific knowledge (genomics, etc.); and analytical tools and technologies (informatics etc.)<sup>2</sup> Large companies commonly license these types of products and technologies from outside companies in the field. In other cases, established biotech and pharma companies use mergers and acquisitions to expand their resources in targeted areas.

In turn, alliances with large companies have become an important financial engine for smaller biotechnology companies as well as research hospitals. Alliances are particularly important for young biotech companies which have no product sales and thus lack the resources to adequately develop the drug candidates in their pipeline or to exploit technology products they have developed for internal use.<sup>3</sup> In addition to providing cash flow, alliances provide small companies with access to a wide range of business expertise. Through partnerships with established companies, small companies can tap broad resources in clinical trials design and development, regulatory knowledge, and expertise in marketing

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<sup>1</sup> Dr. Kenneth Sokoll. "Optimizing Drug Development Strategies." <<http://www.pharmabioingredients.com/articles/2006/09>>

<sup>2</sup> Anthony J. Sinskey and Stan N. Finkelstein. "Integrating the Science and Technology Revolutions." *PharmaGenomics*, May/June 2002. Page 20.

<sup>3</sup> "The Biopharmaceutical Sector," Industry Canada, 2003 <<http://strategis.ic.gc.ca/epic/internet/inbio-pha.nsf/en/df00020e.html#2.1>>

and sales. Successful collaborations can also validate a young company's drug discovery and development program and enhance confidence in the firm, thus improving access to venture capital and equity market financing.<sup>4</sup>

In the end, a large variety of industry players and institutional entities provide expertise as well as funding throughout the many stages of drug development. Massachusetts is striking in that it is home to a strong concentration of major players. The process of product development - including key actors and funders at each of its major phases - is discussed in the section that follows.

### **Biopharmaceutical Development Lifecycle: Phases & Institutional Players and Investors**

The development of a new biopharmaceutical process takes place over a number of phases, each several years long and involving multiple players and investors. In all, the entire drug development process – from discovery to approval can take up to fourteen years per drug at a 2006 cost of close to \$900 million.<sup>5</sup> The major phases of the process, discussed in this section, are as follows:

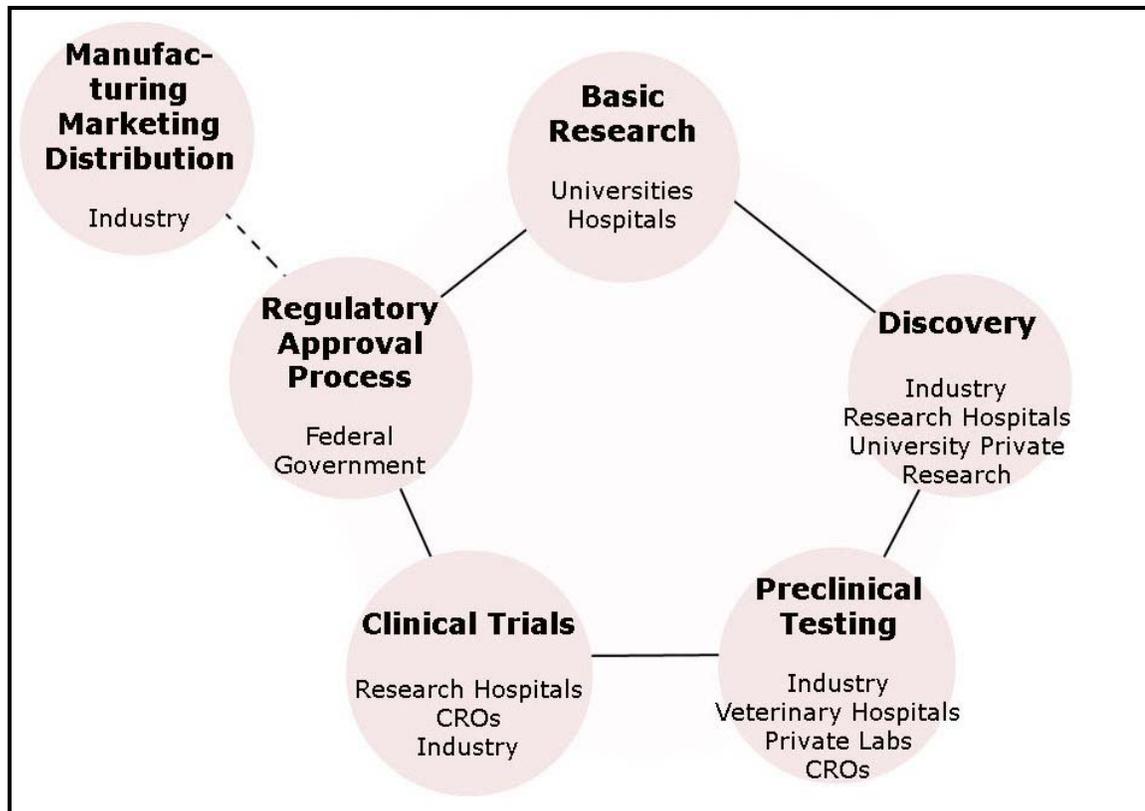
- basic research;
- discovery research;
- preclinical testing;
- clinical trials and regulatory approval;
- manufacturing, marketing and distribution.

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<sup>4</sup> Dan Passeri. "Partnering could provide big benefits to small biotechs." Mass High Tech. October 20-26,2006. Section: Inside Life Sciences and Medical Frontiers, page 14.

<sup>5</sup> Dr. Kenneth Sokoll. "Optimizing Drug Development Strategies." 2006. Page 4. Article released on *Pharma and Bio Ingredients* website <http://www.pharmabioingredients.com/articles/2006/09>.

Figure 1: Bio-pharma Development Lifecycle: Phases and Institutional Players



Source: UMass Donahue Institute, 2006.

### Basic Research

The drug industry is a knowledge-intensive business. In 2005, estimated private biopharmaceutical research and development expenditures totaled \$51.3 billion.<sup>6</sup> In addition to that private investment, public funding has long provided fundamental grounding for private discovery-stage research.<sup>7</sup> Basic research takes place in non-commercial settings like universities and hospital research labs and is funded predominantly by federal government sources, especially the National Institutes of Health.

### Discovery-stage Research

The discovery stage of research focuses on the goal of isolating and identifying promising drug or therapeutic candidates. This stage requires the ability to mine and then integrate a vast and complex body of scientific knowledge. Discovery-stage research involves a number of processes, including

<sup>6</sup> Pharmaceutical Research and Manufacturers of America. "Pharmaceutical Industry Profile, 2006." Washington, DC:PhRMA, March 2006., [www.phrma.org](http://www.phrma.org), Page 2.

<sup>7</sup> Rebecca Henderson, Luigi Orsenigo and Gary Pisano. "The Pharmaceutical Industry and the Revolution in Molecular Biology: Exploring the Interactions between Scientific, Institutional and Organizational Change." The CCC Matrix Project. April 1998. Page 7.

synthesis, biological testing and pharmacological screening of up to 10,000 compounds and can take up to four years.<sup>8</sup> Given the scientific complexity and the time requirements at this stage, the costs are high. Large companies often rely on small biotech companies and research institutions to perform this phase of research. As will be discussed further in the report, alliances between small firms and pharmaceutical and larger biotech companies are often essential both as a source of capital and for the expertise that the established firms can offer.

### **Preclinical Testing**

Preclinical testing involving laboratory and animal studies takes place once a promising drug or therapeutic candidate is identified. This stage of drug development is very time consuming and has become increasingly expensive. The risks at this stage are high: only one of every five to ten thousand compounds tested receives FDA approval. The industry spends 26 percent of R+D expenditures for prehuman / preclinical testing and 35 percent of its R+D personnel is focused on prehuman / preclinical work.<sup>9</sup>

Given the high level of financial risk associated with preclinical testing, venture capital is not a significant source of funding for this stage of research. Instead, the research often takes place in the context of a mutually beneficial partnership – an alliance - between larger pharmaceutical and biotech firms and (typically) small companies. The alliances can take the form of licensing agreements, full collaborations or equity arrangements.

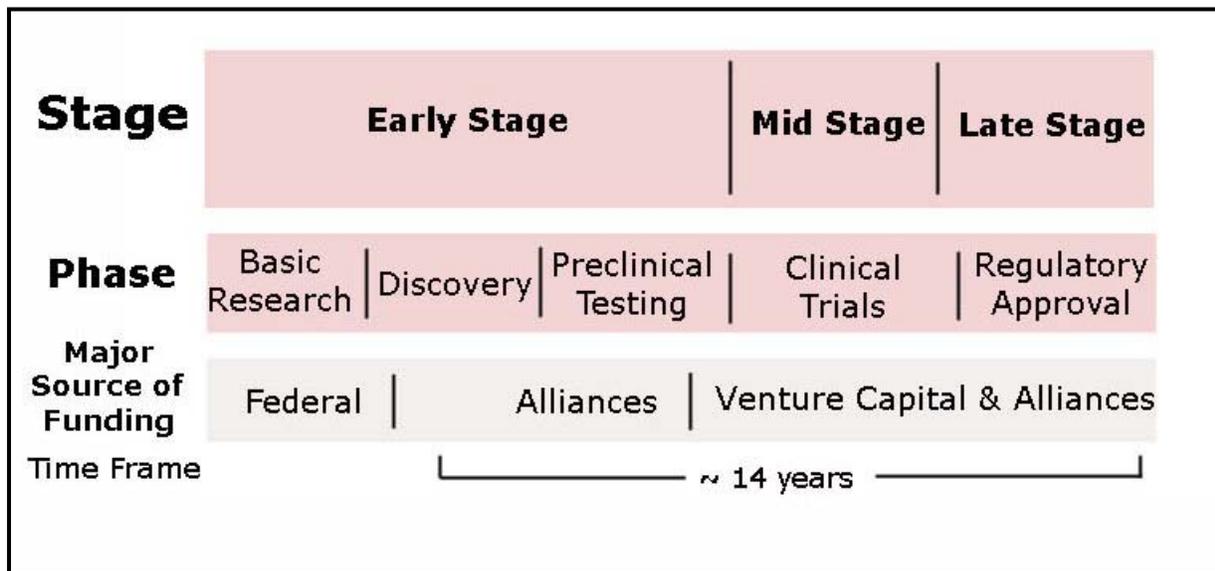
The state's well-established research hospitals also strongly support discovery-stage and preclinical research. In 2005, for example, Partners Healthcare System spent \$33.1 million on pre-clinical research within their system.<sup>10</sup> Research hospitals like Massachusetts General Hospital and Brigham and Women's Hospital fund their research programs through a combination of license income (from license and option fees and royalties), industry alliances, consulting and clinical trials work, as well as federal research funding.

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<sup>8</sup> Stan N. Finkelstein and Anthony J. Sinskey. "The Coming Paradigm Shift in Pharmaceuticals." *PharmaGenomics*, September / October 2002. Page 26.

<sup>9</sup> Pharmaceutical Research and Manufacturers of America. "Pharmaceutical Industry Profile, 2006." Pages 2 & 47.

<sup>10</sup> "Partners Healthcare Research Ventures and Licensing FY2005 Annual Report." Page 6.

**Figure 2: Bio-pharma Discovery Process: Sources of Funding by Stage**

Source: UMass Donahue Institute, 2006.

### Clinical Trials and Regulatory Approval

The period of clinical testing through regulatory approval takes the longest and increases in expense with each phase of trial. The process of Phase I, II and III of FDA clinical trials can last up to eight years.<sup>11</sup> Each successful clinical trial brings an increase in the scale of the test population and this increases cost and time requirements. A 2005 survey of bio-pharma firms shows that of the \$16 billion spent during the clinical trials phases, 60 percent of this is spent on Phase III trials.<sup>12</sup>

If a drug or therapeutic makes it through the clinical trial process successfully, the sponsor initiates a regulatory approval process with the Food and Drug Administration. As a drug goes through the approval process additional resources must be mobilized by the sponsoring firms to prepare for manufacturing, marketing, and distribution. The approval process and related planning can take up to two or three years.<sup>13</sup>

<sup>11</sup> Time requirements for each phase of product development come from various sources including Alliance Pharmaceutical Corporation [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm) and Finkelstein and Sinsky, "The Coming Paradigm Shift in Pharmaceuticals."

<sup>12</sup> Pharmaceutical Research and Manufacturers of America. "Pharmaceutical Industry Profile, 2006." Washington, DC: PhRMA, March 2006., [www.phrma.org](http://www.phrma.org), Page 47.

<sup>13</sup> Ibid.

Drug or therapeutic components that reach the clinical trials phase are often the product of two allied companies. In addition, products in the middle and late stages of development are most likely to receive venture capital investments. In essence, the more predictable the potential return on investment, the more likely it is that venture capital funds will invest in the drug development process.

## Research and Development Alliances

Formal partnerships – or alliances – between companies enhance the ability of firms to undertake the complex and risky process of drug and therapeutics development. Alliances provide capital for all stages of drug development, providing particularly high levels of funding for early stage research. Alliance relationships between companies often include more than one of the following elements: (1) full collaborations involving research, development and commercialization phases, (2) traditional product or technology licenses, (3) contract manufacturing arrangements, and (4) co-marketing and co-promotion agreements.<sup>14</sup>

The financial importance of alliances between pharma and biotech companies has long been recognized within the industry. In the late 1990's, biotech company Ligand Pharmaceutical's CEO David Robinson coined the "10/50/40" formula, a term which refers to the first ten years of funding for a biotech company. According to the formula, funding for the first ten years of a company's life (totaling several hundred million dollars) comes 10 percent from venture capital, 50 percent from pharmaceuticals companies, and 40 percent from public equity markets.<sup>15</sup>

As business risks have increased, alliances values have become more important. Nationally in 2005, more than 650 out-licensing deals were negotiated with total deal values worth more than \$55 billion.<sup>16</sup> The total number of alliance deals has stayed fairly consistent since 2001, between 650 and 700 deals per year. The value of announced deals – agreements for which the total investment is publicly known – has increased from about \$10 billion to \$16 billion. The total potential value of all 650 to 700 deals is estimated to have increased from about \$25 billion to \$55 billion. Apart from the estimated value of all

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<sup>14</sup> Joseph Schohl. "Working Together in the Pharmaceutical, Biotech and Medical Device Industries: Contractual Terms and Conditions." Kellogg School of Management, Northwestern University. August 2004, page 6.

<sup>15</sup> Jon Hess and Elio Evangelista. "Pharma-Biotech Alliances: Jockeying for position in the race to become partner of choice," *Contract Pharma*, September, 2003.

<sup>16</sup> Alliance data used in this study is from the Recap.com database provided by Recombinant Capital at [www.recap.com](http://www.recap.com).

alliances, which is speculative, the value of all announced alliances, \$16 billion, far exceeds the total amount of annual venture capital investment in the sector.

Nationally, alliances generate a significant portion of funding for research and development. However, it appears that alliances between big pharma and big biotech and smaller firms are particularly important for Massachusetts companies. In 2005, the value of alliances in our thirteen company sample totaled over \$1.8 billion, far exceeding the \$562 million in venture capital investment in all MA biotechnology companies in that year. As will be shown later, industry alliances are especially valuable in supporting early stage drug discovery and development in Massachusetts.

### **Bio-Pharma Alliances in Massachusetts: a sample of thirteen companies**

The UMass Donahue Institute sought through this study to characterize the nature of alliances made in the Massachusetts bio-pharma sector from 2000 to 2006. Given the tremendous volume of alliance activity in the state, we chose to limit the analysis to a representative sample of major pharmaceutical and biotechnology companies in Massachusetts. Through the analysis, we sought to answer a variety of questions: the total number of alliances; the nature of the alliance; the investment stage or phase; and the total value of the deals.

To document alliance activity in the bio-pharmaceutical sector, the UMass Donahue Institute analyzed individual company-level records provided by Recombinant Capital's Recap.com, a database. The database has information on over 2,700 bio-pharma companies and contains details on over 13,000 alliances involving these companies. A review of selected Massachusetts-based companies made it clear that a tremendous volume of alliance activity exists within the Massachusetts cluster. Given time limitations, the Donahue Institute chose to focus the analysis on a sample of thirteen companies. The companies represent most of the major large biopharmaceutical companies in the state and include: eight medium and large-sized biotechnology companies and five large pharmaceuticals companies. Specific details about the methodology are listed in Methodology Section at the end of the report.

### **The Total Number and Value of Alliances, 2000 – 2006**

Between 2000 and 2006, the thirteen companies entered into 357 alliances. In each case at least one of the parties to the alliance is located in Massachusetts. The cash value of these alliances totaled more than

\$13.4 billion dollars. The alliances were potentially worth an additional \$14.7 billion downstream. The dollar value of alliance activity among the 13 companies increased dramatically between 2001 and 2006. In 2006, the 13 companies entered into fourteen alliances worth \$5.2 billion. The data for 2006 is particularly noteworthy as the data only reflects alliances formed between January and October of that year.

**Table 7: Thirteen Company Survey, Summary of Alliances and Values, 2000-2006**

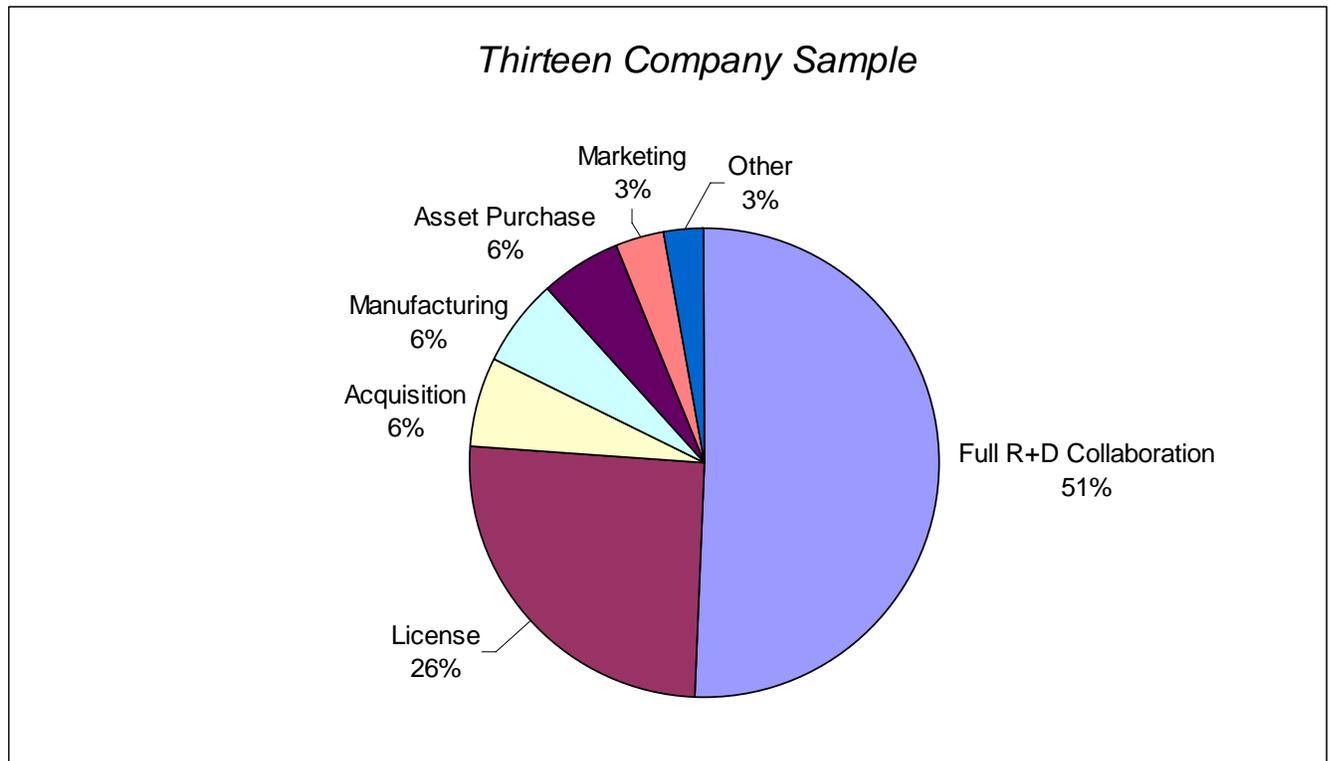
Year	Number of unknown value (N/A) alliances	Number of known-value alliances	Upfront dollar value of known-value alliances	Potential additional dollar value over life of alliance
2000	51	12	359,500,000	2,249,000,000
2001	57	8	783,750,000	529,000,000
2002	39	7	251,400,000	410,000,000
2003	38	18	4,685,900,000	956,000,000
2004	41	9	291,500,000	2,192,000,000
2005	21	16	1,824,083,000	1,367,500,000
2006	26	14	5,214,800,000	6,971,500,000
<b>Total</b>	<b>273</b>	<b>84</b>	<b>13,410,933,000</b>	<b>14,675,000,000</b>

Source: Recap.com; Authors' calculations. Data tables summarize the alliance activities of thirteen selected companies.

## Range of Alliance Activities

The bio-pharma alliances typically include a range of elements including joint research and development activities and legal and financial agreements. In many cases, a license for a product or technology is one element of a broader partnership of shared activities including applied research and development as well as marketing and co-promotion. Many of the alliances also include an equity deal or option. In spite of the diversity of activities conducted within an alliance, it is possible to characterize the agreements by the dominant type of activity. We classify the alliance agreements according to one of the following categories: full research and development collaboration; license agreement; acquisition; manufacturing; asset purchase; co-marketing/co-promotion; merger and settlement.

By far the greatest number of alliances in the sample can be categorized as full collaborations: extensive partnerships between two firms involving research, development and commercialization phases. Fifty-one percent of alliances in the Massachusetts sample – 180 in total - are full collaborations. These alliances were valued at over \$1.3 billion with additional potential revenues valued at \$8.4 billion over the life of the alliances.

**Figure 3: Massachusetts Bio-pharma Alliances by Type, 2000-2006**

Source: Recap.com; UMass Donahue Institute calculations; 2006. Data is for the 13 company sample.

**Table 8: Alliances by Alliance Category**

Alliance Category	# of Alliances	Value	Potential Value
Full Collaboration	178	1,220,583,000	8,401,000,000
License	88	41,500,000	119,000,000
Acquisition	22	2,248,000,000	1,671,000,000
Manufacturing	21	608,000,000	50,000,000
Asset Purchase	20	5,366,600,000	4,426,000,000
Marketing	12	203,750,000	0
Other	10	3,552,000,000	8,000,000
Merger	1	3,500,000,000	0
Settlement	7	52,000,000	8,000,000
Equity	2	0	0
<b>Total</b>	<b>351</b>	<b>13,240,433,000</b>	<b>14,675,000,000</b>

Source: Recap.com; Authors' calculations. Data tables summarize the alliance activities of thirteen selected companies.

A smaller number of alliances involved only a license agreement for a product or technology rather than a full research and development collaboration. Twenty-six percent of alliances – 92 in total – were license agreements worth a total of \$41 million. The licensing agreements fall into three basic categories: the first set allowed access to products like biological compounds for therapeutics; proteins, genes, enzymes and antigens related to specific diseases; drug treatments, and even genetically modified

animals for specific types of research. The second set of licenses provided access to scientific information stored in databases and display libraries. The third set of licensing agreements allowed access to proprietary technologies like imaging systems, software, diagnostic equipment and therapeutic technologies.

In addition, from 2000 to 2006 the thirteen companies in our sample were involved in 22 acquisitions worth a total of \$2.5 billion. Genzyme was the most active initiator of acquisitions, with 12 acquisitions in 6 different states as well as Canada, Germany and Brazil. Other companies involved in acquisitions between 2000 and 2006 include Biogen Idec, Charles River Laboratories, Amgen, Vertex and Cubist.

Another type of alliance activity involved manufacturing alliances. Twenty one manufacturing agreements were initiated, and these were worth \$608 million in revenues. The nature of the manufacturing agreements in the sample varied in nature, ranging from the mass production of approved drugs, such as Sepracor's arrangement with Patheon (Ontario, Canada) to manufacture Lunesta™, to agreements for small-scale clinical production and testing.

Other types of alliances included asset purchases, marketing and promotional agreements, and one case, mergers. The total worth of the 20 asset purchases was \$5.36 billion, by far the most valuable type of deal in the sample, both in absolute terms as well as in terms of the average value per deal. The nature of asset purchases varied widely. Some asset purchases involved buying entire research units – as in Genzyme's acquisition of Impath's New York-based cancer testing unit. In other cases, entire diagnostics and therapeutics units were purchased. Other asset purchases involved acquisitions of plants and operations or patented processes.<sup>17</sup>

### **Locations of alliances initiated by MA-headquartered companies**

The five Massachusetts-headquartered companies in the sample engage in alliance partnerships throughout the U.S. as well as in fifteen different countries. California is by far the most likely location for alliance partnerships: forty percent of alliances with U.S. firms (46 in total) were with a California firm. These alliances were worth \$1.6 billion over the six year period. Alliances with fellow

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<sup>17</sup> From Recombinant Capital; Recap.com database. Biogen Idec press release coded #58F, entitled: *AVANIR Pharmaceuticals (AVN) Subsidiary Acquires Full Ownership Of Patented Human Antibody Generation Process From IDEC Pharmaceuticals (IDPH)*. February 12, 2001.

Massachusetts-based firms were the next most common type of alliance and these alliances had the highest total value of any location. Twenty eight alliances worth \$3.5 billion were made with other Massachusetts firms. No other states after California and Massachusetts drew a significant amount of alliance activity; underscoring the dominance of these two states as centers for bio-pharma activity.

Internationally, Massachusetts headquartered companies were most likely to form alliances with Canada (11 alliances worth \$10.7 million). Though less frequent, there were also alliances with the UK, Germany, France, Switzerland, Holland, and Australia. In terms of the total dollar value of alliances, the \$661 million dollar value of international alliances didn't come close to the approximately \$5.1 billion value of alliances with firms in California and Massachusetts.

### Alliance Activity by Drug Development Stage

The 13 companies examined by our study were involved in alliances at every stage of drug development. However, it is a significant finding that a majority of alliances occurred during early stages of drug development (discovery through preclinical testing): a stage in which venture capital is frequently scarce. In the sample, 118 out of 175 early stage alliances were took place during drug discovery research. Large pharmaceutical companies and the large biotech companies were both very active in supporting drug discovery. The drug discovery alliances were worth approximately \$340 million over the six year period: more than three times the amount of venture capital invested in startup/seed investments during the same period (\$91.9 million). Clearly, the larger Biotech and Pharma companies play a significant role in supporting smaller biotechnology companies in Massachusetts.

**Table 9: Alliances by Stage of Drug Discovery**

Stage	# of Alliances	Value	Downstream Potential Value
Early Stage (Discovery to Preclinical)	175	922,583,000	6,069,000,000
Mid & Late Stage (Clinical Trials to Approval)	48	4,863,500,000	6,820,000,000
Manufacturing & Marketing	27	583,750,000	0
Unknown	107	7,041,100,000	1,786,000,000
<b>Total</b>	<b>357</b>	<b>\$13,410,933,000</b>	<b>\$14,675,000,000</b>

Source: Recap.com; UMass Donahue Institute calculations; 2006. Data is for 13 companies.

In addition to early stage alliances, thirteen percent of the alliances supported the mid and late stages of drug development, from clinical phases I, II, and III through the regulatory approval process. These 48 alliances, while fewer in number than those related to early development, had high average values and represent 37 percent of the total value of alliances in the sample. This likely reflects the fact that

research typically increases in cost from preclinical stages throughout the clinical trials process, while simultaneously gaining in potential value the closer it comes to FDA approval. The remaining (7.6 percent of alliances, worth \$583 million) took place at the manufacturing or marketing stage. Due to limitations in the Recap database, one hundred and seven alliances, worth \$7.0 billion in total, were impossible to classify within a drug development phase.

## Conclusion

Our representative sample of 13 major pharmaceutical and biotechnology companies in Massachusetts clearly documents the essential role that larger bio-pharma companies play in supporting Life Sciences enterprises in Massachusetts. The 357 alliances documented in this report were worth a total of \$13.4 billion and supported drug discovery and product development at key stages of the product development life cycle in which resources can be most scarce. The alliance activity further documents a key insight into private sector investment in Massachusetts: the leading biotechnology and pharmaceuticals companies in the world want to invest in Massachusetts during high value-added stages of product research and development.

The robust alliance activity underscores Massachusetts economic strengths in this sector as documented in Section I of this report. Massachusetts may be less competitive in large-scale manufacturing and other low-wage, lower skilled activities. However, the state is a premier location for research and innovation. The key question of how the state can retain and improve its competitive position in biopharmaceuticals is addressed in the next section of this report.

## Section III. Business Conditions and Opportunities in Massachusetts

The biotechnology and pharmaceutical industries are major employers in Massachusetts and comprise a cornerstone sector in the state's high value-added, knowledge economy. In addition to documenting the robust partnership between pharmaceutical and biotechnology companies in the state, this report seeks to present the competitive strengths and weaknesses of Massachusetts as a location for bio-pharmaceutical businesses. To better understand the competitive and policy challenges facing bio-pharma companies in the state, the UMass Donahue Institute interviewed and surveyed leading figures at half of the approximately two-dozen largest biotechnology and pharmaceutical companies in Massachusetts. The eleven companies that participated in this project report over 16,000 total employees in Massachusetts and more than 500,000 employees worldwide. These leading bio-pharma companies employ over one third of all bio-pharmaceutical workers in Massachusetts.

### The Competitive Position of Massachusetts for Bio-Pharmaceutical Investment

According to bio-pharma business leaders in the state, Massachusetts is one of the premier locations in the world in which to conduct basic research and drug discovery. The quality of the skilled workforce in Massachusetts, typically those with advanced graduate degrees and doctorates, is among the finest in the United States. Massachusetts is fortunate to be home to world-class private companies, universities and research hospitals engaged in biomedical research and development. The business executives interviewed for this report identify the quality of the workforce and Massachusetts-based research partners as the primary reason to locate a bio-pharma facility in the state. One executive noted that biomedical companies must have a research presence in Massachusetts or California to be successful. Another executive pointed out that venture capital funds primarily seek out investment opportunities that are capable of accessing the existing talent in Boston, San Francisco or San Diego. It is difficult to overstate the strength and diversity of talent that exists in Massachusetts firms and institutions engaged in the bio-pharmaceutical industry.

The Massachusetts Bio-Pharma Cluster is particularly competitive in some aspects of biomedical production and less competitive in other areas. As noted, the state is preeminent in basic research and

drug discovery research. According to the companies interviewed, Massachusetts is a reasonably competitive place for preclinical trials and clinical trials and is a competitive location for small-batch manufacturing. In fact, two major bio-pharma companies noted that Massachusetts is a very good location for small-batch manufacturing. According to one of the companies, the co-location of small-batch manufacturing and drug discovery research activities is ideal for the firm because the interaction of the units reduces the time-to-market for products.

Undeniably, the state is less competitive in attracting large-scale bio-pharmaceutical manufacturing facilities. The principal reason offered by bio-pharma companies is the cost of living in the state and its effect on the wages that can be offered manufacturing workers. In addition, other states and countries provide accessible, robust technical assistance and financial incentives for the development of bio-manufacturing facilities. The bio-pharmaceutical production process – from basic research to mass-manufacturing and distribution – operates at a global scale. Massachusetts competes internationally as a location for manufacturing and there are locations throughout the world that are capable of providing high-quality production workers, favorable tax treatment for investments, and very effective state assistance for site location and development. A few companies interviewed identified Ireland, Singapore, India and China as desirable locations for manufacturing facilities. In the United States, the Commonwealth of Puerto Rico and North Carolina are key competitors. No company ruled out Massachusetts as a location for its mass-manufacturing facilities, but each identified significant hurdles that the state would have to address.

The UMass Donahue Institute asked each of the companies interviewed to rate the competitiveness of Massachusetts compared to North Carolina, California, Europe and Asia. The Donahue Institute documented the sector's top key strengths and challenges. Overall, Massachusetts showed impressive strengths compared to its competitors. Massachusetts was viewed as very similar to California in its business and labor costs, and the strength of its labor force and potential research partners. In terms of tax policy, permitting and regulation, Massachusetts was viewed as about equal or slightly more competitive than either Europe or Asia. Massachusetts had a better supply of workforce and research partners than either Europe or Asia. North Carolina presents a far more mixed competitive position for Massachusetts. North Carolina is considered a far more desirable location in terms of business regulation and permitting and the effectiveness of state government in meeting the needs of the industry. To a lesser extent, North Carolina led Massachusetts in the tax treatment of corporate revenue, the level

of employee wages and benefits, and the effect of payroll taxes and workers compensation. Offsetting those less favorable conditions, Massachusetts was identified as having a significant advantage in the quality of its skilled workforce and the proximity of world class research partners.

## The Comparative Strengths and Weaknesses of Massachusetts

### **Key Strengths**

- Availability of skilled workers in Massachusetts;
- Proximity to world-class research partners.

### **Key Weaknesses**

- Business regulations and permitting;
- The effectiveness of state government to meet business needs.

## The Policy Challenges Confronting Bio-Pharma in Massachusetts

The bio-pharma companies participating in this project were also asked to rate the importance of specific policy challenges that could affect the ability of the biopharmaceutical industry to retain its strengths and grow in Massachusetts. Uniformly, the bio-pharma business leaders identified concerns in three basic areas: business conditions, the effectiveness of state government, and federal policies and programs.

### **Business Conditions**

Through interviews and surveys, bio-pharma business leaders in Massachusetts highlighted the critical challenge they face in recruiting the highly-skilled workers that they need. The state has a decent pipeline of talented college and university graduates but the cost of living drives many professionals out-of-state and discourages talented workers in other states from relocating to Massachusetts. Business leaders identified the high cost of housing as a particular factor in why many talented scientists and professionals chose not to relocate to Massachusetts to work for the companies in our survey. The reliability of the pipeline of skilled science, technology, engineering and math (STEM) workers is also a key issue facing the state. Massachusetts has a well-developed pool of highly-skilled, doctoral-level workers but it has greater challenges attracting and retaining workers at the associates, bachelors and masters degree levels. The companies that the UMass Donahue Institute interviewed noted that they

often work with state and national agencies in other regions to ensure that a sufficient pipeline of labor is available prior to constructing new or expanded facilities.

### **Effectiveness of State Government**

The bio-pharma companies who participated in our study all expressed significant concern that state government in Massachusetts does not respond effectively to the needs of individual companies or the industry at large. The first significant concern expressed by the companies is a shared experience that the state does not effectively track company-level needs and concerns or assist companies in navigating often complex permitting and regulatory requirements. One company noted that they have been waiting over fifteen years for the state to construct an on-ramp onto Interstate 93 despite a legislative appropriation to construct the ramp in 1989. Companies repeatedly emphasized two things: they are not looking to avoid environmental or other regulations, they simply need to be able to implement business decisions in a time-sensitive manner; and, competitor states and nations do a much better job of reaching out to companies and following-through on commitments support workforce development, infrastructure or technical assistance.

The second major concern regarding state government that the companies expressed is the predictability and relative competitiveness of business costs. As currently structured, the companies did not express great concern about state taxes; however, many of the firms consider the consistency and predictability of business costs to be essential. One business leader noted that Massachusetts currently has tax advantages over places like California due to its single-factor taxation of corporate revenues, which can be seen as an incentive for the location of headquarters in Massachusetts. The concern expressed is that Massachusetts operates within a competitive environment and should, therefore, base its tax policies on an understanding of its costs relative to other states and nations.

Finally, companies that did state a willingness to expand their manufacturing or processing facilities in Massachusetts noted that it can be difficult to identify and assemble land appropriate for manufacturing and other facilities. The bio-pharma companies expressed support for state efforts to assist existing businesses with land assembly, infrastructure costs and permitting.

## **Federal Policies and Programs**

The bio-pharmaceutical companies in our study expressed very clear opinions about the positive role that the federal government can play in facilitating growth in their industry as well as difficulties that federal policies can present to the competitive environment of biomedical research and drug development. The companies understand that federal funding for biomedical research is essential for basic research and commercialization of discoveries and advocate very strongly for increased funding. The companies stated that there is a state role for Governor Patrick and a federal role for our Congressional delegation in ensuring that federal government clearly understands the opportunities and challenges confronting the industry. In their opinion, Massachusetts should have a loud, clear and effective voice in Washington for the bio-pharmaceuticals industry.

The biopharmaceutical sector's concern over federal policy extends to policies that shape and affect the competitive environment in which investment decisions are made in the industry. Specifically, all of the bio-pharma companies in our study expressed significant opposition to federal policies that would impose drug price controls and to federal and state programs that encourage drug re-importation. Company leaders made two clear points about drug re-importation and price controls. First, Massachusetts should be very careful to understand the impact that a reduction in pharmaceutical revenues (through price controls) could have on private investment in the industry and the flow of research and development dollars to companies based in the state. As this report has shown, there is a robust financial relationship between pharmaceutical and biotechnology companies in Massachusetts. The second point made by the bio-pharma companies is that the state's civic and political leaders have not always spoken clearly as cheerleaders for the industry. Significant changes in federal policies and regulations are likely to have a profound impact on the competitive landscape of Massachusetts life sciences companies. The companies strongly expressed an interest in ensuring that policymakers invite bio-pharma companies into the conversation about the effect that these policies would have on the future of the life sciences industry in Massachusetts and the United States.

## **The Core Policy Challenges Confronting Bio-Pharma in Massachusetts**

### **Business Conditions**

- Improve the pipeline of science, technology, engineering and math (STEM) workers;
- Need for more affordable workforce housing;

### **Effectiveness of State Government**

- Reduce the cost of doing business;
- Streamline the real estate permitting process;
- Respond in a time-sensitive fashion to business needs and concerns;
- Support land assembly and infrastructure for bio-pharma manufacturing in Massachusetts.

### **Federal Policies and Programs**

- Advocate for increased federal funding for biomedical research;
- Advocate for the industry in Washington, D.C.;
- Oppose federal efforts to impose drug price controls or enable drug re-importation programs.

## Methodology

### **Methodology for Analysis of Bio-Pharma Alliances**

The UMass Donahue Institute selected the thirteen companies in our sample of alliance activity from a comprehensive list of biotechnology and pharmaceutical companies operating in Massachusetts. The list was compiled from published company lists from biotechnology newsletters and websites, the Massachusetts High Technology Council and the Massachusetts Biotechnology Council. The Donahue Institute identified the top 100 firms by sales and employment and, from that list, selected thirteen major pharmaceutical and biotechnology companies with either headquarters or significant facilities in the state.

Medium and large companies were the focus of the research as they were most likely to have the resources to initiate alliances and partnerships, if a significant number were, in fact, to be found. The companies included in this analysis are: Merck, AstraZeneca, Abbott Laboratories, Novartis, Wyeth, Cubist Pharmaceuticals, Vertex Pharmaceuticals, Biogen Idec, Sepracor, Amgen, Serono, Genzyme. For comparison purposes, Genentech was included as an example of a major biotechnology company headquartered outside of Massachusetts.

Using the Recap.com database of biopharmaceutical industry SEC filings, contracts and press announcements, the UMass Donahue Institute collected information on all alliances formed by Massachusetts headquartered companies regardless of the location of their partner firm. For companies headquartered out-of-state, such as the major pharmaceutical companies, information was collected for all alliances that included a Massachusetts-based firm. The dollar value of the alliances and all details regarding the nature of the alliances were drawn directly from company press releases and contracts.

### **Methodology for Analysis of Business Conditions and Opportunities in Massachusetts**

The UMass Donahue Institute interviewed 10 business leaders from seven of the largest biopharmaceutical companies and institutions in Massachusetts. The interviews were conducted from September through December 2006 and included the companies included in the alliance analysis as well

as Partners HealthCare Systems, Inc. and Millipore Corporation. The interviews provided in-depth background information for the report and for development of a web-based survey that was distributed in December 2006 to approximately two-dozen firms. The eleven respondents consist of many of the largest life sciences companies in Massachusetts and have, collectively, over 16,000 employees in the state.

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1601 Trapelo Road  
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781.890.6482  
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[masshightechcouncil@mhtc.org](mailto:masshightechcouncil@mhtc.org)

