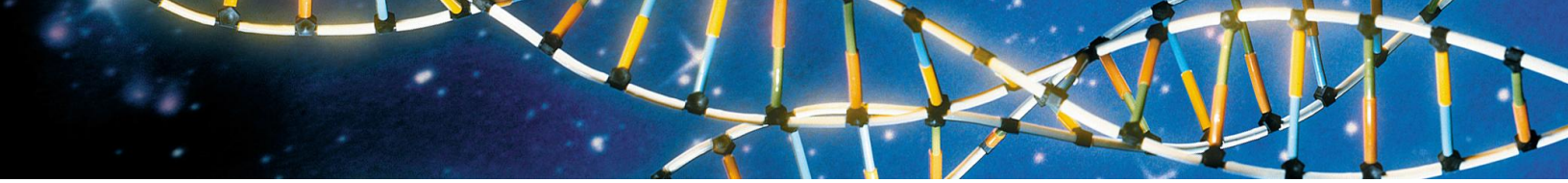
BioNJ 2011 Industry Study

Biotech in New Jersey: Finding Its Way Through Continuing Challenges

August 2012



To our BioNJ Community:

We are pleased to unveil the results of the 2011 BioNJ Study, *Biotech in New Jersey: Finding Its Way Through Continuing Challenges*, conducted by Ernst & Young LLP on behalf of BioNJ.

It is our pleasure to report that the New Jersey biotechnology story remains one of steady growth and a promising future as New Jersey continues to have significant assets that attract companies to this area to develop innovative therapies that will help shape the future of medical care. However, given the all-encompassing nature of the ongoing global financial downturn that originated in 2008 and the capital-intensive character of drug research and development, it is also not surprising that some of the challenges and pressures we noted in our last survey persist.

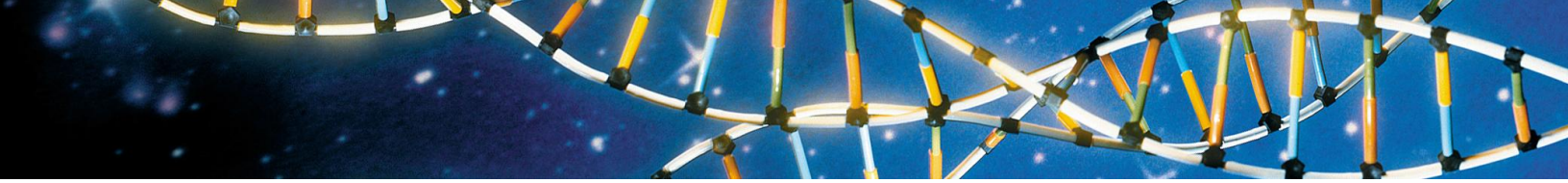
Key Findings:

- The number of biotechnology companies in New Jersey has grown from more than 300 in July 2010 to more than 340 today.
- The number of jobs has increased from approximately 15,000 in July 2010 to an estimated 16,400 today, reflecting a 9.3 percent increase in two years. This figure does not include traditional Big Pharma or medical device companies, nor does it account for the thousands of indirect jobs that support and are supported by the industry.
- Funding for early-stage research continues to experience a decrease consistent with national trends.
- 71 percent of respondents anticipate hiring additional employees in 2012.
- 46 percent of respondents have operated in New Jersey for 5 years or less, reflecting the attractiveness of New Jersey as a location for this industry.
- 37 percent of respondents have been in business for 5 years or less, reflecting ongoing company creation.

Recommendations for Action:

Based on the findings of this survey, the State of New Jersey needs to:

- Develop new and enhance current economic incentives to attract and retain companies and to help them attract and retain key personnel necessary to breakthrough scientific research;



- Support companies at each stage of development, including financially supporting the very earliest-stage companies;

- Reinforce measures to enhance New Jersey's academic environment in an effort to increase its impact on clinical and early-stage research; and

- Maintain and build the entrepreneurial spirit needed to bring breakthrough science to commercialization – encouraging, facilitating, and supporting start-ups.

It is efforts like these that will help to ensure the continued growth of the biotechnology industry in our State.

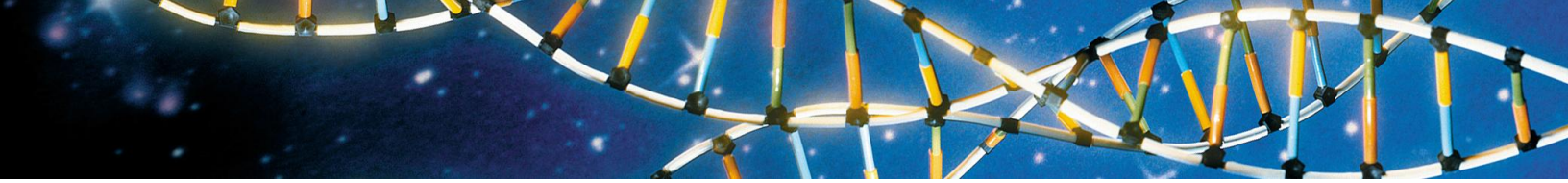
We thank the team at Ernst & Young who donated their time to make this study a reality, the BioNJ Board of Trustees for its steadfast vision in moving BioNJ and the industry forward and our generous Members of the biotechnology community who took the time to respond.

Finally, we are grateful to the men and women who move this cluster forward every day through their dedication to finding innovative therapies and cures to meet the unmet medical needs of patients and their families.

Yours in the BioNJ,

Sol J. Barer
Chairman, BioNJ

Debbie Hart
President, BioNJ



Biotech in New Jersey:
Finding Its Way Through Continuing Challenges

Introduction

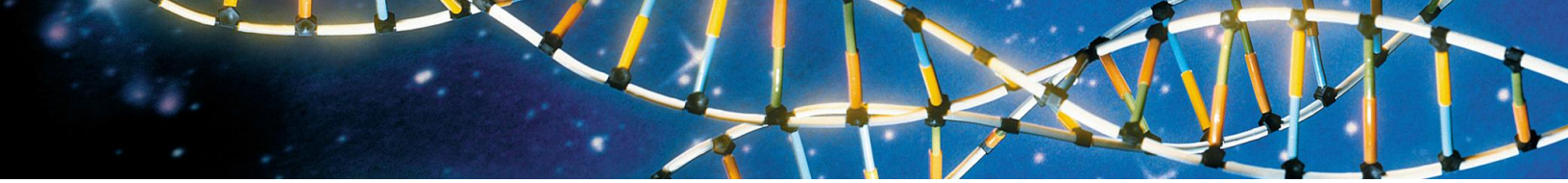
As we have done in the past, BioNJ and Ernst & Young co-developed and conducted a survey of the New Jersey biotechnology industry for calendar year 2011. The goals of the study, as always, were to assess the vitality of the industry in the State of New Jersey and to determine what can be done to improve New Jersey's position as a life science leader going forward.

The survey's results included reports from early-stage to well-established companies that provided a cross section of the industry in New Jersey. The data were benchmarked to previous years to help identify trends within our State and compared to data observed on a national and global basis as noted in Ernst & Young's 2012 "Beyond Borders" biotechnology report.

In our 2010 report, we identified the emergence of a "New Normal," requiring new business models for sustainability in the wake of a global market crash. We are now four years from the global economic crisis of 2008, yet as we survey the biotech industry, it is clear that the pressures on the industry's business model have increased and many of the effects of that crisis continue to impact the New Jersey and national marketplace. Many of the results of our study corroborated many of the observations identified in the national marketplace by Ernst & Young.

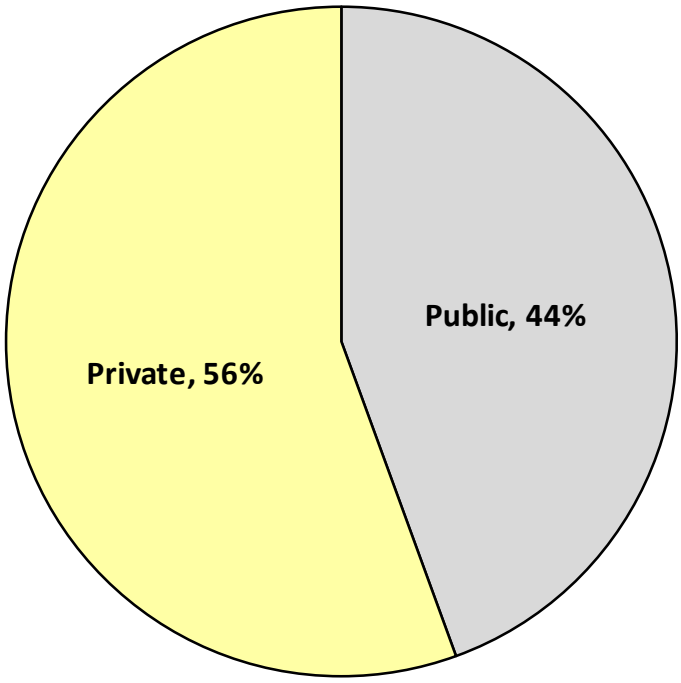
This survey report discusses some of the steps that need to be taken to maintain New Jersey's presence as a desirable place in which to start and maintain a biotechnology company. These steps are particularly imperative given the fact that New Jersey needs to retain the talented people who are being shed from large pharmaceutical companies during a time when the State is also competing with other states, regions and countries for talent and companies in an ever-increasingly competitive global marketplace.

Specifically, New Jersey needs to: (1) Develop new and enhance current economic incentives to attract and retain companies and to help them attract and retain key personnel necessary to breakthrough scientific research; (2) Support companies at each stage of development, including financially supporting the very earliest-stage companies; (3) Reinforce measures to enhance New Jersey's academic environment in an effort to increase its impact on clinical and early-stage research; and (4) Maintain and build the entrepreneurial spirit needed to bring breakthrough science to commercialization – encouraging, facilitating, and supporting start-ups.



A snapshot of the respondents to the survey

First, based on rigorous monitoring, BioNJ believes there are more than 340 biotechnology companies as of July 30, 2012 in the State of New Jersey as compared to approximately 300 biotechnology companies two years ago and just under 240 companies in 2007. Nearly 20 percent of the companies responded to the survey this year. Nearly half of the respondents to the current year study are from public companies as shown in the graph below.

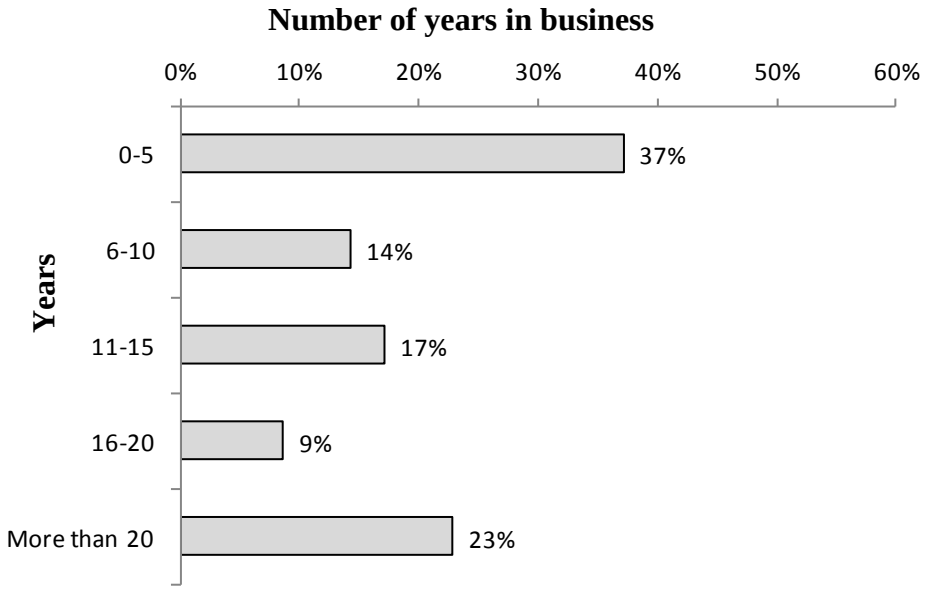


Despite some M&A activity and several companies that shut down operations, the overall number of companies continues to increase with new companies locating to New Jersey and new company formation.

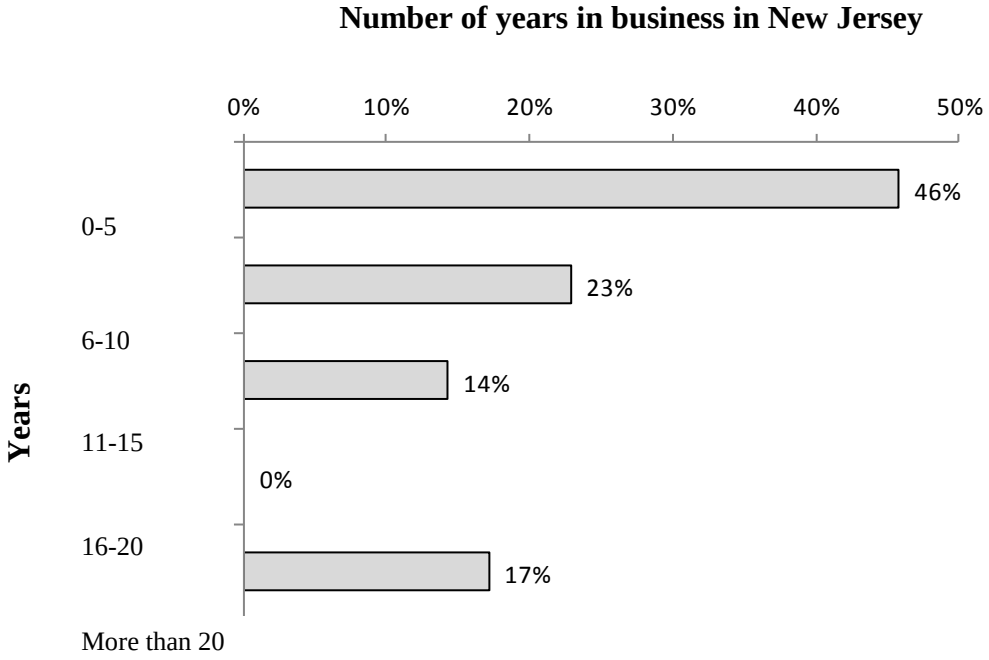
The total number of ***public*** life science companies in New Jersey remained relatively consistent as compared to the prior year report with some M&A activity reducing the number of public companies offset with new public company formation and relocations (Insmed, Celsion, and Pacira). As of December 31, 2011, there were 42 public biotech companies in New Jersey, which is comparable to the prior year study.

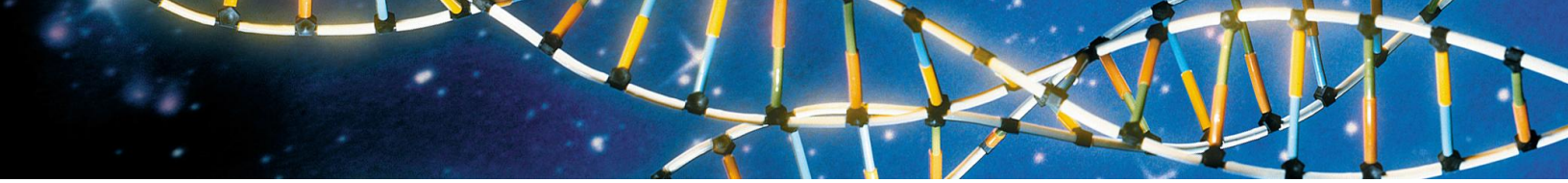
New Jersey has all manner of biotech companies: large mature organizations that generate significant earnings as well as companies that focus principally on research. A significant number of companies that responded to our survey are in "startup" mode (i.e., have been in business five years or less). However, there were also many companies in our survey that have been in business for more than 15 years. This mix of startup and mature companies is healthy for the future stability and growth of the industry. The respondents to our survey

supported a very healthy mix of both mature and emerging companies as shown in the table below:



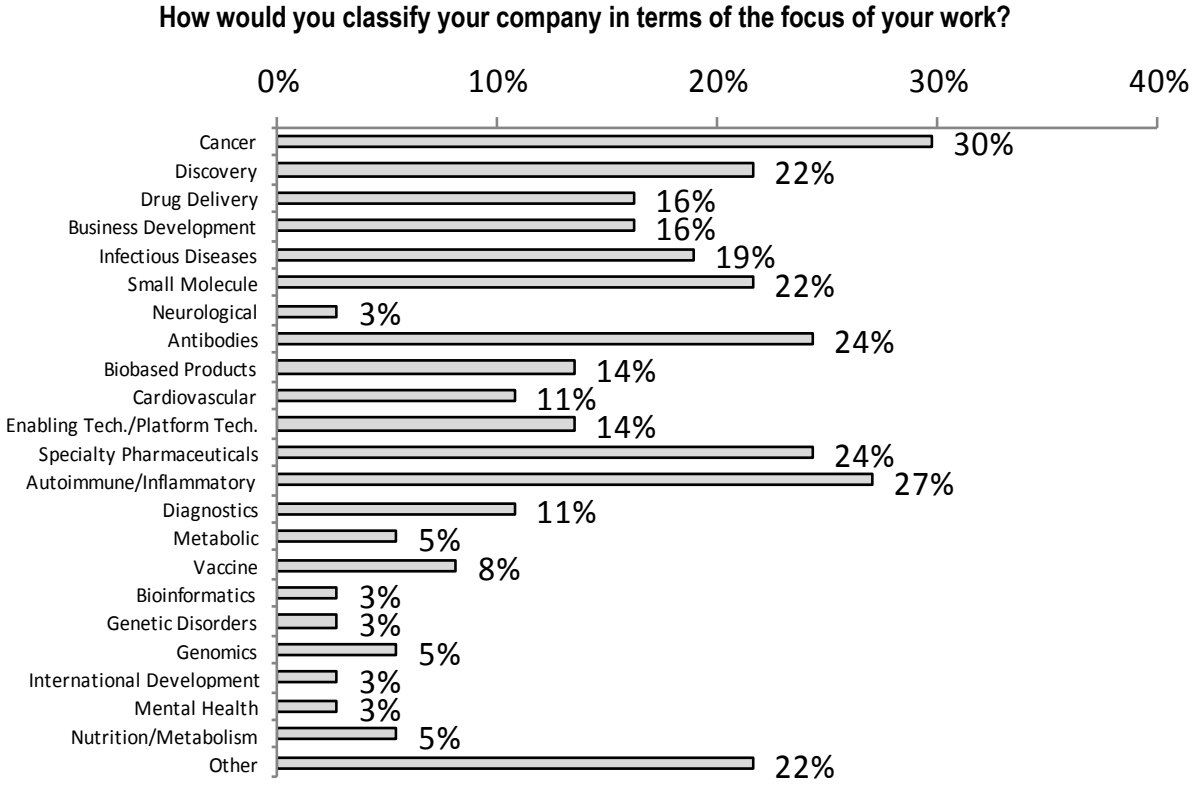
Also, as shown in the table below, 46% of the respondents have been in New Jersey for fewer than five years. Thus, the growth in the number of companies and the growth in the job base is not only due to the formation of new companies, but also, in large part due to companies relocating to New Jersey. For example, since the start of 2011, the following are some of the companies that either relocated to or started an office in New Jersey: Allergan, Amarin Corporation, Celsion Corporation, Oncobiologics and Optimer Pharmaceuticals.

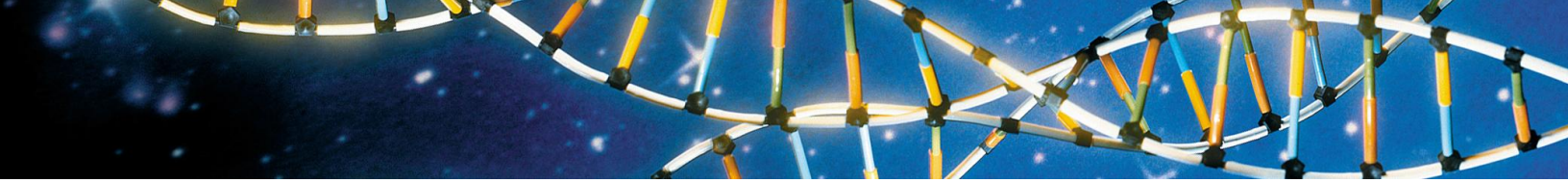




Therapeutic Focus

Consistent with prior year findings, New Jersey companies have a broad therapeutic focus. Of the responding companies, 30% were focused on Oncology, the single largest therapeutic focus in the State, followed by autoimmune/inflammatory.





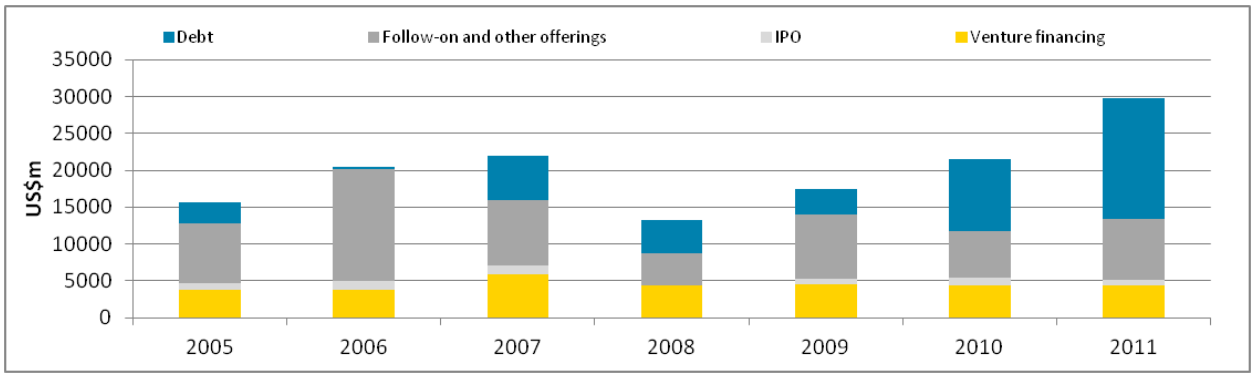
Financing

In our introductory discussion to this survey, we noted that the biotech industry will need to challenge the historical business models in order to thrive in the post-crisis economy. In order to do this and create the context that we can all agree on, we must first define the biotech business model. The biotech business model in our view has two key inputs: (i) funding and (ii) innovation.

Although the industry raised a fair amount of capital in total (as discussed later in this study), the stark reality that many biotech companies face in this economy is that funding is generally harder to find. Venture capitalists have become more discriminating and are investing in this industry at later stages, and the IPO markets have largely been closed to new companies seeking to raise funds from public investors.

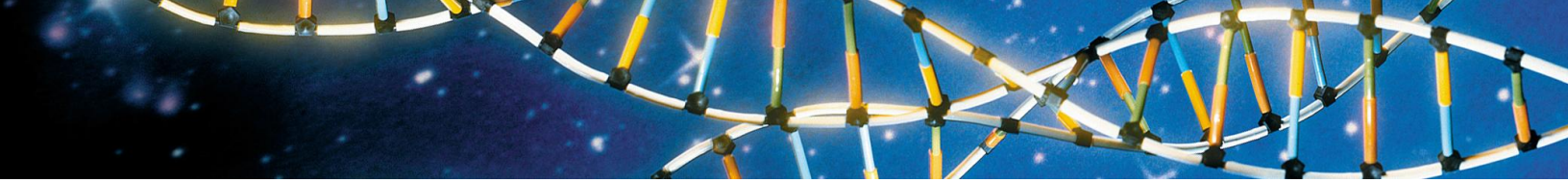
Let's start by looking at the funding input of the biotech business model. Biotech fundraising has always been subject to fluctuations (sometimes severe fluctuations), with public market windows opening and closing with some regularity. In the mid 2000's, however, we saw these fluctuations becoming less pronounced, a trend we attributed to public market investors becoming increasingly specialized and savvy and demanding ever more data before making an investment. Companies with the right data and sufficiently de-risked path to market had reasonably ready access to capital.

If you look at the overall aggregate funding level for the industry (based on information gathered from public companies) the total capital raised in 2011 looks very healthy. In fact, from an aggregate level, 2011 was one of the best capital raise years since the days of the ".com bubble" as shown in the graph below[1].



While the funds flowing into the sector continue to be impressive at aggregate levels, the reality is that the funds are increasingly concentrated in a smaller number of companies – meaning that most companies are facing, and will continue to face, a rough financing road. The significant amount of debt raised in the past two years across the nation is largely due to commercial biotech companies (Amgen and Gilead) rearranging their balance sheets to take

[1] Obtained from E&Y's 2012 Beyond Borders Global Biotech report

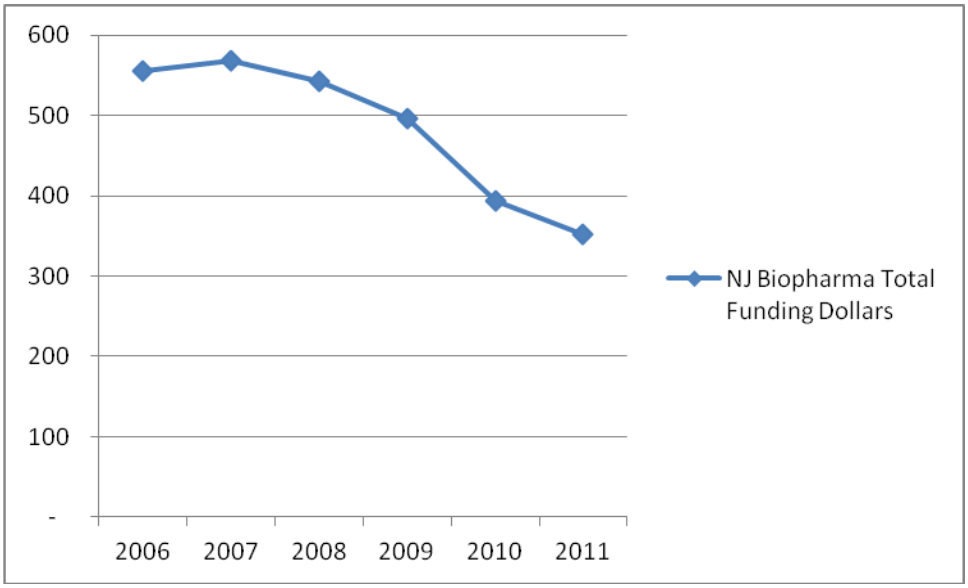


advantage of the low interest rates provided by convertible debt instruments. Total venture funding, however, has been relatively consistent in aggregate levels over the past several years.

When you get further behind the data, you will see that most other companies (i.e. those at an earlier stage of development, or with marginal data, or trying to rebound from a clinical setback) had fewer options. It seems we have seen the end of the era of "easy money," and as a result, the remaining investors have set the financing bar higher. Investors are not just challenged by reduced liquidity; they are also compelled to assess regulatory risk (in addition to scientific risk) much earlier in a product's development cycle – a phenomenon that has discouraged "generalist" institutional investors from playing more heavily in the sector.

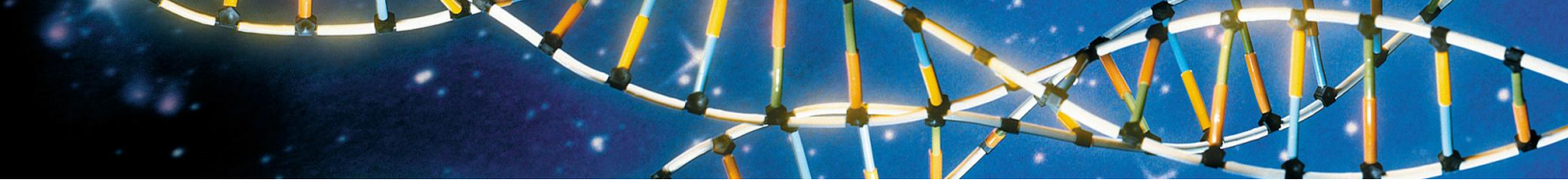
To see how the national trend was impacting New Jersey life science companies, we looked at data obtained from Venture Source, and we can see that the aggregate venture funding levels for New Jersey companies decreased[2] after the crisis of 2008. Venture Source tracks venture funding for many different industries and the data below are for biopharmaceutical companies[3]. For the past three years post the economic crisis, New Jersey biopharma companies raised between approximately $350 million to $500 million per year in total aggregate funding.

NJ Biopharma Total Funding Dollars (in $ millions)
Period: 2006 through 2011



[2] The fiscal year 2007 included two very large private equity inflows of capital to finance acquisitions that is distorting the total capital raise for that year. The chart above excludes those two events to normalize the data.

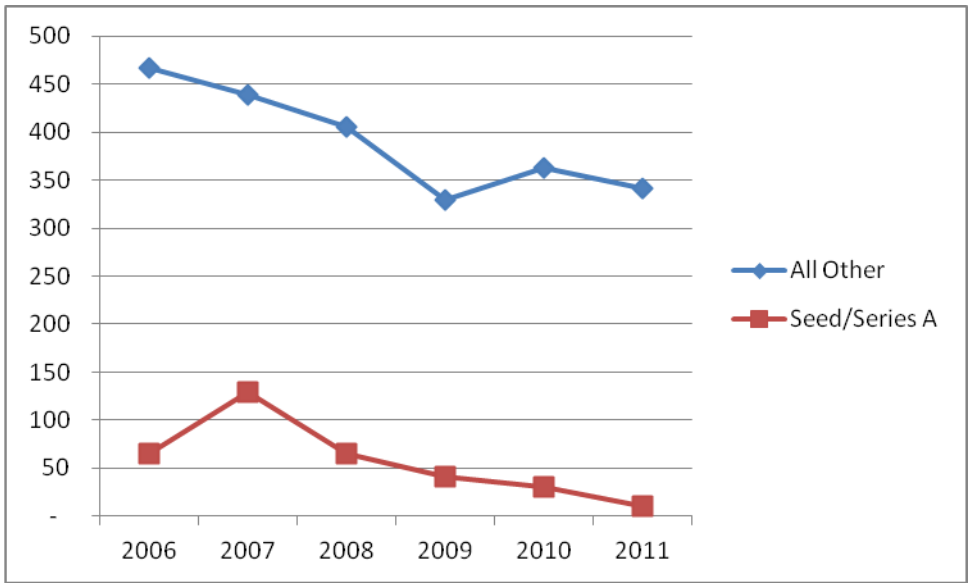
[3] Venture Source data is slightly different than data captured from the E&Y Beyond Borders slide shown above. Venture Source Biopharma sector includes biotechnology companies (companies involved in the industrial use of living organisms or biological techniques developed through basic research), drug delivery companies (companies that develop both a drug and the means of delivery into the body), drug discovery companies (companies developing processes or technologies that research the structure of genes in order to find treatments for specific diseases), and pharmaceutical companies (developers of the more traditional drugs that are derived from plants and other chemical compounds, and do not involve biotechnology).



We then sorted the Venture Source data based on the category of investments. Venture investments that were characterized as "Seed" or "Series A" investments were disaggregated from all other investments. We believe this view more clearly demonstrates how venture investors are investing in New Jersey (i.e. supporting investments of existing companies, or initial investments supporting research of presumably early-stage research or new company formation).

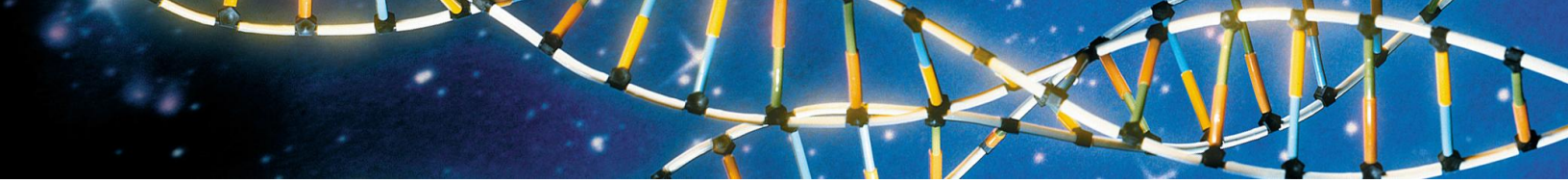
The table below suggests that funding for early-stage research is a continuing challenge as most of the funding appears to be flowing into companies with later-stage assets in New Jersey (as discussed later and consistent with national trends).

NJ Biopharma Total Funding Dollars - Seed/Series A versus All Other Funding
(in $ millions)
Period: 2006 through 2011[4]



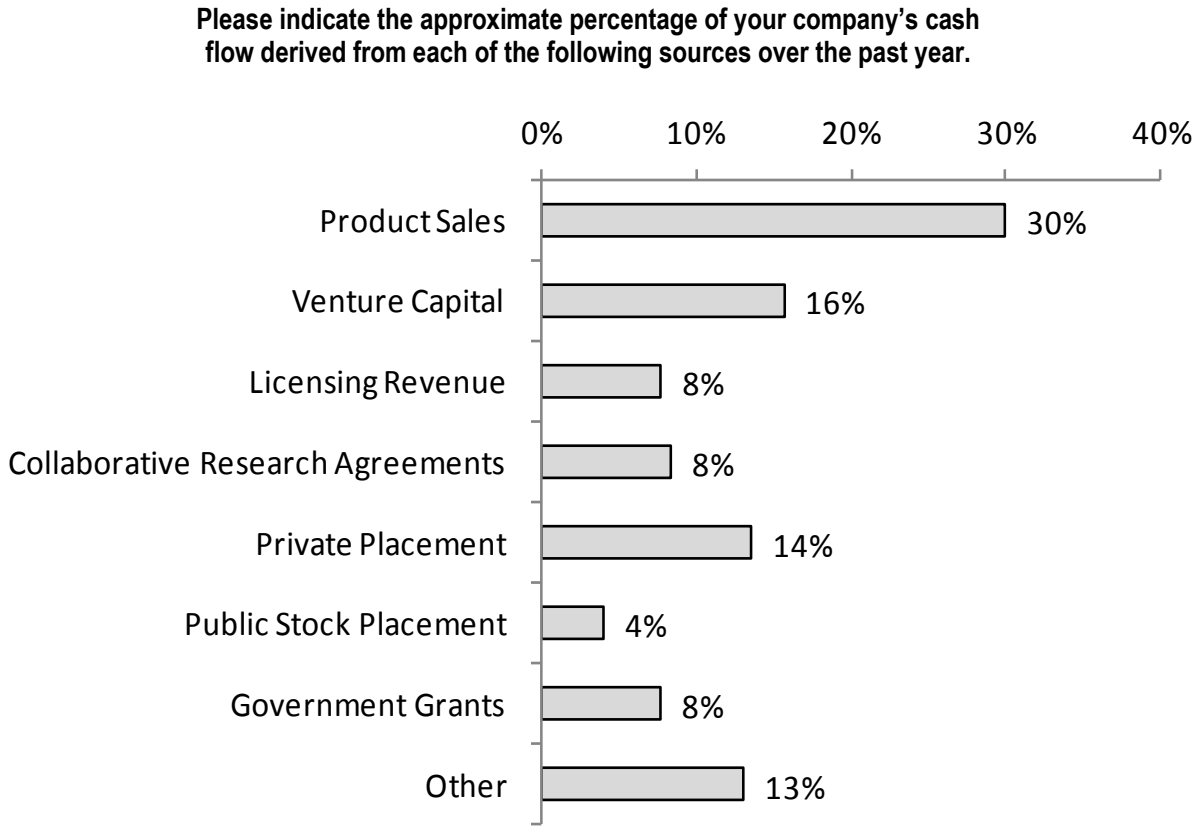
In the capital-constrained realities of the biotech business model, the question is whether biotech companies with early-stage research will be able to access the capital required to demonstrate the potential of the platform technology or the emergence of new therapeutic discoveries and whether we will see solutions emerge that will allow firms to go the distance and mature into large organizations with commercialized products, if indeed that continues to be the goal.

[4] The fiscal year 2007 data were normalized as noted in Footnote 1.

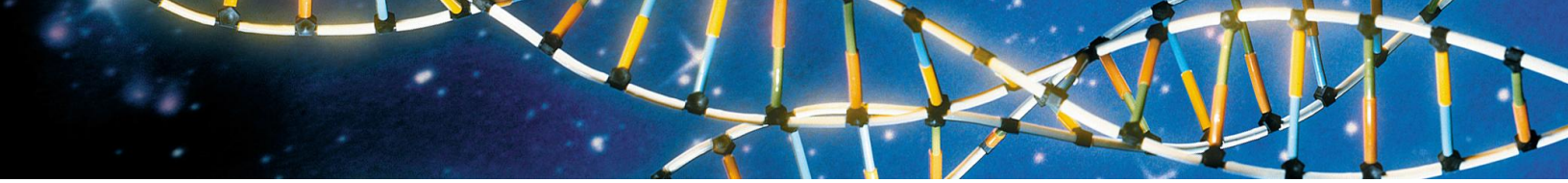


Funding Sources

Traditionally, biotech companies have relied on three principal sources of funding: venture capital, public investors, and alliances with pharmaceutical companies. For some respondents to this survey though, product sales are a part of the mix. Venture capital continues to play a significant role as a funding source for New Jersey-based companies as this was the second largest category of investment, but decreased from 26% of total funding noted in our 2009 report to 16% noted in the slide below. The third largest funding source for New Jersey-based companies is private placements.

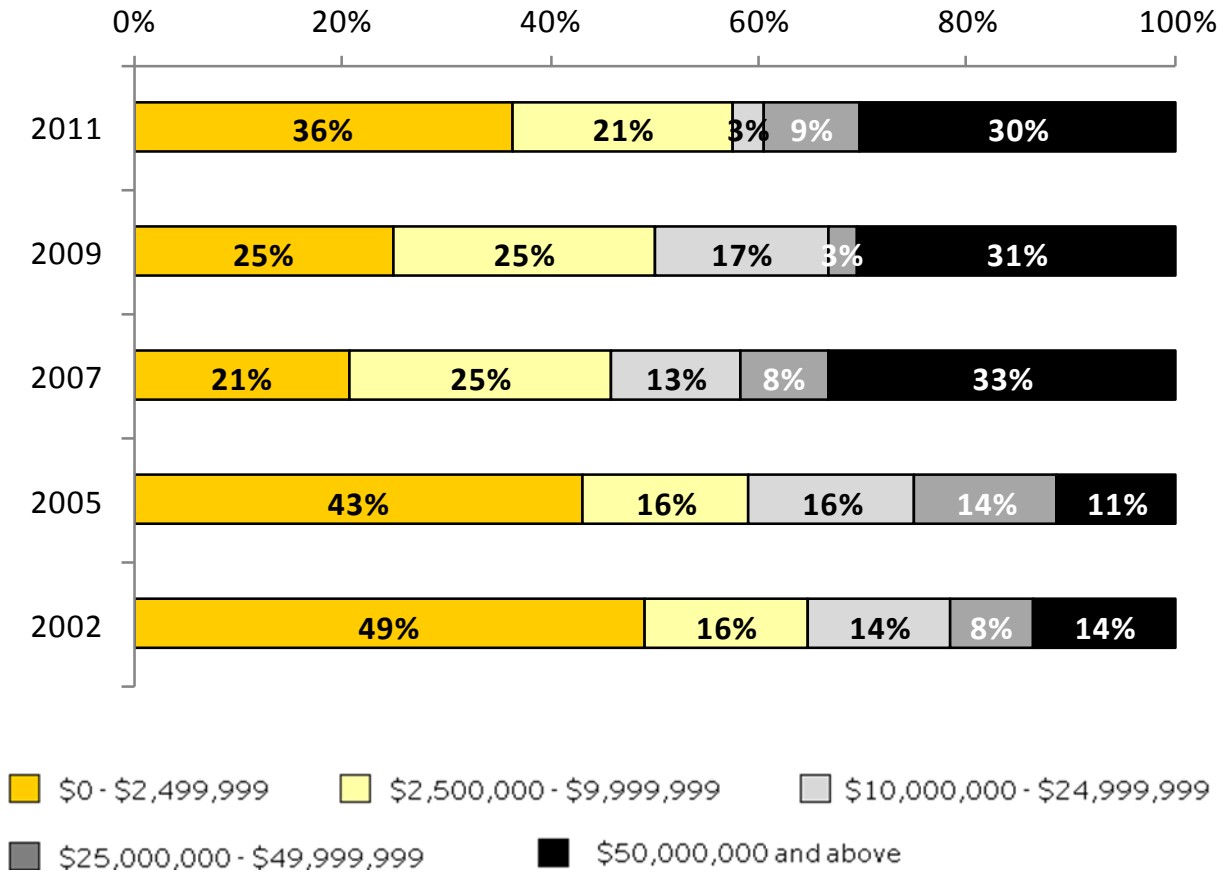


When you compare this survey to that of two years ago, we see a decrease in the amount of license revenue from collaboration arrangements and that is a trend that we notice nationwide. Often collaboration arrangements are with large pharmaceutical companies, and the nationwide trend saw a decrease this year, consistent with our survey. This trend is discussed further under *Deals and Alliances*.

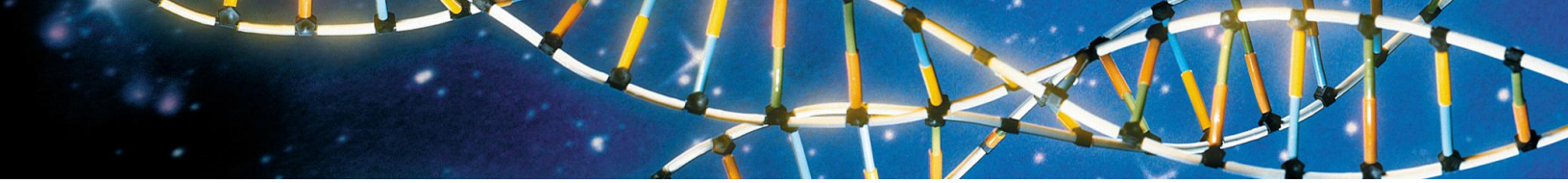


As we look at the survival index (the average amount of cash on hand), it appears that the companies that participated in the survey have a stronger balance sheet (i.e. more cash) than those that participated in the earlier years. However, close to 60% of the companies that responded have less than $10 million of cash as of December 31, 2011 from which to conduct their research and development activities. Given the capital-intensive nature of this industry, that is not a lot of cash to conduct clinical studies.

Please indicate your company's combined cash and short-term investments for your most recent fiscal year-end.



As stated earlier, companies looking to raise money from venture capital face a much higher bar as venture capitalists have become more selective. At a time when exits are scarce, investors have to retain more capital to sustain existing portfolio companies. Also, as the supply of capital from limited partners has diminished, many venture capitalists have not been able to raise the level of funding that they could in previous years. With fewer dollars allocated to funding early stage research, and more competition for those dollars, company valuations continue to be challenged by the investing public.



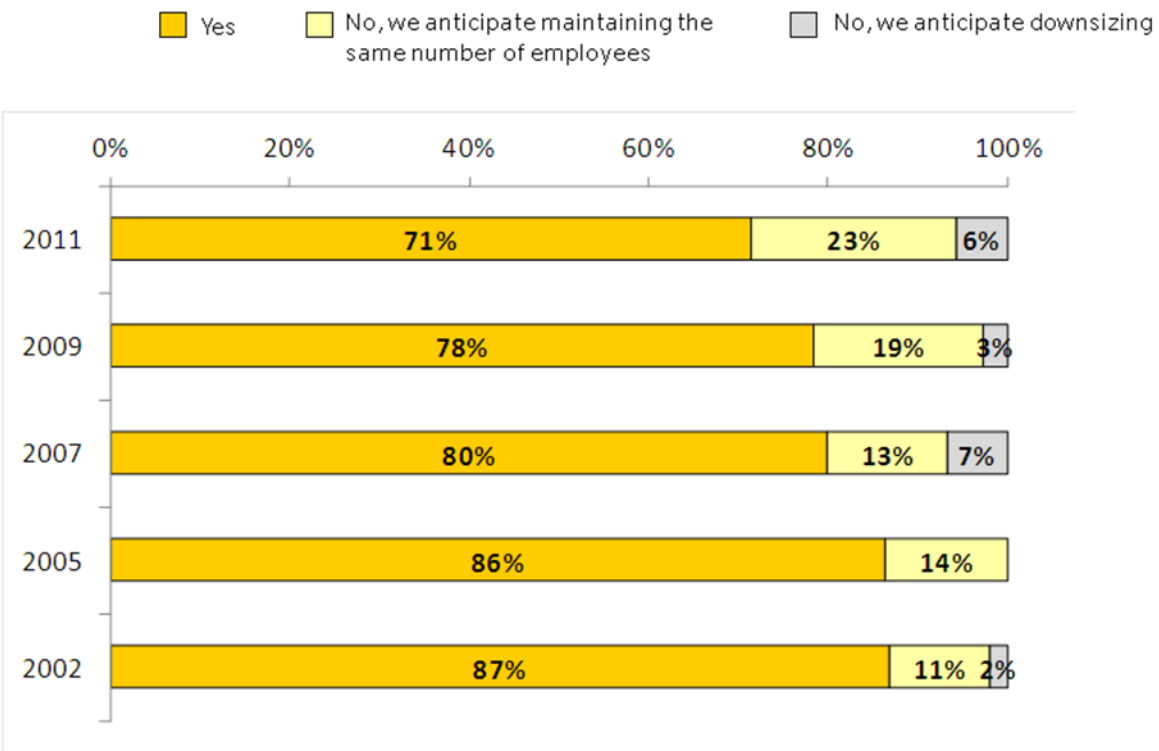
As noted earlier, the trend of the widening gap between the "haves and have nots" continued during 2011. Those companies with near-term commercial opportunity were rewarded with the bulk of the venture capital raised during the past three years, while those companies with longer term financing needs and more speculative therapeutic discovery platforms were punished with decreased valuations and dilutive capital raises. The total amount of venture money raised in North America and Europe was $5.8 billion, of which, less than 10% of the 3,000-plus companies operating across North America and Europe garnered over 70% of the aggregate venture capital invested.

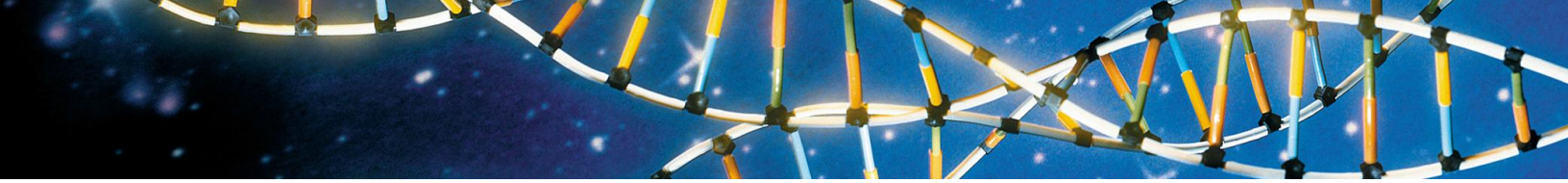
A few New Jersey-based companies were fortunate to raise significant capital during 2011. These companies include: Valeritas Inc. ($76 million), Durata Therapeutics Inc. ($58 million), Pacira Pharmaceuticals Inc. ($42 million), Omthera Pharmaceuticals Inc. ($39 million), Lux Biosciences ($31 million), Aerie Pharmaceuticals Inc. ($30 million), among others. The consistent theme among these companies is that they all have later-stage drug targets.

Hiring Trends

It should come as no surprise that the difficult economic environment is leading to companies being more cautious in their hiring decisions. As you can see from the table below, the number of companies that expect to hire new employees over the next 12 months has continued to slide. However, despite a difficult economy, 71% of all respondents plan to hire additional employees over the next 12 months.

Do you anticipate hiring additional employees over the next 12 months?





Deals and Alliances

Given the realities of a restricted fundraising environment for biotechnology companies, coupled with the continued need for pharmaceutical companies to fill their pipeline gaps, it was reasonable to expect 2011 to be another strong year on the transaction front.

Mergers and acquisitions are healthy for the industry as a whole. First, they provide a necessary exit for the investors in a private company while also providing the incentive and the liquidity for investors to reinvest in the industry. Transactions and alliances are also a way for drug developers to diversify risk when developing drugs.

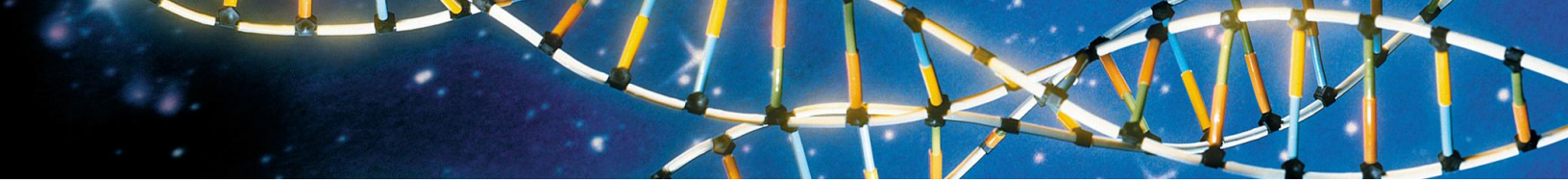
During 2011, one of New Jersey's biotech companies, Pharmasset, was sold to Gilead Sciences for approximately $11.2 billion in cash. This transaction was the second largest transaction in the industry during 2011, second only to the mega deal of Sanofi's acquisition of Genzyme for $20.1 billion.

Alliances and collaborative agreements are also essential to product development and funding as they help to accelerate drug development timelines while substantially reducing the costs of drug development.

As the funding environment continues to be challenging, biotech companies and their investors are still reeling to secure financing or find exits and the bargaining power in deals and alliances remained with the buyers in 2011. Various forms of "risk sharing" arrangements continue to be present, providing biotech companies with less risk than they would have assumed in years past.

The following table highlights the total number of alliances with our respondents which is down slightly as compared to prior year responders.

			Respondents Who have an Agreement		Median Number of Agreements Among the Respondents Who Have Them
			Number	Percent	
Academic Institutions	In-License Agreements	New Jersey	2	7%	1.0
		Out of State	1	4%	1.0
	Out-License Agreements	New Jersey	0	0%	N/A
		Out of State	0	0%	N/A
	Joint Ventures	New Jersey	1	4%	2.0
		Out of State	2	7%	2.5
Major Pharmaceutical Companies	In-License Agreements	New Jersey	1	4%	1.0
		Out of State	1	4%	2.0
	Out-License Agreements	New Jersey	2	7%	1.0
		Out of State	5	18%	1.0
	Joint Ventures	New Jersey	1	4%	1.0
		Out of State	5	18%	1.0
Other Organizations	In-License Agreements	New Jersey	2	7%	1.0
		Out of State	2	7%	1.5
	Out-License Agreements	New Jersey	1	4%	1.0
		Out of State	3	11%	1.0
	Joint Ventures	New Jersey	1	4%	1.0
		Out of State	11	39%	2.0

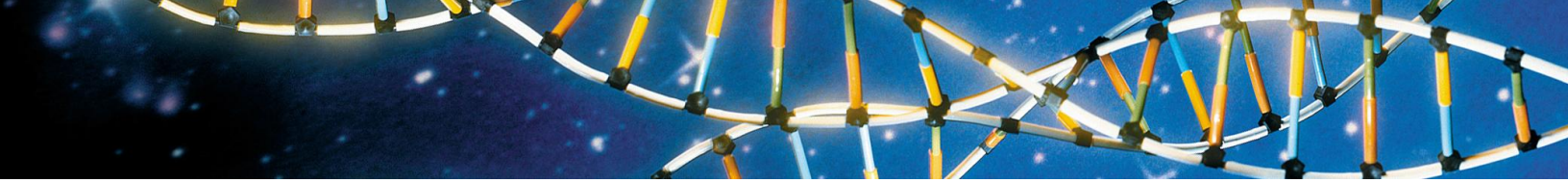


On the mergers and acquisitions front, risk sharing manifested itself in the number of transactions that included milestone payments (sometimes referred to as contingent value rights or CVRs). This was most common in takeouts of many private companies in New Jersey. Biotech buyers continued to use the CVR structure during 2011, in part to bridge differences in perceived value.

Also, on the mergers and acquisitions ("M&A") front, the biotech industry looked robust in 2011. The number of pharma-biotech and biotech-biotech M&As in the US and Europe increased from 49 in 2010 to 57 in 2011, while their total value grew from $20 billion to about $25 billion over the same time period[5]. The $25 billion in megadeal-adjusted M&A transactions represents the second-highest total in the last six years, second only to 2008, when the industry announced $28 billion of M&A deals.

But the overall numbers mask some troubling trends. In particular, big pharma was conspicuously absent from the buyer's table in 2011, with many of the largest deals being driven by non-big pharma acquirers (e.g., Teva Pharmaceutical Industries, Grifols and Forest Laboratories). Given the critical role that big pharma could play in supporting the biotech innovation ecosystem and the fact that the expected exit for most venture investors is an acquisition, this lack of activity is unsettling. With big pharma in the midst of crossing the long-awaited patent cliff, many observers assumed that we would witness a more pronounced upsurge in transactions — particularly for targets with product revenue or very late-stage product candidates. In this light, it's remarkable how few pharma-biotech acquisitions actually occurred in 2011. Even more noteworthy, big pharma was the buyer in only 7 of the year's 57 M&A transactions. We are unlikely to see many (if any) additional megadeals involving big pharma in the foreseeable future, as most companies have announced their intention to focus on smaller "tuck-in" deals (acquisitions of products and technologies) valued below $5 billion, and quite often below $1 billion (e.g., Merck & Co.'s acquisition of Inspire Pharmaceuticals and Novartis' purchase of Genoptix in 2011). This trend continued to be visible in early 2012 with GlaxoSmithKline taking a run at Human Genome Sciences with a $2.6 billion offer, and Bristol-Myers Squibb Co. buying Inhibitex for $2.5 billion and reportedly offering $3.5 billion for Amylin Pharmaceuticals (which, according to media reports, subsequently attracted the interest of other bidders as well.)

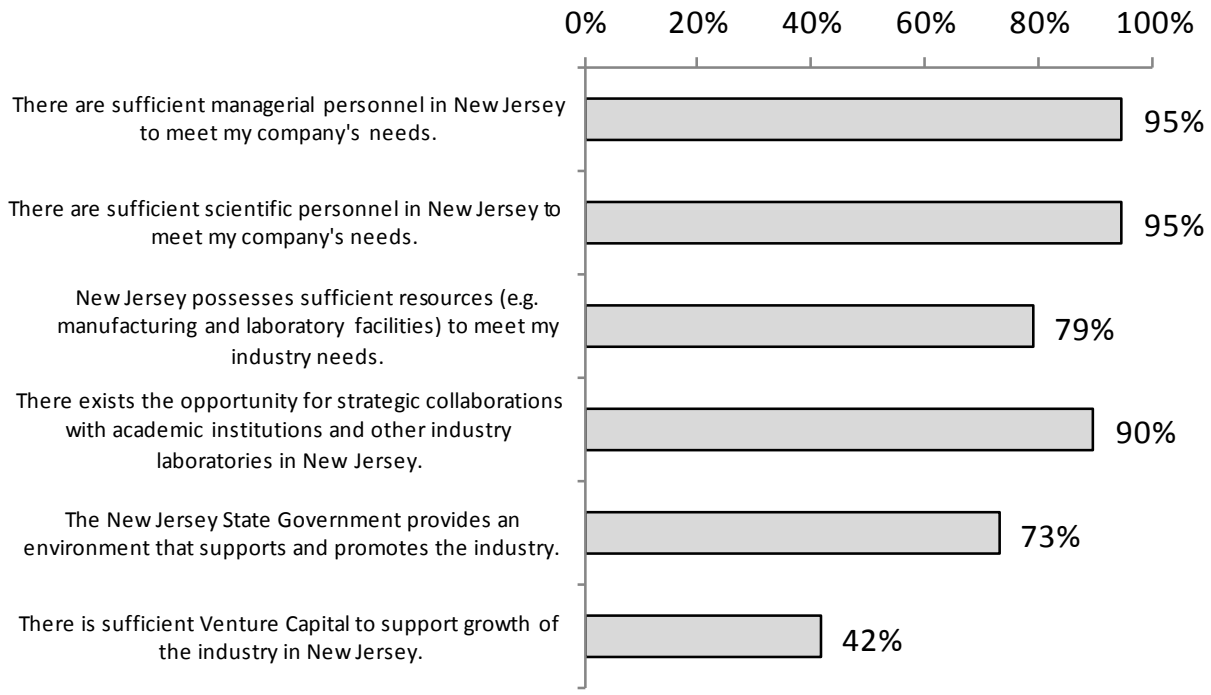
[5] After normalizing the numbers by removing $31 billion of megadeals from the 2011 totals.

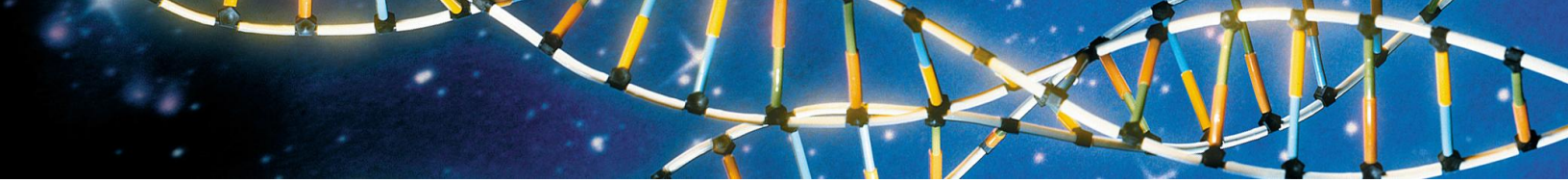


Why Are Companies Choosing New Jersey?

Respondents highlighted many reasons for locating their companies in New Jersey. As noted in the chart below, 95% of the companies responding to the survey indicated that there are sufficient managerial personnel and 95% believe that there are sufficient scientific personnel to meet their company's needs in the State. In addition to tremendous infrastructure in the State due to the presence of the Big Pharma companies, 90% of the responding biotech companies believe that there exists the opportunity for strategic collaborations with academic institutions and other industry laboratories in New Jersey. These high percentages are consistent with prior year surveys.

Percentages represent respondents that agree with the statement.

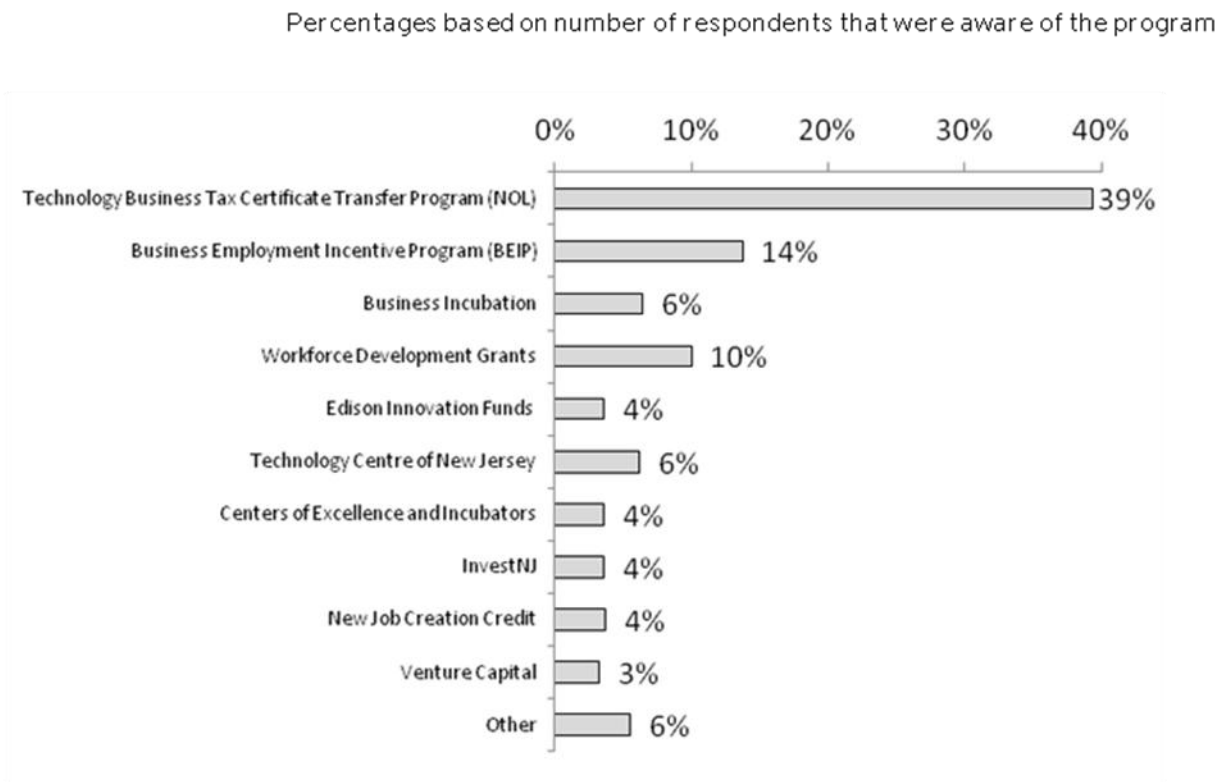


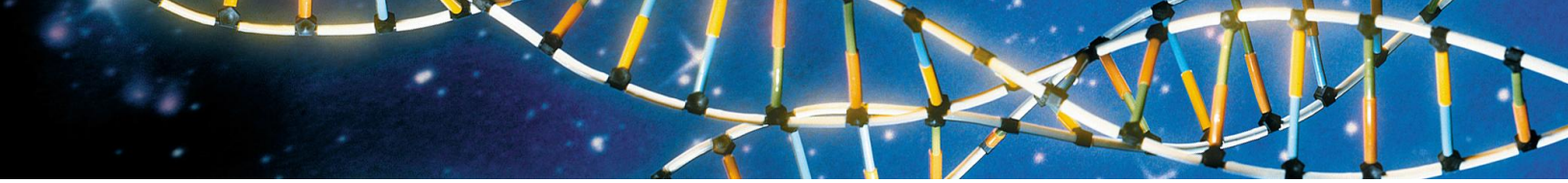


We also observed the frustration of many respondents who report that venture capital funding is difficult to obtain. As discussed, this is indicative of the growing trend between the "haves and the have-nots" and is not a New Jersey specific problem; it is prevalent throughout the industry.

As funding options have dwindled in the current financing environment, companies need to be increasingly creative in finding new sources of capital. It is not surprising that state and local economic development initiatives are getting increased attention, since such incentives can help improve cash flow, pay for capital acquisitions and fuel job creation. But the labyrinth of state and local economic development agencies is unfamiliar territory for many biotech companies, which have traditionally focused their attention on conducting research and development and raising money from venture capital and the capital markets. The table below shows the number of State-run programs in which the current year respondents have participated. The Technology Business Tax Certificate Transfer Program continues to be the most widely accessed.

Has your company participated in any of the following programs or projects offered by the State of New Jersey?





Opportunities to Improve New Jersey's Offering

So how can the State of New Jersey do a better job of spurring the growth of biotech companies in New Jersey? The following question was intended to help answer that question: "*Please identify additional programs that New Jersey government could provide, including programs offered by other states that would be useful and would help New Jersey enhance its support of the industry and to be more competitive with other states.*" Some highlights from responses appear below:

- The overwhelmingly most common response was, at a minimum, to continue the funding for key programs such as the Technology Business Tax Certificate Transfer Program at current levels and to provide additional programs. A program comparable to the U.S. Treasury's Qualifying Therapeutic Discovery Project Credit in 2010 was one of the suggestions.

- New Jersey should consider instituting an Angel Investment Tax Credit and creating an Angel Fund.

- Unrestricted grants.

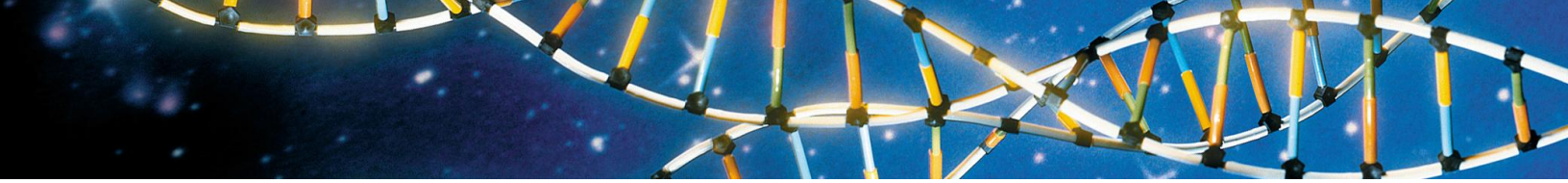
- Lower personal and property tax rates to attract and maintain highly skilled employees.

- One respondent noted that they would like to see public/private partnership or incentives for venture capital to locate or incubate/seed companies specifically in New Jersey.

- Several respondents noted that the burden of applying for programs is difficult, and streamlining the process may spur increased economic development.

Conclusion

New Jersey's biotechnology industry has continued to grow despite the economy and even though the industry at large has been faced with one of the most significant downturns in its young history. The economic and scientific environment indicates that there are many more bright years ahead for biotechnology in New Jersey and nationwide, but not without some concern for how it will be funded. With the significant presence of Big Pharma in New Jersey and the wealth of scientific talent available to continue research and development of life science technology, the future in New Jersey is bright, but government needs to provide a business friendly environment that will foster more early stage research and spur innovation.



About BioNJ

BioNJ is singularly focused on advancing the growth and prosperity of New Jersey's biotechnology cluster through advocacy initiatives directed at State and federal public policy issues and networking and educational programs that bring the community together. Founded in 1994 by New Jersey industry CEOs, BioNJ serves as the voice of biotechnology companies located in New Jersey, seeks to promote their economic growth and development and works to encourage new and established companies from around the world to locate to New Jersey. BioNJ represents companies engaged in biopharmaceutical, biomedical, bioagricultural and bioremedial endeavors. To learn more about BioNJ, please visit www.BioNJ.org.

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