PPI | The Public Policy Institute of New York State, Inc.

CULTIVATING THE NEXT GENERATION OF DISCOVERIES AND DEVELOPMENT IN NEW YORK BIOSCIENCE

May 2012

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"We have all of the essential elements of an innovative ecosystem but it is going to take time to integrate to a point where we can truly call ourselves a high tech community."
–Theresa Mazzullo, CEO, Excell Partners

"Startups give you a shot at growing up companies in your own state."
–Derek Brand, director of business development, Enumeral Biomedical Corp.

Executive Summary

New York's bioscience industry currently supports 250,000 jobs — both direct and indirect — generating $309 million in personal state income tax and over $5.63 billion in wages. Its R&D attracts significant federal funding and is consistently within the top three states in terms of National Institutes of Health (NIH) research awards. In 2010 alone, New York received $562.8 million from the Centers for Disease Control, $32.8 million from the Agency for Healthcare Research & Quality, $4.5 billion from the NIH and $491.9 million from the National Science Foundation (NSF). Arguably, it should be considered one of the state's top innovation industries.

While New York is just one of several players along the bioscience continuum, it has the capacity to strengthen or hinder company and industry growth at several points along that continuum. In his 2012 State of the State Address, Governor Cuomo asked, "How does government spur job creation in a down economy while limiting spending and maintaining fiscal discipline?" The answer, he said, is in "creative public-private partnerships that leverage state resources." In this report, increased coordination between public policy and private investments — in effect, public-private partnerships — is shown as a critical component of the state's strategy to promote growth in the bioscience sector.

Many interviewed for this report agreed that New York has all the "piece parts" of a dynamic bioscience industry, but lacks some of the coordination and support it needs reap the benefits and become more competitive nationally and globally. A better defined vision and model will provide the direction and coordination needed to mobilize the piece parts within a framework that is both specific to the state and conducive to promoting organic cluster growth.

Of particular importance to a majority of those interviewed was the need for the state and Legislature to understand the industry in full — from lab to market — when drafting and implementing policy. There are, on average, 10 to 20 years in between those endpoints encompassing companies of varying sizes with specific needs, multiple pre-clinical and clinical trials, myriad regulatory and policy demands from both federal and state agencies, and investors from angel to venture capital (VC). Each stage between lab and market carries its own set of technical challenges, funding needs, and regulatory requirements. And a potential domino effect is created when these and other outside influences — e.g., health insurance policies, industry trends, regulatory requirements — are introduced or withdrawn.

Startups and early stage companies are the industry's nexus between the university lab and the larger market. As such, this report is centered around the experiences of startup, early stage and mid-size bioscience companies with a presence in New York. Based on interviews with 30 CEOs, entrepreneurs, investors, academic institutions and state agencies, as well as anchor and large bioscience companies across the state, and drawing upon previous research, the Public Policy Institute (PPI) has identified three specific policy and program initiatives to create public-private partnerships for its bioscience industry. They include:

- Establishing a Governor's Council to focus the state's biopharma vision and increase communication and understanding between the state and industry, as well as developing a proactive marketing campaign directed at internal and external audiences that champion New York's bioscience industry and the benefits of doing business here.

- Designating financial resources specifically for bioscience companies. In particular, establishing a matching grant program for bioscience companies awarded Small Business Innovation Research (SBIR) grants, and enacting a bill to create a dedicated Biosciences Commercialization Assistance Fund.

- Increasing the amount of affordable incubator and lab space for startups and early-stage companies.

This report is an opportunity to advance a better coordinated and constructive dialogue among all the players who affect the forward movement of New York's bioscience industry, and to hear directly from the very companies — from startup to established — New York relies on to generate jobs and revenue.

Percent of bioscience industry claimed by NAICS code

3254.....Pharma mfg (100%)

541711.....R&D in biotech (100%)

541712.....R&D in physical, engineering, and life sciences, except biotech (33%)

334516.....Analytical lab instrument mfg (30%)

54138.....Testing laboratories (30%)

4242.....Drug merchant wholesalers (10%)

622.....Hospitals (4.5%)

61131.....Universities (1.9%)

Source: New York Biotechnology Association

Overcoming the Barriers

Basic building blocks: Vision and people

New York's biopharma sector is lacking two critical basic building blocks at the state level for the three PPI recommendations to occur: a clear vision by state officials and an entrepreneurial mindset.

Vision

The lack of a clear vision hinders the development of people, infrastructure, and a strong continuum of company development needed to keep New York competitive and to ensure its leadership in the bioscience industry. Without a shared vision to leverage its assets the state will increasingly lose out to other states that have more focused and coordinated approaches.

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As one biopharmaceutical senior executive pointed out, the message they hear in New York is indifferent or confusing. "In the morning they are asking us what they can do to support us and keep us here, and in the afternoon they're vilifying us." In an article for Xconomy in August 2011, Ron Cohen, founder and CEO of Acorda, wrote that when he was chairman of the New York Biotechnology Association (NYBA), he "got an earful on high taxes and lack of vision in Albany." According to the article, he continues to hear some of the same frustrations today as chairman of the

emerging companies section of the Biotechnology Industry Organization (BIO). The lack of a shared vision for the industry means that the state misses out on opportunities provided by the bioscience industry.

Entrepreneurs and innovators drive the industry, and the state needs to take an equally entrepreneurial and determined approach to grow, attract and retain bioscience companies.

An entrepreneur starts with a vision, and the company he/she forms develops a business plan for its potential investors. Similarly, the state needs to develop its vision and plan for the bioscience industry.

By example, the Massachusetts Life Sciences Initiative, a $1 billion, 10-year program tasked with realizing Gov. Deval Patrick's vision for the state's bioscience industry, has a Five Point Plan "intended to support the life sciences industry through each stage of the development cycle. This work includes making financial investments in public and private institutions growing life sciences research, development and commercialization as well as building ties between sectors of the Massachusetts life sciences community."

As much as the state is asked to invest in the bioscience industry, the state also asks for the bioscience industry to invest in New York as a place to establish and maintain a presence. A clearly articulated vision from the state for the bioscience industry would support both investments.

People

People are at the root of any technology hub. Even as a lack of clear vision hinders New York's bioscience advance, it also contributes to another key limiting factor: the availability of experienced entrepreneurs needed to move the industry forward. "The importance of management cannot be underestimated," noted Theresa Mazzullo, CEO of Excell Partners. "This is especially true in biotech. There is no substitute for a serial entrepreneur, one who has been there, done that before. Absent that, the individual who understands the technology, the market and the long path to glory is critical for a life science startup. Finding the right talent to wrap around a technology is an ongoing challenge in the upstate region, particularly in the life science area."

According to a survey of CEOs included in the 2012 California Biomedical Industry Report, the top reasons why CEOs decided to stay in California and/or expand their operations inside California were the "culture of entrepreneurship or innovation" and "skilled workforce" in the state.

The lack of experienced and serial entrepreneurs was of more concern among a majority of those interviewed than was the issue of workforce, for both startups and established companies. Executives at Life Technologies — a California-based company with a manufacturing plant in Grand Island, New York — noted that they had much more difficulty attracting senior management, who had product and process knowledge, as well as international management experience. Attracting serial entrepreneur Dr. Allen Barnett to Kinex was "extremely important and gave the company great credibility," said Lyn Dyster, a serial entrepreneur and vice-president of research operations for Kinex.

Shreefal Mehta, a serial entrepreneur with a background in biomedical engineering and CEO of the Paper Battery Co., was asked to start a biotechnology executive education program at the Lally School of Management and Technology at Rensselaer Polytechnic Institute, but he "couldn't pull in enough executives with experience in the industry in order to attract the students and executives into the program." The lack of experienced entrepreneurs creates an adverse domino effect: fewer entrepreneurs means fewer mentors, fewer companies started, less revenue generation and less money directed back into the local community.

Joe Scaduto, assistant director of business development for the Center for Biotechnology at SUNY Stony Brook, said, "Linking technologists with experienced entrepreneurs is a big issue," and suggested establishing an Entrepreneur-In-Residence (EIR) program that paid individuals with the appropriate track record and domain expertise a salary for 12-18 months to identify and evaluate technologies with commercial potential, develop a business plan and investor presentation, negotiate a license agreement, and secure the first round of

funding. "It's dedicated people that start and grow these companies. In the absence of an existing cadre of experienced entrepreneurs, we need to attract and focus them by reducing their risk." Some academic institutions and economic development agencies, such as SUNY and the New York City Economic Development Corporation, are also working to change this reality by establishing EIR programs.

Derek Brand, director of business development for Enumeral Biomedical Corp., noted that the overall ecosystem or entrepreneurial network is a "bit more disparate and the bonds aren't the same as in Boston." So he started a networking group that gathers monthly and focuses on attracting people interested in early-stage companies and technologies. "It's flourished so far with an overall list of over 450 people and between 30-50 individuals attending each time." Brand said he knows of at least two startup companies who have found CEOs through these interactions.

Opportunity for a new model

The lack of a comprehensive and coordinated vision can be seen in the current shape of the bioscience industry in the state. One investor commented, "New York should put a stake in the ground and the commitment needs to come from the top." In February 2009, The Archstone Study noted that, of the nine biopharmaceutical regions in New York, "those with the highest number of facilities were New York City and Long Island with the best clustering [occurring on]…Long Island, Rochester and Westchester."

New York needs to develop a nuanced strategy for maximizing the research-based economic development potential of our state's nine individual bioscience clusters.

New York needs to develop a nuanced strategy for maximizing the research-based economic development potential of our state's nine individual bioscience clusters. We should not have all nine compete directly with Boston's and San Francisco's well-established and very focused, integrated urban bioscience hubs on frontline research. New York has two primary hubs emerging - one in the Buffalo-Rochester region and the other in a downstate corridor comprised of New York City, Westchester and Long Island. Nathan Tinker, executive director of NYBA said, the state doesn't have to look far for some great examples. "The Massachusetts Center for Biotech is focused, as is the state, on a 25 mile radius cluster. A bit farther, North Carolina's hub and spoke system is brilliant-a central hub in Research Triangle Park and regional outposts to help grow it without being everything to everyone all the time."

Cohen is adamant that someone needs to "square the circle" on the regional fiefdoms. "We need a vision that is honest and straightforward so upstate and downstate aren't competing to be the bioscience hub for New York. Instead of competing for the same activity, we need to look at the relative strengths of each region and leverage the competitive advantages… And we need visionary leaders with strength, skill and influence to make the vision a reality." This sentiment was echoed by others.

One model presented could help to better leverage downstate's considerable R&D generation, patient population, entrepreneur concentration, and capacity to house post-incubator companies in Westchester County as the potential anchor for New York's bioscience industry. At the same time upstate, with its access to universities, available and educated workforce, lower cost of living, less expensive land and physical space could address the manufacturing needs of the bioscience industry. "There's a huge demand for them. New York doesn't have them in high enough concentration. We need a plan to attract companies and the industry to upstate," Cohen noted.

Upstate's smaller bioscience clusters which have a nexus point between vital academic health based research and existing clinical trial networks, as well as the combination of cheap land, predictable and comparatively affordable power and abundant water resources, can become a magnet for emerging manufacturing based enterprises both for biotech startups bursting at the seams of existing incubators and more traditional big pharma manufacturing. In short, the regional triangle connecting the Syracuse, Binghamton and Albany clusters can become manufacturing magnets that can be more attractive on cost, than the Boston and San Francisco market. The goal should be having each of New York's nine bioscience clusters compete from positions of strength.

New York needs to cross market its strengths across the length and breadth of our state to end the de facto silo marketing which undervalues upstate's bioscience clusters, particularly on the translational research to manufacturing side of the equation. Silo based regional marketing stunts our state's potential for synergistic success across regions. Only a statewide effort can institute a strategic plan where New York's clusters treat each other as tomorrow's de facto partners rather than today's direct competitors.

Doing so could better position New York State to compete in this global industry not only with California, Massachusetts, New Jersey, and North Carolina, but also with Canada, Singapore, India, China, and Germany, among others.

Barry Kappel, vice president of business development at ContraFect Corporation, sees Westchester as a good place to support a small company. "Our build out cost half of what it would have in New York City. We're only 25 minutes by train to downtown Manhattan for weekly meetings with Rockefeller University and Mt. Sinai, have no problem attracting talent, and have access to the intellectual capital in New York City." The manufacturing process, on the other end, is the high value-added component of the bioscience industry because companies must identify and explain their manufacturing process prior to receiving FDA approval for New Drug Investigation which involves human testing. Workforce development, salaries, and tax incentives now become critically important issues for the company at this stage, explained Steven Casper, associate professor at Keck Graduate Institute in Claremont, California.

In its May 2011 report, *New York Must Step Up It's Game*, PPI estimated the manufacturing multiplier advantage. Using models from the Bureau of Economic Analysis, the study determined that "the jobs multiplier for cutting-edge biotechnology and nanotechnology firms is 9.2. This means that for every job in these firms about ten additional jobs are supported." The study also noted that manufacturers "lock in the academic-commercial nexus through participation in university affiliated research parks."

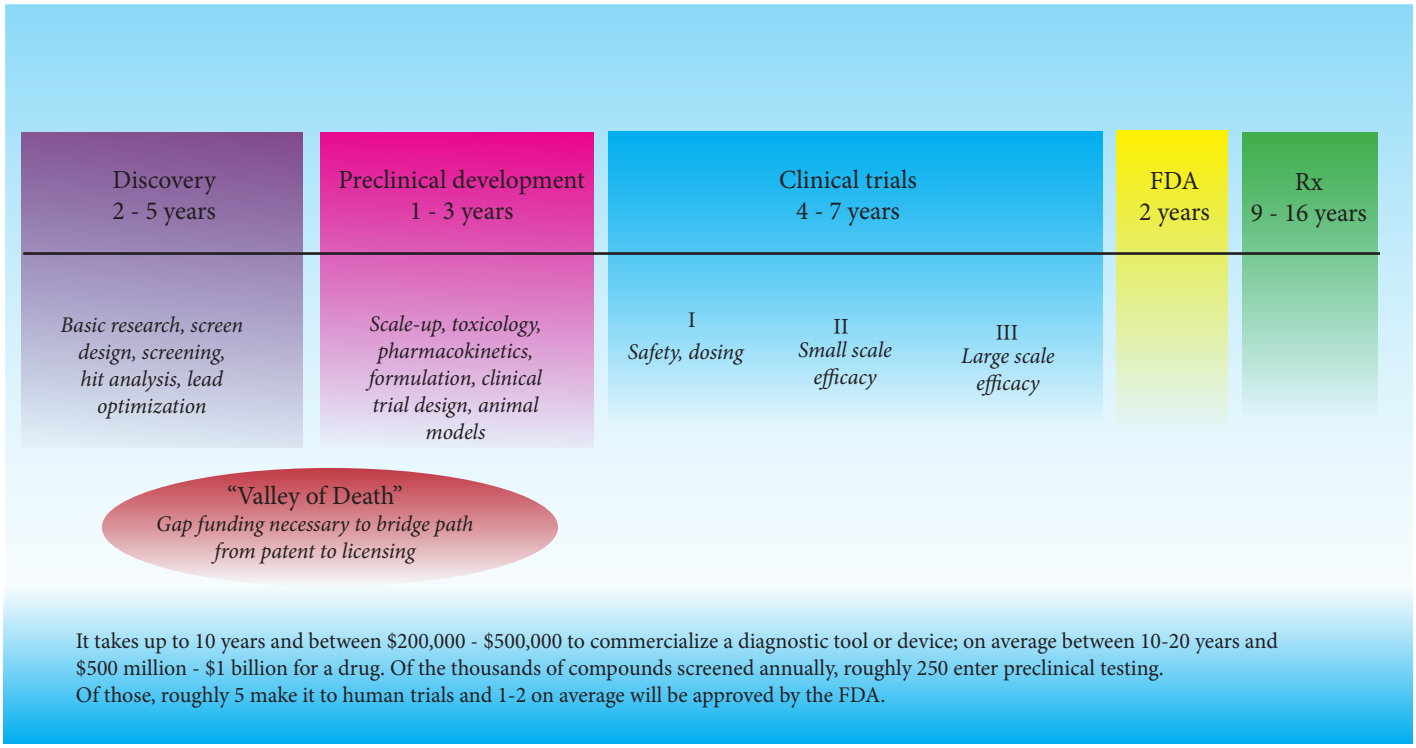
Tying discoveries to economic development: Expanding the metric

As noted above, the connection between scientists and entrepreneurs is an important nexus for the bioscience industry. Moving the science from idea to product, particularly for early stage companies, requires the vital interaction of universities, which house research and scientists, and companies, which commercialize the products. In New York, the requirements for successful interactions are not always known or met. Optimizing the links between

universities and the bioscience industry is, therefore, vital for the development of the industry in New York.

University technology transfer offices (TTOs) play an important role in influencing the path forward for startups formed around commercially viable and promising discoveries. Given this role, a number of those interviewed agreed the traditional set of benchmarks used to measure successful tech transfer should be updated to include, or even focus on, economic development and advancing the startup. Tom Fitzgerald, president & chief operations officer of OyaGen, noted that, "Tech transfer offices are not currently viewed as a cornerstone for economic development. Small companies require more individualized attention where IP and capital are concerned. The latter is put into place as you go, whereas in a large company all of this is already established." Stephen Curry, CEO of ADispell, a two-year-old company out of Cornell, said universities should be looking to generate the next generation of royalties stream.

Typical drug discovery & development timeline



Source: Based on data from PhRMA, Excell Partners and several individuals who were interviewed for this report

The TTOs typically have an operational budget and a limited patent budget, but generally require startups to reimburse them up front for costs associated with obtaining patents and licenses. These costs can run upwards of $150,000 in the first 18 months and exclude the cost of prototype development and reducing the invention to practice. Spinning out companies from universities in this manner sets up a situation that can significantly hinder a startup's potential success or even prevent company

formation around a promising discovery. Even if a startup were well capitalized enough to pay these costs, it doesn't necessarily mean it owns the IP — the university retains those rights in many instances.

Then there is the additional cost to startups to retain their own counsel to negotiate the license and payments going forward to the attorney prosecuting the patent, as well as patent foreign filings and prosecutions in the major global markets — EU, Japan, Canada and possibly Australia, China and India.

According to some interviewed for this report, universities are also assigning unrealistic commercial value to discoveries, which often results in a potential corporate partner or licensee walking away and the technology or discovery "dying on the grapevine." One serial entrepreneur recommended restructuring TTOs with officers capable of evaluating a discovery both for commercial viability and realistic commercial value, if not standard practice already.

Despite this, there are some universities actively working to change how they interact with startups. In his position as vice provost at the University of Buffalo's Office of Science, Technology Transfer and Economic Outreach, Dr. Robert Genco has built a new process and philosophy in place of the old model. "We think it's incumbent upon the university to take these discoveries and commercialize them for the benefit of society," he said. "This is our mission. If you accept federal research dollars, you just can't publish the discovery. It also has to benefit society."

In 2011, SUNY voluntarily joined the federal Science and Technology for America's Reinvestment Metric Initiative (STAR) — which quantifies the influence of federally funded research on the number of jobs created and the multipliers that come out of those jobs. Clarkson University also incorporated economic development indicators such as tracking the number of startups established with traditional technology transfer measures. And the Rochester Institute of Technology reinvented its own incubator — now called Venture Creations — with the express purpose of translating academic research into commercially viable and technologically innovative businesses.

With respect to the upfront costs assumed by TTOs, several alternative solutions were proposed by both entrepreneurs and academic administrators, including:

- A low-interest loan fund to pay upfront costs;
- Scheduling payouts over time;
- Downstream royalties;
- Convertible debt; or
- An equity stake in the company.

Because clinical research is conducted in the universities and hospitals where patients are seen by doctors, the university-industry connection is both inherent and essential. And the current industry environment is driving how large pharmaceuticals work with universities and TTOs. Companies like Pfizer are "trying out" a new business collaboration, or shared partnership, that leverages each partner's strengths. In 2011, Pfizer launched the Centers for Therapeutic Innovation (CTI) to speed up translation of academic ideas into drugs, address differentiation, and de-risk them early.

Jeanne Magram, executive director for Pfizer's New York Therapeutic Innovations, noted that "the CTI partnerships mimic a venture capital-funded biotechnology startup, whereby Pfizer invests in novel target ideas to generate drugs and translate them into the clinic in a collaborative manner, offers equitable intellectual property and ownership rights to support continued experimentation and exploration, as well as broad rights to publication. This new model maximizes the potential of the academic science by applying professional drug discovery and development capabilities including access to Pfizer's proprietary antibody libraries and advanced research tools."

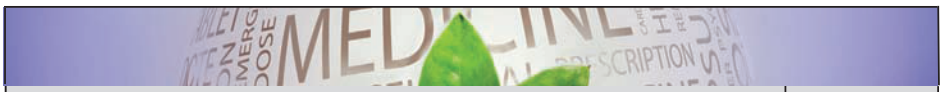
There are no upfront costs, and if the shared-research does not achieve success, the scientist and university retain the IP including what was discovered. If the research yields what Pfizer is looking for then the discovery advances into the Pfizer portfolio and more advanced clinical testing. Pfizer then has one year from the trial end to decide and if the project moves ahead, pre-negotiated terms are in place including success milestones.

There are currently 20 institutions in the CTI network (including all CTI sites), eight of which are in New York.

Investing in bioscience

There is an old business truism that you need to spend money to make money. Perhaps nowhere is this truer than in the bioscience space, which requires large amounts of funding to develop ideas into viable products, and small startup companies into large companies capable of having significant impacts on local and state economies. Investments at key points in the bioscience continuum can pay significant dividends for the state and all stakeholders.

New York State in Bioscience



Metric	State rank
Direct biopharmaceutical employment	4
Annual growth in direct biopharmaceutical employment (since 1996)	38
Average wage (excluding benefits) per direct biopharmaceutical employee	31
Total federal taxes paid by direct biopharmaceutical employee	5
Average federal taxes paid per direct biopharmaceutical employee	31
Total R&D expenditures by biopharmaceutical firms	7
Total R&D expenditures by biopharmaceutical firms, per direct employee	19
NIH dollars awarded	3
Venture capital investments in biotechnology	13
NSF dollars awarded for biological science research	2
Number of active clinical trials	2

Source: New York Biotechnology Association

Both cost and timeline are contributing factors to shrinking VC investment in biopharmaceutical companies specifically, and why those who do invest are waiting until the company is farther along the continuum. Dedicated financial support from the state, when offered at the right time, could be the potential game-changer for bioscience companies.

Fitzgerald said New York is "…baby stepping it where licensing and funding is concerned in the life sciences, making it more likely that the technology will migrate away from New York subsequently." As an example, he noted that one of the quasi-public seed capital funds is hamstrung because funding from the state is uncertain, and very small in scope for advancing life science opportunities, and they are subject to many filters. Bioscience, like nanotechnology and renewable energy technologies, is capital and time intensive.

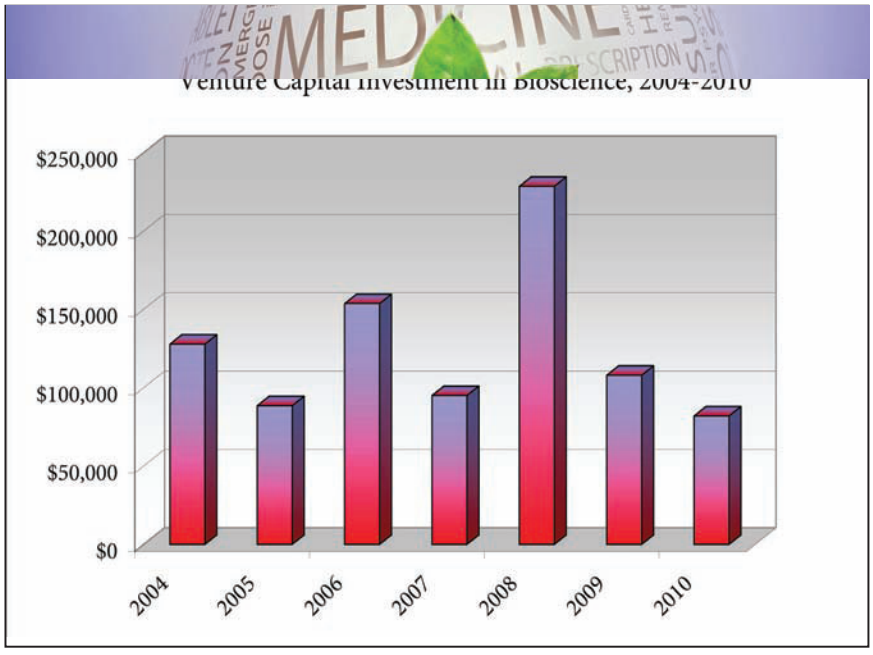
According to the February 2009 report by Excell Partners, Venture Capital & Seed Activity in NYS, "The financial requirement to get [life science] companies through the seed stage is…$750K." It also noted that, "the majority of the investments the New York Angel Network — consisting of over 300 individual investors — were in the range of $350 - $400K." And it is this point, the "valley of death," that offers a very meaningful opportunity for the state to take a more robust role as a catalyst at a critical stage in startup development. Genco said, "gap funders — principally seed funds and successful entrepreneurs — are a key resource to startups struggling to bridge this 'valley of death' between the patent and licensing stages." But the Excell report noted that this resource itself is also underfunded in New York.

The recent regional economic development council initiative resulted in the state awarding $50 million to seven regions for bioscience initiatives. And New York offers several emerging technology or high-technology funds and incentives to support innovation, job creation and high growth entrepreneurship at various stages along the continuum. But again, they are diffused across multiple, capital-intensive industries with specific needs, including bioscience. Innovate NY is New York's newest seed stage equity fund for technology and high-growth companies, capitalized with $26 million in federal monies. The Appleseed Initiative was launched in 2010 with $15 million to create the High Peaks Seed Venture Fund, part of the In-state Private Equity Program.

By comparison, New York bioscience companies are part of an industry that collectively spent $67.4 billion on R&D in 2010, and according to the U.S. Congressional Budget Office, is one of the most research intensive industries in the U.S., investing as much as five times more in R&D relative to their sales or the average U.S. manufacturing firm. And New York's R&D is consistently within the top three states in terms of NIH research awards.

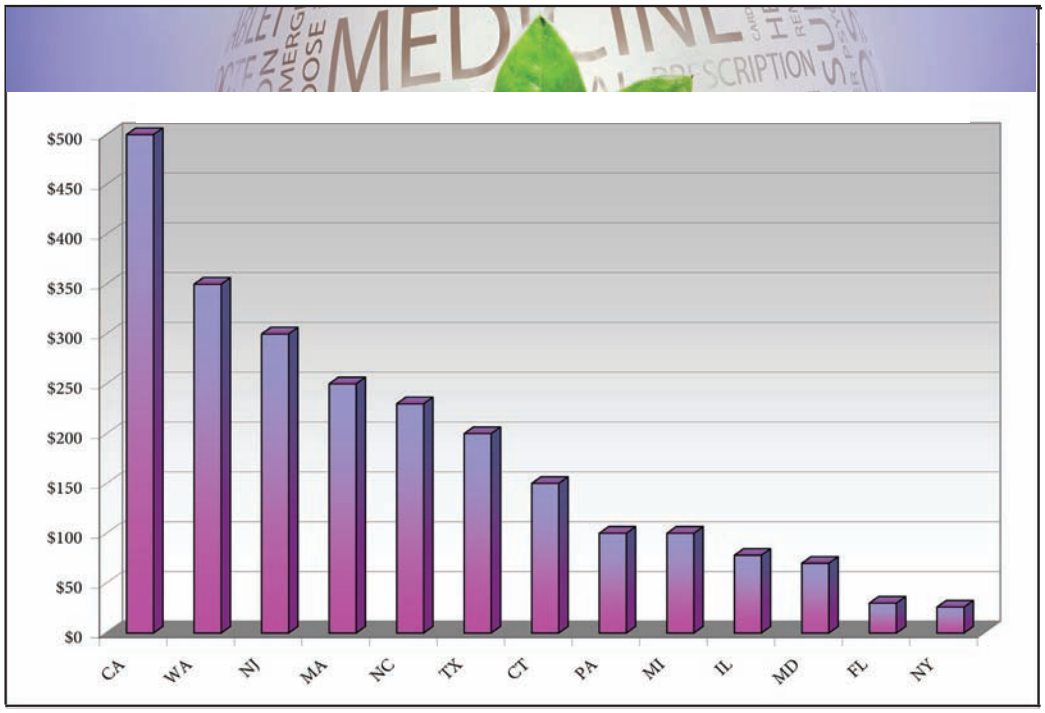
Even so, converting ideas and discoveries into companies is a perennial challenge exacerbated by the lack of funding, including venture capital. New York Biotechnology Association maintains that until this is fixed, there will be little progress in seeding bioscience startups and early stage companies in New York. Strategic investment by the state would be a major step forward in this effort.

Venture Capital Investment in New York Bioscience (in thousands), 2004-2010



Source: PricewaterhouseCoopers Money Tree

State-Supported Investment Funds (in millions)



Source: New York Biotechnology Association

The State as a Catalyst – "The Ask"

Growing out of interviews and discussions over a six-week period with 30 individuals, including academic administrators, investors, development and quasi-state agency representatives, industry organizations, and of course, bioscience companies, the following recommendations directly address the issues raised in these interactions and focus on the key areas identified by bioscience stakeholders: coordination of efforts; the growth of industry capacity through strategic funding; and the development of an infrastructure that will create opportunities for the development and strengthening of the industry.

A Governor's Council: Bridging the communication gap and marketing New York bioscience

"What I'd like to do is work with the state on bringing together public forums and talk about what we do; how we do it; about our new business model — it's an experiment; a venture; partnering with universities; talk about the importance of the industry; the economic development impact."
-A senior biopharmaceutical executive

As simple as it seems, communication appears to be a perennial problem between government and business. "There are many different perceptions, and people need to get around the table and talk," said Cornell's Alan Paau. A Governor's Council on bioscience could close this communication gap. It could also be instrumental in closing a perceptual gulf that has existed between New York City, upstate and the state, added David Barthel, president and CEO of SmartPill. He said, "Upstate has had to deal with the perception that there isn't anything between Albany and Buffalo."

A state bioscience council — comprised of the Governor's closest advisors, industry representatives, entrepreneurs, university TTOs and investors — could also greatly aid the state in crafting a plan to support its vision. The overall message: New York State is interested in this industry.

A similar approach has been taken in Massachusetts with the creation of the Massachusetts Life Sciences Center (MLSC), a quasi-public agency closely affiliated with the Executive Office of Housing and Economic Development. Its advisory board consists of industry and academic representatives. The MLSC is the primary agency "tasked with realizing the vision of Governor Patrick's Life Sciences Initiative," and is focused on five points of the development cycle to ensure a comprehensive statewide strategy: funding, planning, research, development and commercialization.

A bioscience council in New York could also be tapped to assist the state in designing a marketing plan that champions the state's bioscience industry and the tremendous benefits available to companies who choose to locate and build a business here. Where marketing is concerned, many executives said they would like to see New York take a much more proactive and aggressive approach directed at national and international audiences.

Reviving the inactive "NY Loves Bio" marketing campaign provides one potential way to jumpstart this effort. Coordinated by the New York State Economic Development Council (NYSEDC), "NY Loves Bio" is dependent on grants to run programs, but there haven't been any of these in the last few years, according to Brian McMahon, executive director of NYSEDC. And it's this program, with its 3,500 square foot state-of-the-art trade show pavilion, that last showcased New York's bioscience industry at the BIO International Convention in 2009, with 20 small New York companies, 12 colleges and universities, and economic development representatives. Since that time, New York's presence at the BIO Convention has been underwritten and administered by NYBA.

"The Governor has to say New York is open for bioscience business. He needs to be its champion. It doesn't have to be a $100 million campaign. Funding for major trade shows, appearing in the right publications, sending the right ambassadors to the right conferences, and reminding internal constituencies would help tremendously," according to Tinker.

In 2007, Massachusetts took just such an approach to marketing its bioscience industry at the BIO International, where the state announced the Massachusetts Life Sciences Initiative, designed to establish Boston as a leader in the life sciences. According to an interview with Mass High Tech prior to BIO 2011, a representative of the MLSC said, "BIO is our best opportunity to interact with international biotech companies. We are looking for prospects that are ready to open or expand their U.S. presence, and we want them to locate to Massachusetts." BIO International could provide New York with the same high profile platform to declare "New York is Open for Bioscience."

A Governor's Council — and the state grants — should be tied to an outreach aimed at attracting venture capital from the private sector to invest in New York's bioscience clusters. Last year's PPI report called upon the Governor and the Comptroller to "lead and cooperate with local and regional economic development partners to increase the interactions between venture and other capital firms and promising startups and mezzanine firms in the sector."

The creation of a bioscience council could be a strong step in the process of creating a unified vision for the industry in New York and in developing a plan to promote New York's assets.

In addition to the Governor's Council, New York's Comptroller should convene a conference inviting

VC firms to learn about investment opportunities in New York's expansive bioscience clusters and their companies. Working hand in hand with this newly created Governor's Council, New York's Comptroller should be enlightening venture capital firms about the advantages of investing in New York. We are not talking about the Comptroller pitching individual companies but the Comptroller should personally advance the vitality of the entire sector to the VC community.

Dedicated funding for the bioscience industry

"The best solution is a set of benefits that is competitive for mid-size companies and aggressive support of young or startup companies."
—Derek Brand, Enumeral

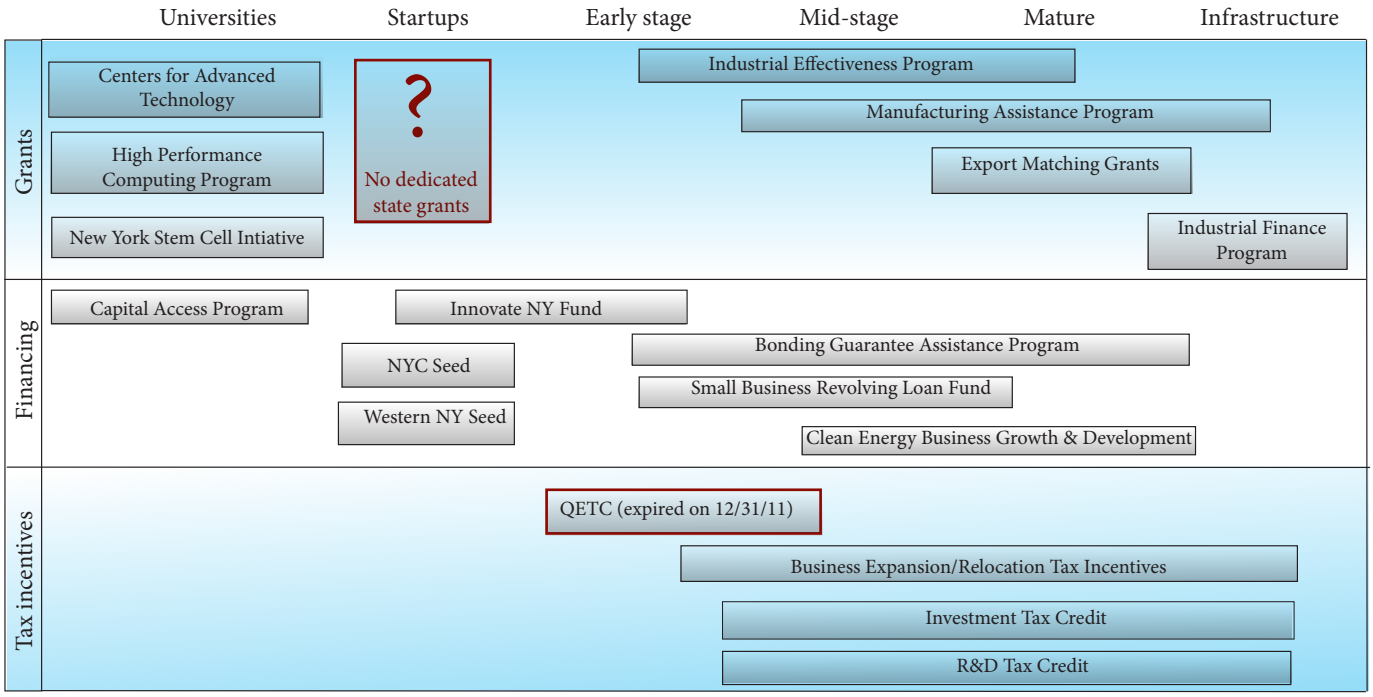
Just as the bioscience industry is looking for a focused vision and plan from New York with respect to the industry, the state's funding initiatives also need to be well-capitalized and industry specific, in order to efficiently and effectively promote the growth of bioscience companies and the industry as a whole. By example, with respect to Innovate NY, Tinker said, "While it's a start, [it] should be capitalized with $300 million to $500 million when you consider the extensive cost associated with just one high-tech or emerging technology industry today." Entrepreneurs by nature are agile and more likely to "go figure it out." Barthel thinks New York is a great state for business but it "can be challenging for CEOs who have never done a startup before, especially where finding the resources, such as funding, is concerned." He agreed that "it can be a bit of a maze" to line up the resources.

Fund for bioscience companies

Total New York State investment in Tech Valley and nanotechnology has exceeded $13 billion, according to Empire State Development; concentrated and consistent funding for the bioscience industry could help New York reap the potential economic benefits from an industry capable of generating five to nine additional jobs for every bioscience job created. The commitment from the state also sends a message that no single investor is going at it alone.

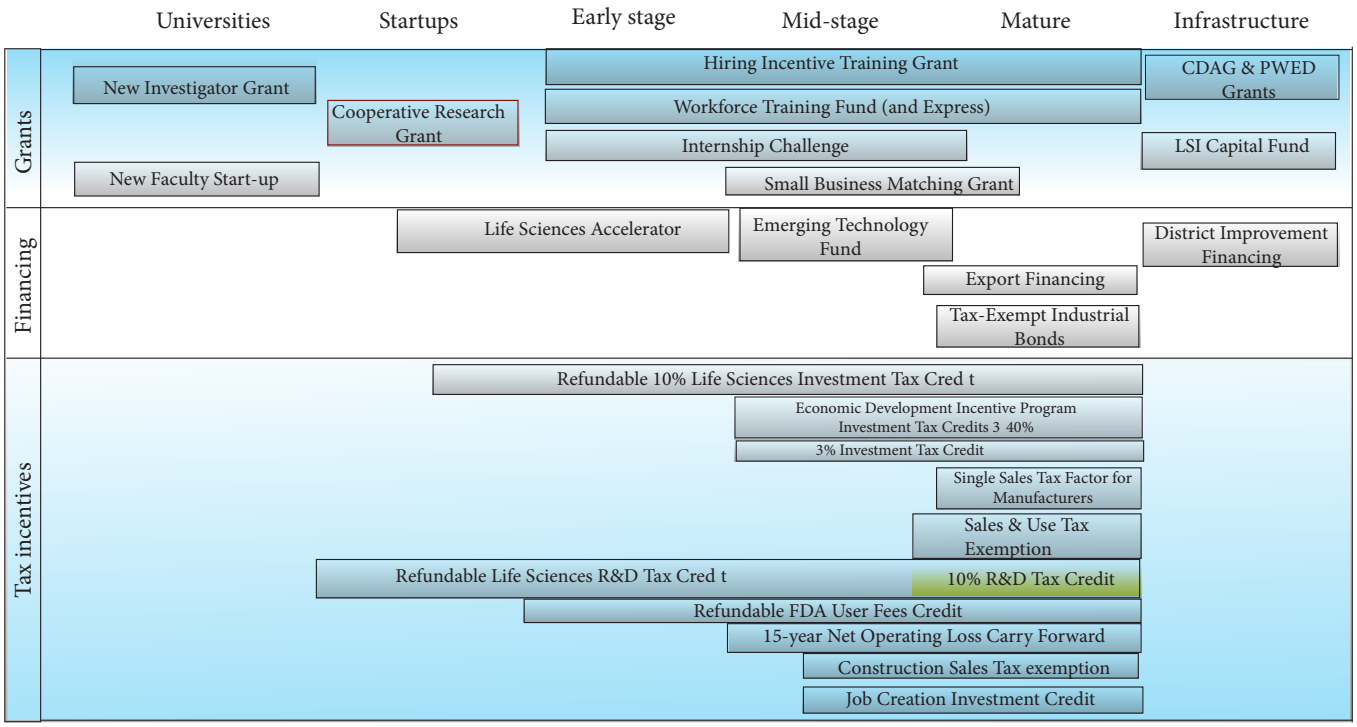
The Governor and Legislature might consider enacting legislation similar to S.2710, legislation under consideration in New York that would create a dedicated biosciences commercialization assistance fund for the development of drugs, therapeutics, diagnostics, or devices. It is focused on "advancing early-stage development of commercially promising inventions" and provides capital to "eligible research entities, startups, small companies, and other businesses in New York State with anticipated commercialization time frames of up to 15 years." Moreover, the bill provides investments in startup companies formed by entrepreneurs who have licensed IP in the focus area and are located in New York.

State Funding Sources Available to New York Life Sciences Organizations



Source: Based on data from the New York Biotechnology Association

State Funding Sources Available to Massachusetts Life Sciences Organizations



Source: Based on the Massachusetts Biotechnology Council's life sciences incentives matrix, which includes a sampling of state business assistance programs

"The Division of Science, Technology and Innovation in the Empire State Development Corp. is a good place to house the fund where there is expertise. We don't always do that well in New York," said Barthel. The office could offer the state and the bioscience industry the anchor it needs, just as NYSERDA has done for New York's clean energy sector.

Enhancing the SBIR effect

In building a portfolio of potential bioscience funding initiatives, several individuals suggested that the state could participate in a significant capacity by establishing a matching SBIR grant program, with Stay in New York clawbacks. Doing so would fill a critical gap in funding for startups and early stage companies. While the SBIR grant covers research costs, the state match would provide funding for company operations, allowing management teams and entrepreneurs to focus on building out the team and advancing early-stage companies.

Massachusetts funds a program for SBIR Phase II award recipients. Phase I grants are typically awarded for one to two years at a range of $150,000 upward to $300,000 annually from the NIH, NSF and the Department of Defense. Phase II grants, on the other hand, can range from $750,000 to $1 million and are awarded to companies that have successfully undergone a technical and an operational review. Scaduto noted that a SBIR/Small Business Technology Transfer Phase II matching grants program just might help to increase the number of applications and award recipients, leveraging federal investment in emerging companies across New York. Such a commitment may further enhance New York's opportunity to capitalize on the tremendous amount of IP generated by its universities, foster new venture creation and support emerging company growth.

While matching SBIR grants removes the contentious political landmine of the government choosing winners and losers, as well as the geographical bias, from a fiscal perspective, matching SBIR Phase I grants could prove to be the most efficient way for the state to spur an increase in the number of companies started annually, explained Brand. By way of example, Brand explained, "Let's assume New York wants to spend $10 million annually. With that amount, it could support either 10-12 Phase II recipients or 50-60 Phase I winners at $150,000 each." But as Colleen Gibney, technology consultant and SBIR program director at Industrial & Technology Assistance Corp (ITAC) pointed out, Phase II recipients are further along toward commercialization and are going to create economic impact relatively sooner.

While Phase I and Phase II matching grants would provide different benefits, a program in either area could strengthen the state's position by supporting the bioscience industry at critical junctures.

Creating affordable office space for startups

"The goal is to increase the number of startups and the likelihood of their success."
-Peter Flint, general partner, Polaris Ventures

Whether or not to pursue incubator space is yet another, and early, decision for a new company to make — some startups such as ADispell and

Ezra Pharmaceuticals find that operating in a virtual office space works best for them at the moment. But dedicated incubator space for startup or early stage bioscience companies with wet labs at no cost for some period of time at the outset is difficult to access. The expense of contracting out research to a contract research organization (CRO), contract manufacturing organization (CMO), university lab or large biopharmaceutical company can be less than a startup paying for this space, "especially once you consider the need to rent the space, outfit it, stock it, and hire a team to do the work," in Kappel's opinion. "There is overhead, sometimes significant, when working with academic institutes and contract organizations, but they have quality systems in place, experience, equipment, etc., that allows a company to get off to a quicker, cheaper and more nimble start than an incubator does." But he also acknowledges that, "there still is something to being able to think of an idea and execute on it immediately that only comes with your own lab benches (and not sponsored research agreements or contracts)."

The lack of affordable incubator space was one of the primary reasons why Ophidion, a startup spun out of Rockefeller University, left New York for Pasadena, California. Co-founder Dr. Andreas Walz said the move was, in part, a direct result of the lack of VC funding and the lack of affordable laboratory space made the decision easy. "We couldn't afford the Alexandria/East River Incubator, nor would they let us in — that space is suitable for well-funded startups and large companies," said Walz. Although lab space is important, some noted that access to capital is more important than lab space *if only* because then a company has the capital to move into some of the more expensive facilities available.

While there are some good examples of initiatives promoting entrepreneurship in general, and bioscience companies specifically, to be found in New York, the costs associated with some of these programs can still be prohibitive for startups faced with securing funding to cover patent costs, pre-clinical trials, and licenses. Currently, the state is a partner in the New York City Bioscience Initiative, which includes the City of New York, more than a dozen research institutions, business leaders, and the investment community. The initiative not only promotes the bioscience industry in the NYC Metro Region, it is also developing a network of state-of-the-art facilities — Alexandria Center for Life Science® – NYC, Audubon Center, SUNY Downstate, and the Brooklyn Army Terminal — "to accommodate commercial bioscience businesses and related research activities throughout New York City and the surrounding region." With the exception of the Alexandria Center for Life Science — which some who were interviewed said carried a higher price point and is a space better suited for established companies — downstate incubators can range in cost from the mid- to high-$30s per square foot, excluding utilities.

The PPI recommends enacting legislation similar to S.6860, which would create a New York incubator network to provide operating support that incubators can consistently depend on to develop operational capability and to provide continuity in business development services for their tenants.

Refining the incubator model

"For the early stage companies there is the need to have access to management and scientific talent, increasingly sophisticated and expensive equipment and a sufficiently developed core of support and specialty systems that are accessible to the early stage companies without stripping away the cash resources that drive product development," explained Fitzgerald. "The creation of a hub or hubs that establish the needed support network is something the government could provide support and coordination."

In addition to the upfront costs associated with obtaining patents and licenses, some startups are also paying for lab space at universities. If universities update how successful tech transfer is measured, and if tech transfer is considered a "cornerstone" to economic development, then weaning new companies from universities is vitally important to take these new companies to the next stage.

Elements from the New York City Bioscience Initiative could be integrated into the incubator model used by Dogpatch Labs to create a hybrid specifically for bioscience startups and early stage companies spun out of New York universities, as well as those established independently of a university. The model could also help to:

- Facilitate increased investment in bioscience by more high net worth individuals and VC firms; and
- Actively develop the organic entrepreneurial community that is key to attracting and retaining entrepreneurs, scientists and investors.

Launched by Polaris Ventures, Dogpatch Labs provides pre-funded technology and biotechnology startups with free space for at least six months, in addition to mentoring, access to other VC firms and angel investors interested in meeting with tenants in Dogpatch Labs, and other amenities all at no cost. Why? Peter Flint, general partner at Polaris Ventures, explained that, "In the technology area, it's good for entrepreneurs and VCs to get to know each other. It doesn't have to happen in one pitch deck." In addition to giving Polaris Ventures an opportunity to meet entrepreneurs early-on and identify potentially interesting deals for the firm, "it gives back to the community by helping NYC build its entrepreneurial community," he added. The company's Boston and Palo Alto locations house a number of bioscience startups.

When asked if the model Dogpatch Labs uses lends itself to a public-private partnership with the state, Flint said, "It would be hard to say no." Such a partnership might take several forms, but one in particular could give promising upstate bioscience companies access to a downstate incubator like Dogpatch Labs, as well as other resources concentrated in New York City. "We see companies from upstate without the resource access that NYC entrepreneurs have, and in many cases, they don't have the resources to move to NYC to take advantage of the resources that are here."

The additional space could also contribute to the creation of a structured, and gradual, separation of companies from using university facilities once licensed in addition to more flexibility in faculty support for startups in which they are involved would help the entire process.

Conclusion

New York has tremendous potential in its bioscience industry. The preceding policy and program initiatives include:

- Establishing a Governor's Council to help focus the state's biopharma vision and increase communication and understanding between the state and industry, as well as developing a proactive marketing campaign directed at internal and external audiences that champion New York's bioscience industry and the benefits of doing business here;
- Designating financial resources specifically for bioscience companies. In particular, establishing a matching grant program for bioscience companies awarded Small Business Innovation Research (SBIR) grants, and enacting a bill to create a dedicated Biosciences Commercialization Assistance Fund; and
- Increasing the amount of affordable incubator and lab space for startups and early-stage companies.

These recommendations are intended to help kick start a new phase of public-private partnerships to better leverage New York's existing resources, and to capitalize on the large number of bioscience discoveries generated each year at its universities. Better collaboration between the state and industry will reap richer economic and social benefits for New York, and allow the state to better compete on the national and global levels.

Company Overviews

Below are company overviews from interviews with nine bioscience companies — from startup and early stage to anchor — willing to share their experience of starting and growing a bioscience company in New York. Of the nine, one relocated to California. All offer reasons why New York is on the right path with an eye on how to better integrate or shore up the "piece parts" in order to fully capitalize on one of the state's greatest economic assets — bioscience. As a whole they illustrate the points raised in the report regarding funding, infrastructure and people that underlie the preceding recommendations.

Ron Cohen, founder and CEO of Acorda, was born, raised, and attended medical school in New York City. Unlike other entrepreneurs he knows, his decision to stay in New York and "persevere in an inhospitable environment" was largely influenced because he didn't want to leave friends and family. But he's also convinced that all the elements needed for a vibrant biotech industry are in New York.

Cohen initially ran Acorda out of his apartment and then a 40-50 square foot sublet before finding office space in 1998 in Westchester built out with a laboratory and a lease hold agreement paid by the previous tenants. Prior to settling on Westchester, though, Cohen considered New Jersey, Pennsylvania, Maryland and others. "They all looked attractive because they offered programs with startup incentives, including affordable lab space which New York did not have outside of the Audubon Incubator" priced, at the time, around $40 per square foot. The decision to stay or leave New York presented itself again when Acorda outgrew this space and had grown to more than 300 people, over half of whom were located in Westchester. Cohen again looked within a 50-mile radius, including New Jersey, ultimately settling on an Ardsley facility as the most attractive for location and incentive.

Even when Cohen served as chairman of NYBA, there was, and remains, a widely held bias among himself and his peers that overall, New York is not industry friendly where taxes and incentive programs are concerned, and falls short on a combination of scaleable lab and office space at affordable prices. He pointed out that there needs to be a natural progression of where to go from an incubator. And once the company is established, you need a reasonable commuting time.

It would be helpful, "If there was a way to broker a process where all these jurisdictions collaborated on a vision. New York City could serve as the main bioscience incubator hub because of the concentrated number of research universities. The technology or discoveries from these universities could be placed into startups and then into an incubator. Westchester could then function as the transition area for post-incubator companies with expansion needs, and upstate New York as a manufacturing hub. "It's tough to get to the scale you need in an inner urban center. The closest we get to this is in the Boston/Cambridge/Waltham cluster. In San Francisco the cluster doesn't sit in downtown San Francisco," noted Cohen.

During the most recent relocation, Acorda was in touch with Empire State Development Corp. and collaborated with BioMed Realty, a realty group interested in developing the Ardsley facility. This was a very productive process, and New York State, Westchester County and local officials were very collaborative in structuring an incentive package. Cohen also sees Mayor Bloomberg as a leader who exhibits an appreciation for the bioscience industry and has the creative impetus to support it. The much touted Alexandria/East River space, however, is suited for large, not small, bioscience companies.

Startups are the life blood of the industry, in Cohen's opinion. Because of this, he believes university TTOs and the metric used to measure their success is a critical need that's not adequately addressed. In one instance, Acorda tried to license a technology from a New York University but the process was abysmal and left him with the thought that the overall sophistication of TTOs needs to improve markedly. "Boston and Palo Alto get it. They have top-of-the-line tech transfer offices with people who are senior managers in business, broker deals, educate academics regarding IP and spinouts. Leaders at the city and state levels should bring all the university presidents together for a workshop, with world-class folks from around the country to develop ideas that will elevate our game."

ADispell
Dispelling the fog of Alzheimer's Disease

ADispell was founded in 2010 and is operated on a virtual basis. According to its CEO, Stephen Curry, this is a useful and economical model for university-related tech transfer projects, which start with limited resources on a quest for commercialization of academic discoveries. Curry took on the project at a point when he was actively seeking a medically-relevant project with, primarily, an eye to the future rather than on short-term gain in mind.

The company's inventor and one of its four co-founders, George Hess, has dedicated more than 20 years of his extensive neuroscience career studying nerve function. Around 2004, he discovered a link to Alzheimer's that was patentable. Curry met Hess at a pre-seed workshop where he was serving as a coach. Intrigued by what he heard, Curry encouraged Hess to form a company around the patent. Two years later a follow-up discussion led Curry to approach Cornell and say he thought the science was worth developing commercially and that there was a business model to make it possible. Cornell agreed. The negotiated license agreement gave exclusive rights to commercialize the patent to ADispell, with Cornell maintaining ownership of the IP through the patent in addition to a flow back to the university when the company generated revenue.

Investment in the project is much needed, and some of the potential investors would have required the company to relocate which, though possible, would not be attractive at present. "Our relationship with Cornell remains very important to what we are doing presently; the project has only half left the university," explained Curry. So for the foreseeable future, ADispell will remain in New York, and investors willing to allow that are needed. He explained that, "ADispell's primary goal is to enhance and raise awareness of the project. There is no way a small startup can undertake the cost of clinical trials. We hope to have one or two compounds ready to license to a large pharmaceutical company in two to three years. Overall, we see this as a three to five year process. ADispell wants to add value to the project before handing it over to the pharmaceutical industry. In this way we can fill the critical gap between academic discovery and product development."

Curry said that funding difficulties for medicine-related startups and early-stage companies is compounded by the fact that investors in general

are scared of the bioscience industry, particularly of pharmaceuticals, because of the long-term investment horizon demanded. And the FDA, some people believe, has a habit of killing investors' and inventors' hopes. Angel investors are especially cautious at present, and there is very little VC funding in upstate. For ADispell, a small amount of angel funding and foundation grants make up its lifeblood. The latter are focused directly on conducting specific tests to advance the project.

When asked if the current metric used to measure successful technology transfer should be refocused or expanded to include "how many companies a university can spin out," Curry thinks, "It would be good if universities were friendlier toward investing in their own discoveries through startups. They should be focused on cultivating the next generation of royalty stream." He goes further to explain, "As a policy, it would be terrific if there was a fund universities could tap into to help these companies get started. For the likes of ADispell, the first $50,000 – $150,000 to get going is incredibly difficult to secure. A dedicated fund like this would improve tech transfer efficiency." But he also acknowledges that a university's charter might also make it difficult for it to invest in its own startups.

Asked where he thought the state might play a role in supporting the growth of startups and the industry in general, Curry responded by saying he thinks the state could be a catalyst in terms of better coordination of funding for startup companies and a contributor, where appropriate, in relation to economic development and/or public health goals. This could help the startups stay close to their universities and help local discoveries catalyze local economic growth.

CELMATIX

This young company could very well be on its way to emerging as one of New York's next greatest bioscience success stories if the energy, resourcefulness and determination of founders Laura Towart Bandak and Piraye Yurttas Beim are any indication. Celmatix, Inc. is already considered a success story by the Long Island Angel Network.

Founded in 2009, Celmatix is a New York City-based biotechnology company developing diagnostic tools to improve reproductive health outcomes for female infertility. Their offerings will help physicians interpret clinical data, clarify causes of failure, and optimize treatment strategies to improve success rates. Their innovative, non-invasive test will also assess the genetic indicators underlying egg quality and female infertility. This information will allow reproductive specialists to diagnose genetic cases of infertility at the beginning of the treatment process. By using genetic biomarkers to assess potential problems, physicians can develop optimal treatment paths, plan for egg preservation, and pre-screen prospective egg donors.

The founders met during graduate school in New York City at Weill Cornell Medical College, where Bandak studied Neuroscience and Beim was in the Biochemistry, Cell and Molecular Biology program.

As early stage entrepreneurs, they were determined to meet everyone

in the local bioscience space. "We joined NYBA, attended every event we could, and reached out to the Center for Biotechnology (CFB) at Stony Brook to participate in their Bio-Strategy Sessions," said Bandak. While at the first Bio-Strategy Session, Bandak realized she knew Joseph Scaduto, CFB assistant director of business development, from a shared background growing up in Long Island. The founders credit Scaduto and his colleagues at the CFB with critical guidance in the early stages of their venture. Their contacts at the CFB provided an extremely important introduction to the Long Island Angel Network (LIAN). During the course of attending additional entrepreneurship workshops, Bandak and Beim were introduced to a member of the LIAN who turned out to be a VC from TopSpin, the successor fund to the Long Island Venture Fund and an affiliate of Renaissance Technologies. That meeting led to Celmatix presenting directly to TopSpin.

At the time of that presentation, Celmatix was subsisting on angel funding and government grants. In February 2011, Celmatix closed on a Series A lead by TopSpin. This funding allowed the company to expand their operations, including hiring additional employees. "We're growing," said Bandak. "And we just closed on another mid-round (Series A3) of $1.5 million, which will permit us to further expand our R&D activities." The company plans to raise a Series B in mid to late 2012. When asked what she thinks the state could do to increase the number of startups generated in New York, Bandak suggests offering grants to companies whose technology isn't discovered in academia, saying, "There are some promising mechanisms for people spinning out technology from academia, but we still have to bridge the gap for companies like Celmatix that have chosen to develop technology independently." Added Beim, "Our story also underscores the impact that state funds for Centers for Excellence such as the CFB at Stony Brook are having on economic development in New York State."

Derek Brand, a serial entrepreneur with a background in medical technologies and a graduate of Hamilton College, is director of business development for Enumeral Biomedical Corp., a newly-funded startup created around technology discovered by an MIT scientist and headquartered in New York City with its lab in Cambridge, Massachusetts. Although Enumeral's lab is located in Cambridge, the company has been building its clinical operations for access to patient tissue — "extremely critical to Enumeral," — in New York City.

The connections Brand built in New York City while working at the New York Academy of Sciences is Enumeral's network in this capacity, and it allows him to move the company's business development and technical process forward much faster than he could by cultivating a new network in Boston/Cambridge. Brand is currently working on setting up collaborative partnerships with the Multiple Sclerosis Research Center of New York and the New York Blood Center, giving Enumeral access to a wide variety of patients and samples.

While Enumeral has a strong network through Brand and its CEO, Arthur Tinkelenberg, who was an early-stage venture capitalist in New York, the overall ecosystem or entrepreneurial network is a "bit more disparate and the bonds aren't the same as in Boston." So Brand started a group that gathers monthly on a social basis and is focused on attracting people interested in early-stage companies and technologies. "It's flourished so far with an overall list of over 450 people and between 30-50 individuals attending each time," said Brand, who knows of at least two startup companies who have found CEOs through these interactions. These networks are also important to attracting venture capital firms. The "scientist/management team is more highly valued in bioscience than in other technology companies. This is [the combination] they [venture capital firms] are betting on so you need the serial entrepreneur," he said.

Brand pointed to the EIR program and Bio-Accelerate New York City as evidence that the New York City Investment Fund is building great steps in the right direction. "If I'm New York and saying bioscience is important, I need to really think about how I'm going to foster an environment that encourages people to create companies like ours and grow them," Brand said. "Entrepreneurs are built and not born in biomedical sciences: there are fewer opportunities to get into an early-stage company than in other fields, for a wide variety of reasons."

Brand thinks there is a role to play for the state. "What it can push on is policy and developing assets and facilities such as lab space for early-stage companies and listening to entrepreneurs," he said. Lab space is especially important for early-stage company formation. But at the same time, Brand noted that access to capital is more important than lab space because then a company can move into some of the more expensive facilities available. Brand sees New York City as a great place to start a bioscience company; if you can find a core space for your first few scientists, you always have the option of moving to Westchester to expand. Ultimately, it would be a far better option to have something affordable and accessible in Manhattan. "From the standpoint of an investor, you want the money directed at the science — the people, in other words, not the not lab space. There needs to be efficient ways of making that happen, or New York will continue to be disadvantaged with respect to other regions."

On the funding front, Brand sees a potentially beneficial role for the state in providing matching grants for Phase I SBIR grant recipients. From a political standpoint, a statewide matching grant program eliminates the geographical bias — the typical "upstate vs. New York City" challenges in statewide programs — and more important, the state is not choosing winners and losers. "Everyone can offer economic incentives to attract a company to their state but that's really limited to known entities and in the end it is a zero sum game," Brand continued. "This program would fill a key funding gap in growing startups in New York."

Enumeral closed their Series A funding in June 2011, which included a lead VC, and a number of accredited individuals who invested in the company. "We are fortunate that our investor base has a good understanding of where the value lies — it has allowed us to develop a plan based on where our platform can take us, rather than a typical clinical path for 'single asset' companies," he said. As for the company's future, Enumeral has the potential to significantly expand its operations, and would consider a location in New York that made more sense in terms of access to patients and samples. "If we could duplicate our lab in Cambridge in New York, who knows — it would potentially be a great advantage to establish physical labs here alongside our medical collaborators." When asked about state programs like Massachusetts' life science accelerator fund, which has applications for grants and subordinated debt of up to $750,000, he said "funding at that level would give Enumeral the capacity to fund three people full-time for two years to work on two full disease programs and give them a shot at producing two licensable compounds."

Ezra Pharmaceutical is a two and a half-year-old company built around an existing FDA-approved drug on the market, which it is reformulating and repurposing to address diabetic complications. The process is "a little less rigorous in procedure and will get to market sooner than the 20 years it can typically take, because you're dealing with a known molecule and a safety history, according to Daniel Knecht, Ezra's CEO and founder. Although the company is located in New York because the entire team is here, its pre-clinical work is conducted at sites in Michigan and the Netherlands. "In an increasingly interconnected world, startups need to

seek opportunities across the globe, whether it be collaborating with preclinical ophthalmic experts in Michigan or polymer specialists in Europe. Although New York has much to offer, opportunities abound for the global-minded entrepreneur," he noted.

A physician and MBA graduate of Cornell, Knecht recognized the tremendous potential of a basic science discovery by Randi Silver, Ph.D. Her lab elucidated a novel player in the development of diabetic retinopathy and wound healing. Despite an effort to reach out to corporate partners by Cornell's TTO, the IP surrounding this potentially paradigm-changing medical discovery remained fallow.

The role of tech transfer remains "opaque" to him in terms of what the TTO's role is vis-à-vis the startup. In launching Ezra, Knecht worked with three officers at Cornell. "Two were laid back, encouraging and helpful, whereas one's affect vacillitated between cordial and adversarial, and as a result made negotiations for a licensing agreement more challenging than necessary," Knecht recalled. "High-tech entrepreneurship is difficult enough." The experience left Knecht with the perception that some TTOs like to play intermediary between entrepreneur and scientist in trying to get a short-term gain at the expense of optimizing the success of the long-term relationship. "They should have been a bit more relaxed on the costs and happy to move technology forward when I approached them," said Knecht.

While Knecht thinks it would be wonderful if the university profited from eventual products initially conceived within its walls, he always understood the role of the TTO to be one in which it helped to foster the commercialization of academic discoveries and proliferate society-benefiting technologies. "There are two organizations that approach the tech transfer office: the cash-strapped entrepreneur and the large pharmaceutical company. Although the established company has deeper pockets to fund lower risk discoveries, the entrepreneur can bring fresh blood and energy to the academic lab, and the possibility of bringing a breakthrough discovery from bench to bedside."

What would impress Knecht is if TTOs extended startups' seed capital and in return would obtain a larger stake in equity or royalty. This would shift the incentives of the TTO from trying to recoup capital investment in IP to a stakeholder in the success of the startup. In this capacity, according to him, the TTO would also be responsible for evaluating which startups received seed capital and which endeavors lacked the right ingredients for success. In terms of Ezra Pharmaceutical's financial future, the company attracted an angel investor, and is evaluating possible clinical collaborators in India. Regarding early-stage biotech funding opportunities from the government, Knecht believes it will continue to play only a small role in fostering biotech startups because the inherent nature of the government is bureaucratic and risk adverse in nature, two completely incongruent characteristics with early stage startups.

Kinex Pharmaceuticals

Kinex is a pharmaceutical company co-founded in 2004 by Lyn Dyster, Vice President of Research Operations, David Hangauer, Chief Scientific Officer, and Allen Barnett, formerly CEO and now president emeritus. The early-stage biopharma company is focused on the development and commercialization of next generation therapies for cancer and immunomodulatory diseases. Headquartered in Buffalo, Kinex has a pipeline that includes four compounds at various stages of development and two platform technologies that give it the capability to discover new therapeutic products, according to its website. Dyster sees the company growing to 75 employees prior to having a product — they currently employ 15.

Dyster earned her Ph.D. in biochemistry from the University of Buffalo (UB) and started her first diagnostic company based on internal research. Dyster met Hangauer, a former Merck scientist who returned to Buffalo, through the Upstate Innovation Alliance and started a conversation around the technology he had discovered as a UB chemistry faculty member. Tapping her network, Dyster arranged for Hangauer to deliver a presentation through which he learned his platform technology could serve as a foundation for a company.

A deal struck with UB put the burden on Kinex to achieve specific milestones, which they did, and in doing so secured the license from the

University. Dyster acknowledged that UB Vice Provost Dr. Robert Genco helped Kinex break through the red tape. Otherwise, their beginning was typical for most startups — achieving milestones, raising the first $1 million, hitting technical benchmarks, and working for nothing the first few years. A virtual company, Kinex outsourced its work and continues to use this model today, choosing to work with New York-based CMO AMRI and QuaDPharma Inc., a new CRO based in Clarence, New York.

Attracting Dr. Allen Barnett to Kinex was extremely important in the company's development, and "gave Kinex great credibility," said Dyster. Barnett, who spent a successful career at Schering-Plough until 1998 and brought four drugs to market including Claritin and Zetia, first met Dyster on a panel at UB. They got to know each other while Dyster was at the university's incubator, and Barnett was eventually brought on as CEO.

In an industry where there are fewer and fewer molecules in the pipeline, Kinex currently has four. "We are at a critical point in our business where we are on the verge of being liquid, but need to raise $30 million to move through Phase II trials," said Dyster. Kinex raised $25 million over the last five years and received a few grants to help fund their work during the recent economic downturn.

Dyster pointed out that the company is located in Buffalo for many of the same strategic lifestyle reasons startups choose to locate in a particular area — the co-founders were living in Buffalo when the company was started; an easy life style; less expensive to do business there. She added, "If we didn't have these positive factors, we likely would have moved."

She noted that a disconnect exists between marrying funding and IP, and she said that there should be some mechanisms to accelerate businesses that are further along — a sentiment and strategic consideration echoed by other executives and entrepreneurs interviewed. "If the state wants to strengthen its bioscience industry and increase the number of startups, it must invest in its human capital and the companies that are on the verge of generating revenue and creating jobs," Dyster pointed out.

OPHIDION

Ophidion spun out of Rockefeller University in 2008 with four employees and financed exclusively by government grants. The company is developing a new class of drugs to address an unmet need for more effective cognitive treatments of Alzheimer's disease and other dementias, as well as Parkinson's disease, depression, ADHD, schizophrenia and autism, to name some.

Co-founder Dr. Andreas Walz said the company left New York at the end of 2008 with SBIR grants to move to Pasadena, California. The move was, in part, a direct result of his partner landing a position at CalTech. The lack of VC funding and lack of affordable laboratory space made the decision easy. "We couldn't afford the Alexandria Incubator, nor would they let us in — that space is suitable for well-funded startups and large companies," said Walz. Alexandria Real Estate Equities, Inc. is the developer of that site and, according to its website, "the leading provider of real estate to the life science industry."

Walz said, "We could have found space outside of New York City, but then the question of community became an issue. This is an area we feel the state could fill an important need." While he acknowledged that the workforce in New York is first-rate, tapping this workforce becomes an issue when you add a 45- to 60-minute commute one way. "It's a damper," said Walz.

Ophidion did not receive any assistance from public officials or an economic development agency prior to leaving the state, and Walz stated that, "It could have helped." While they looked at lab space in the Department of Health (DOH), it was complicated to work with the department, and Walz noted that a liaison between Ophidion and the DOH would have been good. Presently, the company is a tenant in the Pasadena BioScience Incubator, of which the city's Mayor also serves as the director. "If we have questions, we go to him," said Walz. "Politicians always seem to ask, 'What can we do?' Space is the issue."

In addition to the difficulty in locating affordable incubator space, Walz explained that, "It took us two years to spin out Ophidion from Rockefeller University. They were unhelpful. And it didn't help to keep us in New York."

By comparison, Walz said, the TTO at CalTech is "…one of the best we've ever interacted with. The technology gets commercialized through you, not a large company; they don't make any onerous demands on you." In short, he said they are there to help the company get started and "…when you make it big, hope you'll remember them." This is a practice shared by other universities such as Stanford and MIT. Walz explained further, "If you have a good idea, anything we start developing in Pasadena we own. In New York City, the university co-owned it so we were working for the university and not ourselves. There was no incentive. Anything that distracts me from doing the research and working on the product is not good. The metrics to determine success should be changed," he said.

OyaGen's President & Chief Operations Officer, Tom Fitzgerald, brings a bi-coastal perspective to this 2003 upstate spinout from the University of Rochester. A lawyer by training with 30 years experience in the biopharmaceutical industry, Fitzgerald has worked with a range of early stage companies, as well as more established domestic and international businesses. His business partner is the Founder and Chief Science Officer, Dr. Harold Smith, a tenured professor of biochemistry and biophysics at the University of Rochester's School of Medicine and Dentistry. The company is focused on developing and commercializing pharmaceutical therapies that seek to utilize editing enzymes as disease targets or therapeutics.

Fitzgerald, who heard about Smith through his own network, was brought in to help Smith in 2004 after the university's TTO directed Smith to Trillium Group as a potential investor, and who Smith initially convinced to invest $350,000 in the company. Smith quickly realized that in therapeutic development that amount doesn't get you much further than a license.

Shortly after Fitzgerald joined OyaGen, the company learned that research on a particular aspect of editing enzymes research applicable to HIV, which complemented what Dr. Smith was doing, was being conducted at the Thomas Jefferson University (TJU) in Philadelphia. OyaGen's lack of laboratory space in Rochester led OyaGen to rent and fund lab space at TJU for one year at a cost of $200,000. While expensive, it was more efficient and immediately available to OyaGen, as opposed to alternatives available in Rochester. The decision ultimately led to OyaGen to license TJU's intellectual property, which gave Dr. Smith and OyaGen a foothold to move the company forward. At the end of the year, OyaGen moved the development work being done at TJU back to the University of Rochester and rented lab space at the URMC that was in close proximity to Dr. Smith's academic lab but cost more than TJU. Collectively, the Rochester labs gave OyaGen access to personnel and the equipment they needed to generate research under the supervision of Dr. Smith and enabled the company to do its initial angel round financing in the Rochester area.

In terms of funding, Fitzgerald said he's certain, that unlike Smith, "without the local support of local angel investors seeking to invest in Rochester businesses, OyaGen would not have survived long given the long time lines for therapeutic development and the significant amount of capital required." Although OyaGen received

initial funding from a venture seed fund focused on spinout businesses from the University of Rochester, and successfully raised local funds, the company has been handicapped by limited capital and has relied heavily on grant and other funding from public and private sources. The company employs people educated in the region, and tries to use local vendors and contractors to the extent possible. However, the biopharmaceutical industry is not just local, so over time OyaGen has had to consider how and to what degree to engage resources from beyond the region and has had to forgo several potential funding sources that required a relocation of OyaGen, Fitzgerald said.

What is clear, he explained, "Is that companies usually end up residing where the money is. A mid-range financing option for us is not available locally so whether or not OyaGen will stay is a question the company must address." At the moment, Fitzgerald said the company is looking for a potential industry partner to work with to help finance the next stage of its product development activity which, according to Fitzgerald, is a better option than others because it likely wouldn't require them to relocate, though it will ultimately depend on the shape of the collaboration agreement.

As did others, Fitzgerald thinks tech transfer is not currently viewed as a cornerstone for economic development. From a policy perspective, he explained that a philosophical issue must be resolved first. "Is there an imperative for these large institutions to generate economic development within their communities? If you want the university to be an economic driver then there must be a systematic approach to solve several issues first. For the early stage companies there is the need to have access to management and scientific talent, increasingly sophisticated and expensive equipment and a sufficiently developed core of support and specialty systems that are accessible to the early stage companies without stripping away the cash resources that drive product development. The creation of a hub or hubs that establish the needed support network is something which the government could provide support and coordination. The institutions are usually torn because faculty isn't fully supportive of private commercial activity. Startups need to be weaned away from their institutional sources in a more nurturing fashion. For instance, companies, once licensed, could benefit from a more gradual separation from using university facilities and more flexibility in faculty support for startups in which they are involved would help the entire process."

With respect to licensing, Fitzgerald shares the view of others that New York is "…baby stepping it where licensing and funding is concerned in the life sciences, making it more likely that the technology will migrate away from New York subsequently." As an example, he noted that one of the quasi-public seed capital funds is hamstrung because funding from the state is uncertain, the amount funded is too low and they are subject to many filters.

In terms of infrastructure and management-skilled people, Fitzgerald suggested bundling early stage businesses geographically with the infrastructure they need — people are part of this infrastructure picture — that is livable, changeable and within close proximity of the people, both scientists and the entrepreneurs. "The lack of a concentrated, integrated infrastructure compounds New York's problem by limiting its ability to

efficiently and effectively tie into the global bioscience community unlike Boston and San Francisco. Upstate is financially manageable and livable, and this is not exploited by the state."

Lastly, while seed money seems to be available, it is gap funding from VCs that's needed and no one seems to be coordinating this group, Fitzgerald said. "What the state really needs to provide is an early stage safety net consisting of equity support, more freedom for the institutions to operate in terms of providing space and resources to the developers for these technologies."

SmartPill
The Measure of GI Health®

In 2003, David Barthel was brought in to start SmartPill. He was introduced to the company's technology idea by the University of Buffalo's TTO because it had a non-invasive capsule-based technology for diagnosing gastrointestinal disorders with a wireless motility capsule procedure developed in the 1990s, and didn't know what to do with it. Barthel understood the business model needed and could raise capital.

Based in Buffalo with 18 employees, SmartPill has generated revenue since 2007 and has its CE Mark for international distribution, is ISO 13485 certified as a medical device manufacturer, and has just received approval for a Category 1 CPT Code for reimbursement for insurance coverage. And Barthel thinks SmartPill could be one of the success stories in the area. "There aren't too many successful startups in Buffalo and interested VCs wanted the company to move to Boston. But I made a commitment to the University of Buffalo to stay and build the company in Buffalo." SmartPill's unique medical device was a key factor that influenced Barthel to make the commitment.

He is extremely positive about the area and thinks New York is a great state to do business. When asked why New York is perennially perceived as "closed to business," Barthel said, "Taxes are the fall back reason, but the tax basis isn't much higher than in other states. Yes, it's cheaper in some states, but not by much and the benefits here include a financial center in New York City, an educated workforce, engineering capabilities, great universities, airports and transportation." In short, Barthel maintained that New York is a "one-stop shop" for business, though difficult to navigate "the maze" at times, and suggested the state could make the process easier by providing some sort of a roadmap identifying the state's available financial and non-financial resources.

SmartPill has certainly benefitted with an experienced manager at the helm. Under Barthel's guidance, the company has grown with the help of Empire Zone credits and support from the Office of the Comptroller, through its investment with High Peaks Venture Partners of Troy, New York, and who is a significant investor in SmartPill. The company also has received strong local support through the Erie County Industrial Development Agency (ECIDA), the Office of the Mayor of Buffalo, Byron Brown, and NYSTAR. Contrary to what typically occurs when a company receives venture capital funding, Barthel convinced SmartPill's VCs to keep the company in New York, citing the cost of labor and access to a good pool of manufacturing talent.

Just as New York has long been perceived as a difficult state to do business in, upstate has had to deal with the perception that there isn't anything between New York City and Buffalo. Barthel asked, "How does upstate communicate that to downstate? SmartPill's biggest investor is Psilos Group Managers in New York City, who has been a key contributor to the success of the company. This is where the state could be instrumental and fill the communication gap between New York City, upstate and the state."

And according to Barthel, a win, just as in sports, would attract people to upstate. Which is another way of saying the investments made need to be made in the people and the companies on the verge of breaking through or that are creating jobs. He figures SmartPill is probably two years away from being that potential win. But what that win could look like is also unknown — it could be significant growth for SmartPill leading to the hiring of 50 more people; selling the business for $250 million and it remains in New York; an IPO; a brand new indication for use for the SmartPill capsule? Any way it would be a win for the investment community and for the state of New York.

Of all the steps the state could take to better integrate and strengthen New York's bioscience industry though, the most important, in Barthel's opinion, is to "Get the right people around the table when we talk policy. There is a model here that needs to be fine tuned. Research and funding are happening now and can be tweaked as the

industry changes. Models are developed only to then stay static for 10 or 20 years, and they can take 10 to 20 years to develop." We need to move quickly to take advantage of the opportunities in New York.

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Massachusetts Biomedical Initiatives

Massachusetts Biotechnology Council

New York State Center of Excellence in Bioinformatics & Life Sciences

Pfizer

Pharmaceutical Research and Manufacturers of America

PricewaterhouseCooper MoneyTree

Small Business Innovation Research/Small Business Technology Transfer

Glossary of acronyms

BIO.....Biotechnology Industry Organization

CMO..... Contract Manufacturing Organization

CRO..... Contract Research Organization

CTI..... Centers for Therapeutic Innovation

EIR..... Entrepreneur-in-residence

ESD.....Empire State Development

IP..... Intellectual property

MLSC..... Massachusetts Life Sciences Center

NIH..... National Institutes of Health

NYBA..... New York Biotechnology Association

NYSEDC.....New York State Economic Development Council

NYSERDA..... New York State Energy Research & Development Authority

NYSTAR..... Division of Science, Technology and Innovation

SBIR.....Small Business Innovation Research

STAR..... Science and Technology for America's Reinvestment

TTO..... Technology Transfer Office

VC.....Venture Capital

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