

Report of Proceedings

Biotechnology Town Meeting
With Governor-Elect Beverly Perdue

Monday, November 24, 2008; 1:00 p.m.
North Carolina Biotechnology Center
Research Triangle Park, NC

Introduction

Overview of Life Science Industry. Biotechnology is an important source of innovation for North Carolina's life science industry. NC BIO considers the life science sector to include a variety of products, including pharmaceuticals, biologics, regenerative medicine, medical devices, diagnostics, medical testing, agriculture, industrial fine chemicals, and biofuels. Companies in these product areas are learning from one another and beginning to produce new products that merge existing concepts and technologies. This convergence is producing new combination products, particularly in the realm of health care.

North Carolina's life science industry also includes companies of different size, maturity and capitalization. At the earliest stage of commercialization, these are start-up businesses that have only recently licensed or patented new technologies and are conducting proof-of-concept or early product development work. These start-ups often mature into to later stage emerging companies that are conducting later stage product development, manufacturing process development, clinical trials and other activities necessary to bring new products to market. Ultimately, emerging companies may develop into mature businesses engaged in the manufacturing, marketing, and distribution of products. Alternatively, emerging companies or their technologies may be acquired by existing companies and the manufacturing, marketing and distribution of the new products merged into existing product portfolios. Of course, North Carolina's life science industry includes many large pharmaceutical, biomanufacturing and other mature companies.

Meeting Participants and Background. Participants at the November 24th town meeting represented a cross-section of companies and institutions in North Carolina's life science sector – spanning nearly all life science product areas and stages of corporate development. In addition, the November 24th meeting included representatives of major North Carolina universities conducting biotechnology research, and a variety of service businesses – such as clinical research organizations, legal and accounting firms, and consulting companies – that support North Carolina's core community of life science companies.

At a luncheon just prior to the town meeting with the Governor-Elect, participants in the November 24th program were briefed on various life science policy initiatives supported

by NC BIO. Participants were invited to adopt NC BIO's positions regarding these issues, or to express differing or conflicting opinions at the meeting with Governor-Elect Perdue.

Organization of Report. In an effort to improve the usefulness of this report, the meeting report set out below categorizes the comments offered to the Governor-Elect into several issue areas. These are: capital formation and entrepreneurial development; technology transfer; education and workforce training; retention and expansion; agriculture; and biofuels.

In this report, we include references to NC BIO policy position statements relevant to comments offered by meeting participants; copies of these statements are attached.

We invite your questions or comments concerning the meeting report. To contact us, please e-mail Sam Taylor, President, NC BIO, at staylor@ncbioscience.org, or call us at (919) 281-8960.

Report of Meeting

Capital Formation and Entrepreneurial Development. North Carolina has historically lagged behind states like Massachusetts and California in availability of venture and other forms of start-up capital. Venture capital under management in California, for example, is more than twenty-fold that in North Carolina. North Carolina could begin to address this problem by encouraging venture funds that receive investments from our State Treasurer to invest some of those funds in North Carolina companies. Other measures, such as a capital gains tax exclusion for founders stock, i.e., a Founders Credit,¹ would be very helpful in improving access to capital in North Carolina.

Unfortunately, the recent economic downturn and collapse of world credit markets are going to make capital formation even more problematic for small life science companies. Many companies will soon face a cash crisis during which they may be forced to sell intellectual property cheaply, leave North Carolina to access capital, or shutdown entirely. It is a situation unlike anything we have seen before. Up to a third of all small and mid-cap life science companies could run out of cash within the next year.

This is an urgent problem, but it is also an opportunity. North Carolina could capitalize on the current crisis to build its prominence as a life science location by preserving its existing companies and attracting high-quality early stage companies that are faltering in other states or nations. Between \$100 million and \$200 million could be deployed productively in this way. One mechanism might be to provide low-cost space to start-ups and emerging companies. Such an initiative could be particularly helpful to our growing community of science parks; e.g., Piedmont Triad Research Park. Another mechanism would be NC BIO's proposed Life Science Development Corporation,² which would provide emerging companies affordable debt financing for start-up manufacturing facilities, equipment and other capital needs. Such programs can be crafted so that they

¹ See NC BIO Policy Fact Sheet: Qualified Business Venture Founders Credit.

² See NC BIO Policy Fact Sheet: Life Science Development Corporation

do not require immediate cash appropriations by the state, but can instead be financed over time.

It should also be noted that North Carolina is not the only state investing in biotechnology. No fewer than 36 states are trying to grow or expand biotechnology clusters. Massachusetts, Maryland, and California, for example, are putting billions of dollars into biotechnology research and economic development. In the area of stem cells, particularly, other states are making major financial commitments – including strong recruitment incentives. Many start-up companies will wind up going where the money is.

Technology Transfer. It is very important for North Carolina to do the best possible job of getting new life science-related technologies out of our research universities. Entrepreneurship is a crucial element of this process. In recent years, there have been up and down efforts to improve technology transfer, but we should consider new approaches that might allow us to do better. We must create a welcoming environment with supportive infrastructure and financing that will help innovators and entrepreneurs get new ideas to market faster. Opportunities to commercialize innovations and discoveries also can play an important role in attracting research talent to North Carolina's universities.

The absence of start-up capital is a key impediment to commercialization.³ In the pharmaceutical industry in particular, it can take between \$3 million and \$5 million of initial capital to advance a new product idea to a point that it is ready for venture funding. Start-up funding requirements for medical devices are generally lower, but access to capital remains a problem even for device companies.

Education and Workforce Development. North Carolina needs to make sure it continues to have the talent pool necessary for success in the life sciences. The need for a deeper pool of talent is particularly acute in the medical device sector. North Carolina has good engineering schools, but the state needs to do more to attract seasoned talent in order to be competitive with larger device and diagnostic centers, such as Minneapolis and Boston.

North Carolina has made tremendous progress assuring a qualified work force for large biomanufacturing programs through the NCBioImpact training initiative. Many of the manufacturing companies that have located or expanded here might not have done so in the absence of this capability. But our community colleges and public and private universities need to continue graduate people with the skills and in the disciplines needed in the life sciences. Novozymes NA at Franklinton, for example, is now trying to fill forty positions requiring post-secondary degrees.

NCBioImpact has been a big success, but other states and nations are now investing in similar workforce initiatives. To remain effective, NCBioImpact institutions need to stay in close touch with the current and future workforce needs of the biomanufacturing industry. NCBioImpact would benefit from fuller integration of curriculum and planning

³ See NCBIO Policy Fact Sheet: SBIR Matching Grants.

among its three constituent institutions (BioNetwork at NCCCS, Biomanufacturing Training and Education Center (BTEC) at NCSU, and the Biomanufacturing Research Institute and Technology Enterprise (BRITE) at NCCU). The distance learning capabilities built into the NCBioImpact facilities at North Carolina State University can be an important aid in providing relevant education and training throughout the state.

It is also important that North Carolina reach out to children in our secondary schools who might be interested in careers in biotechnology or the life sciences.

Retention and Expansion. North Carolina also needs to provide continuing support to its existing biomanufacturing and pharmaceutical industries. The presence of these companies is a big advantage to North Carolina. In the pharmaceutical and biologics sectors, large companies now partner closely with small biotechnology firms in North Carolina and around the world to develop new products. Large firms also contribute substantially to North Carolina's pool of life science management, technical and research talent. Keeping North Carolina's mature life science companies here should be a top priority.

Large life science companies with facilities in North Carolina also have operations in other locations around the globe. Many of these companies would like to place new product lines or other expansions in North Carolina, but company leaders must make the business case for such decisions.⁴ If North Carolina's economic development incentive packages only support very large investments with hundreds of new jobs, then the State is likely to miss out smaller expansion or similar investment opportunities that add fewer jobs, but make it easier to keep current employees on payroll and add new ones later. State investments in water, wastewater and other infrastructure are also important factors in attracting and retaining life science companies.

North Carolina can also signal its strong interest in growing, retaining and attracting life science companies by adopting life science-friendly public policy. A good example is state Medicaid reimbursement policy. North Carolina has a strong history of letting doctors and patients make decisions about health care and health care products. By assuring that patients have access to medicines selected by physicians and patients, North Carolina reemphasizes its commitment to growing a strong life science sector.

Agriculture. Biotechnology has a lot to contribute to advancing North Carolina's agricultural sector. North Carolina is one of the world's leading centers for agricultural biotechnology research and development. Many agricultural biotechnology technology companies have located in North Carolina to take advantage of the research synergies here. However, in order to be truly successful, North Carolina must attract more funding for agricultural biotechnology research grants. Federal grant programs, in particular, represent an important opportunity.

⁴ See NCBIO Policy Fact Sheet: Life Science Retention/Expansion Support

The North Carolina Biotechnology Center is setting up a six-month process for developing a clear vision for the state's agricultural biotechnology future. The process will involve more than 100 participants from agricultural and related interests.

Biofuels. North Carolina should continue to invest in biofuels. Agricultural biotechnology has a lot to contribute in this area. Continued research in plant biotechnology will be crucial to development of North Carolina's renewable energy potential. The state can take other steps to support the growth of biofuels and other bio-based products. One such measure would be to create a bio-based preference for state purchasing activities; the federal government already has such a program.

Participants in the meeting expressed strong appreciation for the Governor-Elect's interest in biotechnology. Companies and institutions represented at the event expressed a desire to work with the Perdue administration to continue North Carolina's growth and prominence as a world-recognized life science center.

Next Steps

Governor-Elect Perdue asked NCBIO to facilitate several additional "next steps" in connection with the November 24th event. These were:

- Provide this report on the meeting.
- Provide additional information regarding the proposed capital gains tax exclusion for founders stock, life science development corporation, and expansion incentives options.
- Develop recommendations for accelerating technology transfer.
- Contact the State Treasurer regarding strategies for encouraging venture investments in North Carolina.
- Prepare to appear before the Governor's Education Cabinet to discuss coordination of state life science-related education programs.

Summary

This report reflects the views of representatives from a broad cross-section of North Carolina's life science industry. Participants at the November 24th meeting identified the following issues of importance and related recommendations:

- *Capital Formation* – North Carolina has historically lacked the depth of venture and other startup capital of states like California and Massachusetts. This situation is likely to be exacerbated by the current economic downturn. The downturn, however, also represents an opportunity to assure the long-term prominence of North Carolina's life science community through strategic government actions including (i) adoption of a capital gains tax exclusion for founders stock, (ii) creation of a life science development corporation, and (iii) encouraging venture funds receiving investments from North Carolina's State

Treasury to invest in our state. All of these initiatives can be accomplished without near term impacts on tax revenues or appropriations.

- *Technology Transfer.* Continued, dedicated funding for North Carolina's SBIR matching grants program will aid technology transfer. Attention should be given to the development of other means to accelerate commercialization of university innovations.
- *Education & Workforce Development.* The NCBioImpact Program has been tremendously successful, but the NCBioImpact institutions must continue to track and meet industry's changing work force needs. There is also a need for better coordination of NCBioImpact's various institutions and programs. The industry will continue to need post secondary education graduates of all types. This need is particularly acute in the medical device sector.
- *Retention and Expansion.* Expansion of existing facilities should be encouraged providing incentives for continuous incremental investments. Current health care reimbursement policies, which respect physician-patient decisions about treatment options, should be continued.
- *Agriculture.* North Carolina should seek to attract additional federal research funding for agricultural biotechnology. Attention should be given to recommendations of the North Carolina Biotechnology Center's pending agricultural biotechnology strategic planning initiative.
- *Biofuels.* North Carolina should continue to invest in biofuels and related research in plant biotechnology. The state should consider implementing a bio-based purchasing preference similar to that of the federal government.

In follow-up to the November 24th meeting, NCBIO is providing this summary with referenced attachments. Pursuant to the Governor-Elect's request, we will be working with the State Treasurer to investigate strategies for encouraging venture investment, working with our university partners to develop recommendations for accelerating technology transfer, and preparing recommendations for the Governor's Education Cabinet regarding coordination of life science-related work force training and education.

NCBIO and the meeting participants appreciate the opportunity to share ideas and perspectives with the Perdue Administration. We look forward to continuing the dialogue begun at the meeting on November 24th, and will be pleased to provide further information regarding these and other matters at any time.