

Response to SB402

N.C. General Assembly 2013-2014 Session

February 28, 2014

Life Sciences North Carolina

Making the Connections that
Create Biotech Jobs

- New Ideas
- Applied R & D
- IP Translation
- Company Startup
- Company Expansion
- Business Attraction



**North Carolina
Biotechnology Center**

ncbiotech.org

Response to Senate Bill 402

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Executive Summary

The worldwide brand of North Carolina's life science industry has long been represented by the North Carolina Biotechnology Center (NCBiotech). Through program development and funding activities, NCBiotech facilitates growth in the state's company base, catalyzing industry expansion to more than 600 locations statewide today. The state's life science job growth is the fastest of leading life science clusters, and the industry contributes \$1.7 billion annually to state and local tax bases.

The Board of Directors has always worked closely to oversee NCBiotech funding, programs and staffing. The Board proactively convened two committees in 2012 - one to look toward future industry support activities and one to look at staffing needed to support those activities. The Board identified several opportunities for new activities at that time, including larger award programs to better support company growth.

In the spring of 2013, proposed budget cuts spurred a different review of NCBiotech activities. Based on Board discussions, several scenarios were developed for potential budget cuts. In July, Senate Bill 402 passed, finalizing the state budget and a 27 percent cut in NCBiotech appropriations. The Board and NCBiotech's leadership began implementing plans to reduce programs and staff, concentrating on retaining activities that most directly lead to near-term job creation. In making these decisions, the Board had no choice but to cut some important support activities that enhanced the vibrancy of the state's life science cluster.

In SB 402, the legislature asked the Board to examine eight aspects of NCBiotech operations. A committee led by Robert A. Ingram was appointed to evaluate activities, staffing, cash management and Board oversight. The study has affirmed the choices made in summer 2013, and it also confirmed that NCBiotech is an efficient and effective mechanism for supporting life science industry growth. NCBiotech's combination of funding and programmatic activities creates an ecosystem unique to North Carolina and conducive to company growth. These findings are discussed in detail in this report and its appendices. A summary of the responses is below:

NCBiotech is an efficient and effective mechanism for supporting life science industry growth. Returns to the community include:

- An average of \$28 in additional funding per \$1 in research grants,
- \$117 raised per \$1 loaned, and
- 31 company expansion projects since 2008.

- NCBiotech's activities are designed to work together and provide a full spectrum of support for the state's substantial and growing life science industry.
- Regional offices link these activities across the state.
- Current staffing is strategically aligned. Expert funding and program staff are required for success.
- Grants and loans have an impressive track record, and the procedures used to administer them ensure state dollars are awarded in a cost-effective manner.
- Cash balances cover commitments and a modest operating reserve, according to good business practices.
- The size of the volunteer Board allows diversity of representation and effective oversight of the broad range of NCBiotech activities. The cost to operate the Board is about \$18,000 per year.
- NCBiotech activities occur at an earlier stage than Department of Commerce activities. Both are needed to continue life science cluster growth.

The Board has taken or is planning the following actions as a result of budget cuts and this study:

- Eliminated five funding programs, and reduced one funding program and multiple programmatic activities judged less critical to near-term job creation. Total savings is \$3.5 million.
- Reduced the regional office budget by \$409,820.
- Reduced staff by 26 percent, or 22 positions for a savings of \$1.6 million.
- Allocated unrestricted cash reserves to the FY 2014 budget in order to continue to support program and funding activities.
- Will continue evaluation of progress in workforce development activities, expenses and activities in the regional offices and partnership with the N.C. Department of Commerce.
- Will enhance policies governing the level of unrestricted cash reserves. Invest or award reserves currently available according to this policy (estimated \$2 million).
- Will appoint a Board committee to review Board size by June 30, 2014. The committee will consider a balance of regional and professional representation to guide NCBiotech's operations.

Further, SB 402 requested anticipated funding needs. The Board is advocating an increase in funding for NCBiotech. This funding expansion, detailed in Question 4, is slated to five activities:

1. Establish an industry/university partnership grant to leverage significant private investment in North Carolina's universities. This grant also has an economic development component. \$3.4 million
2. Create a program with a \$500,000 loan to help small companies leverage venture and angel investment, bridging one funding gap these companies face. \$1.5 million
3. Expand the Economic Development Award program, which addresses unique challenges of life science companies looking to locate or expand in North Carolina. \$0.8 million
4. Extend program support for North Carolina's growing ag biotech sector. \$0.5 million
5. Begin implementation of specific activities to grow the biodefense sector in North Carolina. \$1.1 million

The Board recommends a \$7.3 million increase to NCBiotech's \$12.6 million appropriation, bringing total state funding to \$19.9 million. The Board believes that this funding level correctly leverages the infrastructure now in place to award funding and run programs that support industry growth. More importantly, additional funding will have an immediate impact on job creation.

Other states are putting tens of millions, even billions, of dollars into supporting life science. (Appendix C) The General Assembly must invest in NCBiotech and its proven approach to cluster growth.

North Carolina's position as a leading life science cluster depends on it.

Legislative Response Study Committee

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UNC Health Care System and
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Victor J. Dzau, M.D.

Duke University and
Duke University Health System

Full Board of Directors list is in Appendix F.

Introduction: A North Carolina Success Story

North Carolina's life science industry contributes \$59 billion to the state's economy. It provides a total of 237,000 jobs. It has posted the fastest job growth among leading biotech states in the last decade – 23.5 percent, more than triple the national average. (Appendix B)

Leading biotechnology employment growth over 10 years is no accident, as life science products can take a decade or more to make their way to market. The technology development process goes through a multiple-step process that is highly regulated. At each point, the technology is at risk for falling into a gap -- from lack of funding, from lack of supporting research, or from lack of expertise in leadership.

In examining activities and operations, the Board affirmed that NCBiotech targets its activities to bridge those gaps. By focusing on activities that keep technology development moving forward, the Center has produced remarkable results.

- North Carolina researchers use NCBiotech grants to develop and build on ideas. These projects then attract between \$4 and \$73 in additional funding for each \$1 that NCBiotech awarded. The overall average for research grants is \$28.
- NCBiotech loans to small companies come at a time when few will invest in unproven technology. The Center's loan due-diligence team reduces risk from these investments. Companies go on to raise \$117 in external funding for each \$1 loaned.
- Company expansion and recruitment projects announced since 2008 have created or are projected to create 2,298 jobs. This focused effort is only one of NCBiotech's programs, and it has created a biomanufacturing cluster that is the envy of leading and emerging biotech states and nations.
- As a demonstration of the value NCBiotech brings to the life science community, more than 1,000 senior executives, scientists, and community leaders donate nearly 10,000 hours annually to NCBiotech activities. These hours have a conservative estimated value in excess of \$1 million. (Appendix K)

The long-term approach to industry development began with grants to universities to recruit research faculty and strengthen research programs. Collaboration with the community colleges led to a worker training program that lured industry to the state. These resulted in a cluster of companies that gave North Carolina a head start on other states looking to develop a life science industry. These other states are starting to catch up, driven by the industry's high-paying jobs (\$78,000 average salary in N.C.). Consider these recent news items:

- GlaxoSmithKline and the University of Texas' MD Anderson Cancer Center signed a cancer research collaboration and licensing deal potentially worth \$335 million.
- The Department of Defense awarded \$358 million to a Florida company to build a facility to develop and produce countermeasures for a range of biological threats to military personnel.
- Baxter's production facility for plasma-based treatments is under construction in Georgia. When up and running, the \$1 billion facility will employ more than 1,500.

What is biotechnology?

NCBiotech's working definition of biotechnology is:

the application of life science technologies (including biology, bioengineering, mechanical approaches, material science, and bioinformatics) to yield products and services that benefit health, the environment, agriculture or industry.

To align with industry terminology, we have used life science throughout this report.

- Massachusetts has committed \$467 million to life science startup companies, leveraging \$1.2 billion in additional investment and creating thousands of jobs. The state plans to invest a total of \$1 billion.

Additional state incentives for life sciences are documented in Appendix C.

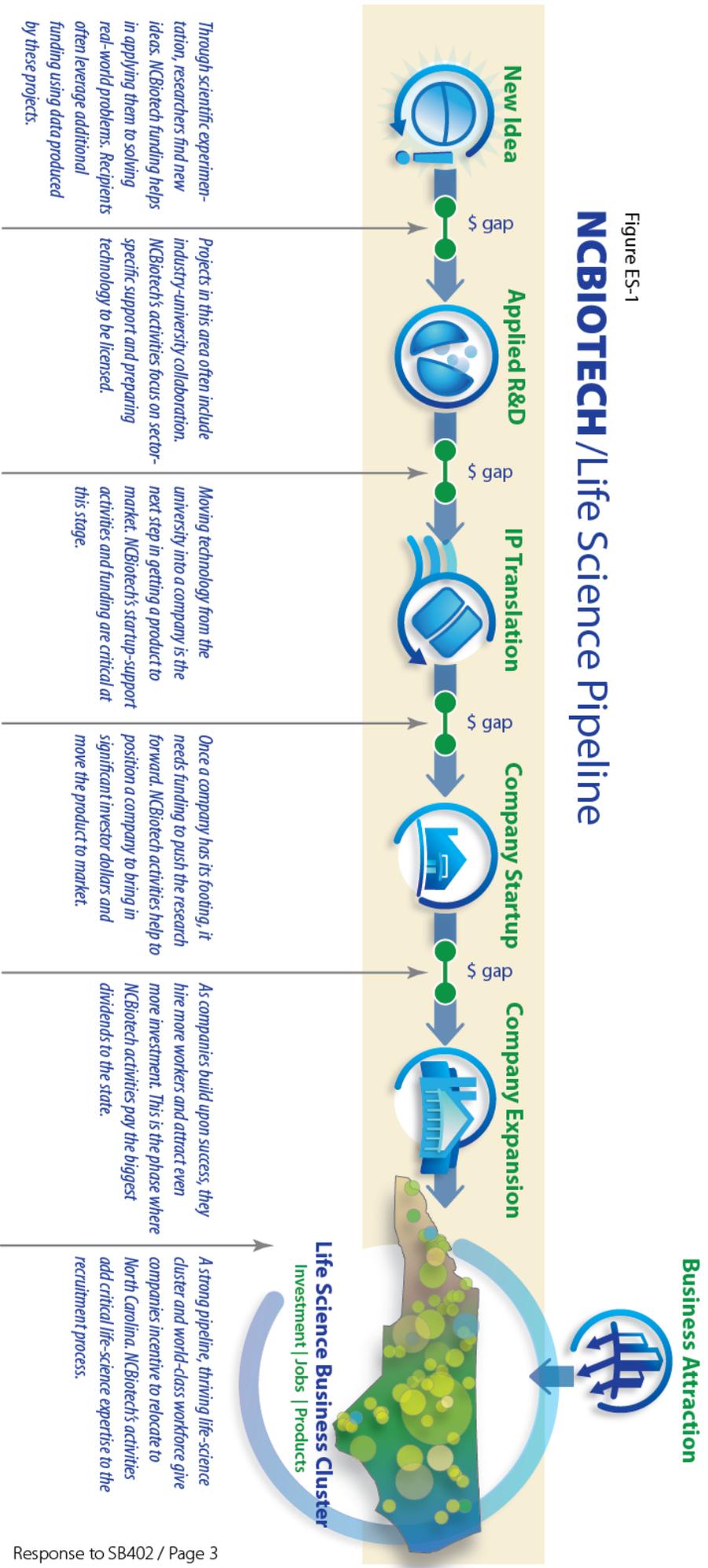
North Carolina has counted on its strong foundation and coordinated approach to technology-based economic development for an advantage. But without new ideas and continued support, this firm foundation will not spur the same rate of growth. Looking toward 2020, North Carolina must pivot and shift its life science efforts from building a foundation to building on the foundation.

Doing so will require new programs, targeted activities and greater funding. North Carolina's best path forward in the life sciences rests with NCBiotech. The organization has assembled a strong team of experts, portfolio of programs, and connections with industry that work to North Carolina's advantage.

This report looks at NCBiotech program and funding activities, staffing, governance and cash balances in order to ensure that NCBiotech is operating effectively and efficiently. The conclusion is that North Carolina's life science foundation is strong and NCBiotech is ready to invest more dollars in creating jobs.

Figure ES-1

NCBIOTECH/Life Science Pipeline



Activities at Headquarters

1

*The board shall review... the **activities conducted at the Center's headquarters** in Research Triangle Park to determine how each and every activity is necessary to achieve the goals for which State funds are appropriated. Any unnecessary or duplicative activities shall be reduced or eliminated.*

Response

The Board began the review process by examining the bylaws and confirming the mission of NCBiotech. The bylaws state: "The Corporation shall provide long-term economic and societal benefits to North Carolina by supporting biotechnology research, business and education statewide."

In July 2013, the state budget cut NCBiotech funding by 27 percent. As a result, the Board examined all NCBiotech activities. Following its strategic oversight committee's direction, the Board worked to concentrate resources on the programs that most directly achieve the mission. As a result, five funding programs were canceled, programmatic activities were cut back, and the Center reduced its staffing by 26 percent. This will ultimately save \$3.5 million for programs and \$1.6 million in staffing.

This review examined both funding and programmatic activities. Staff assistance is as important as funding dollars to the industry's growth. The Board concludes that the remaining programs and staff are critical to the success of NCBiotech's mission and North Carolina's biotechnology industry.

Discussion: Investment, Jobs and Products

NCBiotech's approach to life science development is to fill strategic gaps in the biotechnology product and business development process with funding and programmatic activities. (Figure 1-1.) By filling gaps, NCBiotech positions state dollars where companies or researchers most need them and can best leverage them to bring in additional funding. In fact, one NCBiotech loan dollar is followed by \$117 in external funding on average (Appendix M). NCBiotech grants also stimulate major external investments (from \$4 to \$73 per \$1 granted with an average of \$28), in research in North Carolina. (Appendix O) This is return to the company, university or state, not to NCBiotech.

These programs are just some of the overall NCBiotech efforts that foster the right environment for the creation of more than 60,000 high-paying biotechnology industry jobs. One example of these results comes from the NCBiotech loan program, which has led to the creation of 2,952 jobs (question 4). Since 2008, the Bioscience Industrial Development team has worked on 31 winning projects that have added or will add 2,298 new jobs for the state.

Subsequent indirect creation of jobs in other industries multiplies life science impact by a factor of four to six (Appendix B). This means North Carolina's 60,000 bioscience employees ultimately translate to a quarter of a million jobs. This puts North Carolina consistently among the nation's top biotech clusters. North Carolina has posted the fastest employment growth of top biotech states in the last decade, 23.5 percent compared to a loss of overall private-sector jobs in the state.

The Center's programs have also resulted in societal benefits through healthcare products that have been commercialized to extend and improve patients' lives, and through agricultural biotech products that have enhanced our food supply. More than thirty new products have been launched by companies subsequent to NCBiotech loan funding. (Appendix D)

Program and Funding Activities Review

This systematic approach to business development relies on many different types of programs for the decade-long product development timeline. This concept is illustrated in figure 1-1, which diagrams where NCBiotech activities fit in the technology-development continuum. At each transition, technology is at risk for falling into the gap. NCBiotech activities are designed to bridge the gap.

While funding activities use the majority of the dollars spent by NCBiotech, this diagram shows that funding and program activities are interconnected. Eliminating one decreases the effectiveness of the other. Qualified staff with expertise in life science, business and finance is required to execute both funding and program activities. This review found the quality of the staff is critical to both funding and program success.

Nevertheless, the Board had to cut some activities following the 27 percent state budget cut. The Board prioritized those activities that had the most direct impact on near-term job creation, cancelling:

- Funding Activities
 - Multidisciplinary Research Grant
 - Regional Development Grant
 - Industrial Fellowship Program
 - Education Enhancement Grant
 - Undergraduate Research Fellowship
- Program Activities
 - Summer Educator Workshops
 - Classroom supplies
 - NCBiotech Investment Profiles
 - Investments in NC-based venture capital and angel funds
 - Southeast Venture Philanthropy Summit 2014
 - National Cancer Institute SBIR Investor Forum in North Carolina

The following funding and program activities were reduced:

- Classroom equipment loan programs
- Life science cluster marketing activities
- Networking and community events
- Centers of Innovation

Staffing was reduced by 26 percent as part of this effort and is discussed in more detail in question 3.

Unique programs

NCBiotech's activities contribute to the development of a technology-based cluster, filling in gaps where technology is most likely to fail. This mediated approach has been used as a case study in economic development. Researchers found that by pairing expertise with incentive dollars, companies were more likely to meet their job-creation targets. (Appendix V)

Figure 1-1 details NCBiotech activities along the technology-development pipeline. Funding activities are spread across the continuum. While several program activities exist at each point in the development pipeline, these programs do not duplicate each other.

For example, pharma-academic partnering links multi-national companies with North Carolina university research, leading ultimately to licensing deals for the state's universities. Meanwhile, NCBiotech partnering events facilitate meetings between large and small companies. Both activities lead to company expansion here in the state, but they work in different ways.

The Board concluded that these program and funding activities are also not redundant with programs or activities of other organizations, agencies or institutions. In fact, NCBiotech activities often link and leverage separate programs at other organizations to better serve the life science industry. The Center has often acted as a neutral third party among universities, companies and organizations, forging common ground in a way that any one party could not.

The Board's examination of NCBiotech programs concluded that several new Center activities be initiated (detailed in question 4).

Actions

- Five funding and multiple other programs judged less critical to job creation or that were duplicative of activities provided by others were canceled.
- The Board will review the Center's education and workforce mission, objectives, and purpose to consider new activities that have an even stronger focus on understanding and improving the workforce available to employers.

Programs Speed Duke Idea to Jobs

In 2003, a \$50,000 NCBiotech grant funded some Duke scientists creating a new diagnostic test – a lab on a microchip.

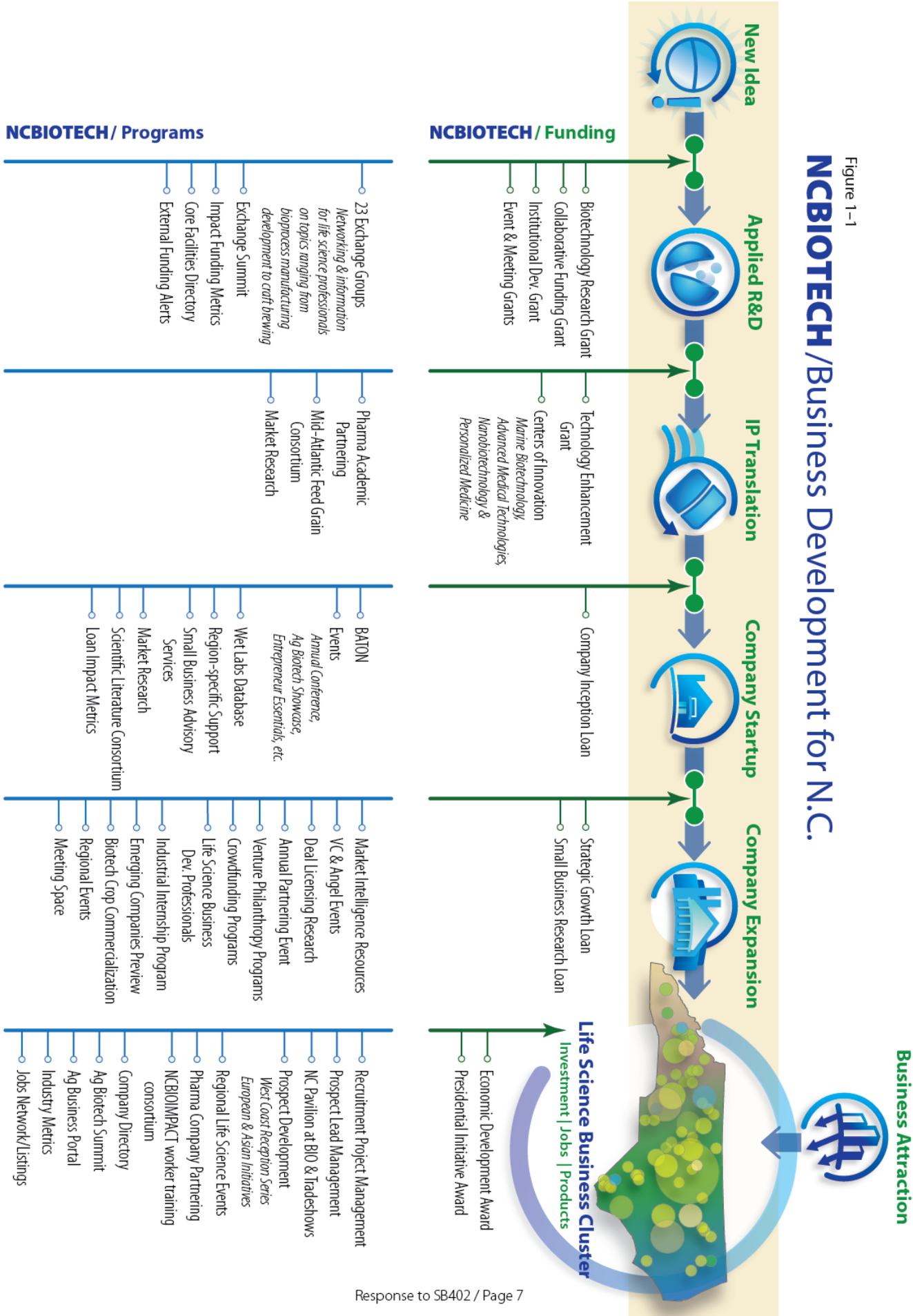
Advanced Liquid Logic (ALL) formed the next year to develop the technology. ALL then received four loans totaling \$468,000 over four years. One helped to launch the company. One paid for critical research on its lead product. The third and fourth helped ALL bridge the early-stage funding gap.

Founders say that funding helped to keep ALL alive and led to more than \$56 million in funding. By 2013, ALL was selling gene-testing products, employing more than 80 people. One employee was an NCBiotech Industrial Fellow. CEO Richard West participated in three NCBiotech-led venture capital events. ALL repaid all loans in full, with interest.

In July 2013, gene-testing powerhouse Illumina bought ALL for \$96 million. That's how NCBiotech programs (figure 1-1) pay big dividends.

Figure 1-1

NCBIOTECH/Business Development for N.C.



Regional Offices

2

*The board shall review ... **the activities conducted at the Center's regional offices** and how these activities can be consolidated and performed in fewer locations.*

Response

NCBiotech delivers programs to the regions through offices in Asheville (West), Charlotte (Greater Charlotte), Greenville (East), Wilmington (Southeast) and Winston-Salem (Piedmont Triad). Local business leaders, chambers of commerce, government officials and other community leaders in the region drove creation of these offices. Regional office directors are crucial to early-stage business development activities that lead to cluster development.

The Board concludes that the regional offices are a modest investment considering their potential payoff in jobs and investment. NCBiotech has trimmed regional office expenses \$409,820 — more than the cost of a single office — to accommodate budget cuts while preserving the activities.

Discussion

Regional offices grew from community conversations with leaders who sought high-paying life science jobs for their region. Technology-based economic development (figure 1-1) relies on myriad resources that create an ecosystem for success.

Regional office directors are the boots on the ground developing that ecosystem. They link universities, companies and community leaders to develop a life science sector based on the region's unique strengths. For example, the Piedmont Triad concentrates on regenerative medicine, while the East develops agriculture.

Each regional office determines activities with the help of a voluntary advisory committee (Appendix J), which works to determine the direction for the region. These committees also help to hire the regional directors, who have varying combinations of business, life science and non-profit experience. These skills in addition to local connections make the regional office directors the hub of life science activity in their regions.

This direct attention and university strengths have spread company development across the state. The map on the next page shows companies (green dots) clustered around research universities and regional offices. (Counties served by each office are documented in Appendix H.)

Regional reach is represented in the number of organizations receiving NCBiotech funding. Over five years, 159 different organizations have received 630 grants; 59 companies have been awarded 74 loans.

Regional Offices

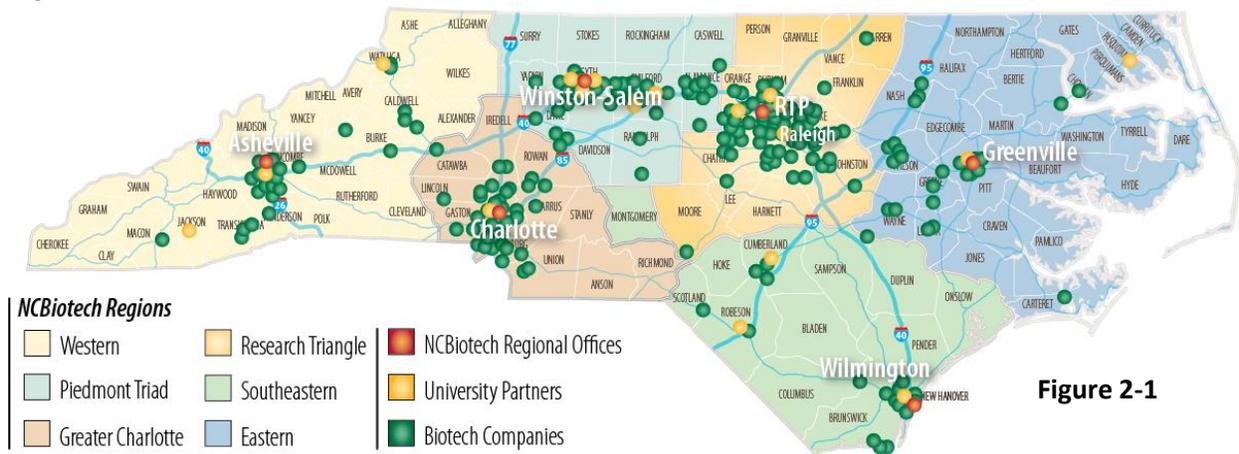


Figure 2-1

Regional Growth

Results often take time. The Research Triangle's cluster developed over 30 years with help from NCBiotech, the first organization to focus on life science development for a state. The first regional office, located in the Piedmont Triad, has posted significant growth since its 2003 opening:

- From 2006 to 2012, the region's bioscience employment grew from 5,272 to 7,901. (BioSciNC)
- 46 percent of the regional biotechnology companies are less than five years old. (BioSciNC)
- From 2008-2010, employment growth in the Triad region outpaced growth in RTP. (BLS)

Other regional offices are moving quickly toward those kinds of numbers. For example, more than one-third of Charlotte's bioscience companies launched since the office opened in late 2006. Early accomplishments in other regions include:

- Initiated recruitment of Genome ID to the Greenville area in the Eastern Region. In the next three years, the company plans to hire 120 employees, with an average salary of \$85,000.
- Supported the Western Region's craft beverage industry through technical workshops and curriculum and technology development grants. The Brewers Association reports N.C.'s industry grew 33 percent in 2012, versus 21 percent in California and 15 percent nationally.
- Created the NC Coast Clinical Research Initiative in the Southeastern Region to link the 50 local companies that employ more than 2,500 knowledge sector workers.
- And a number of other individual company success stories. A sample from the last quarter of 2013 is included in Appendix I.

Similar to other NCBiotech activities, regional offices leverage additional investment, in the form of volunteer time. Each office works with an advisory committee made up of business executives, academic experts and community leaders. In addition, many use ad hoc teams to develop activities in a specific sector, like agricultural biotechnology in the Southeast, or plan events, such as Triad BioNight in the Piedmont Triad.

In FY 2013, 400 community leaders across the state donated an estimated 5,676 hours to NCBiotech regional office activities. The approximate value of those hours is \$862,000 (Appendix K).

Conclusion / Streamlining Operations

In evaluating regional activities, the Board considered the current environment and several options for action. The state has a diverse landscape and extensive footprint. Consolidating or closing offices would spread resources too thinly and reduce effectiveness. This could reduce attention to specific sectors of regional importance, for example, marine biotech along the coast.

The concentrated effort to develop regional life science ecosystems is proving successful, with the greatest success in the first office. This indicates that the newer offices are on the brink of economic gain. Abandoning any one office right now would mean leaving jobs on the table.

Second, the Board considered the opportunity cost. A regional office costs, on average, \$200,000 a year, which the Board believes is a modest amount to spend in identifying regional strengths, aligning the business community and identifying new start-up company opportunities. The cost is also less than a single NCBiotech small-company loan.

Third, NCBiotech staff has already reduced regional office expenses by more than \$400,000 – more than the cost of a single office.

	2013		2014		Total Change
	Personnel	Operating	Personnel	Operating	
Piedmont Triad	\$170,720	\$ 61,351	\$169,082	\$ 54,951 ¹	(\$8,038)
Western	\$169,229	\$ 41,120	\$142,483	\$ 53,120	(\$14,746)
Eastern	\$163,077	\$ 51,800	\$162,965	\$ 52,262	\$350
Southeastern	\$162,379	\$ 60,832	\$125,010	\$ 62,832 ¹	(\$35,369)
Greater Charlotte²	\$153,585	\$185,599 ²	\$162,437	\$174,864 ²	(\$1,883)
Statewide Oversight³	\$453,417	\$203,162	\$272,676	\$21,075	(\$362,828)
Total					(\$409,820)

¹ Triad and Southeastern office will have lower rent costs than projected in the 2014 budget.

² Charlotte costs include activities for a \$300,000 grant funding for BioMoto, regional STEM project.

³ Statewide VP position was combined with Eastern regional director, saving one FTE.

The Board believes that regional offices are still in their early stages and are just beginning to show success. Significant cuts to expenses in FY 2014 reduced operations by the equivalent of one office. Given those factors, the Board recommends keeping all five regional offices open as currently established and continuing to monitor their metrics.

Actions

- The regional office budget has been reduced by \$409,820 to accommodate budget cuts. The savings came from combining an oversight position with a regional director position, consolidating administrative support, eliminating two staff members, and reducing rent expenses. This is the equivalent of closing more than one office.
- The Board will continue to review success metrics for the regional offices.

Staffing Requirements

3

*The board shall review ... **staffing requirements** at the Center's headquarters and at the regional offices and to determine whether some staff positions are duplicated and, if so, whether those duplications can be reduced or eliminated.*

Response

NCBiotech's grant and loan award recipients leverage significant additional investment, between \$4 and \$117 per dollar awarded by NCBiotech, depending on the program. This return, documented specifically in questions 4 and 5, is driven by personnel who have expertise in specific functional areas and can evaluate, manage and mitigate financial and technical risk. This review determined that such positions are not duplicated within NCBiotech, and that the number and type of positions are critical to achieving the significant return for state dollars.

NCBiotech has reduced staffing from 86 to 64 following budget cuts and program review (question 1). These cuts included staff for eliminated funding and programs as well as professional support positions.

Discussion

Question 4 (grants and loans vs staffing), discusses the specific expertise and individual attention required to run NCBiotech's funding programs. Each job description for funding staff requires a different mix of education, scientific and business expertise, and industry experience. This is true of programmatic activities like agricultural biotechnology, which requires sector-specific expertise.

NCBiotech also employs professional staff for financial management and accounting, human resources, conference center operations, information technology and communications. These staff members specialize in a specific job activity. While cross-training does occur to maintain business continuity, job descriptions are not redundant.

The majority (73 percent) of NCBiotech positions are client-facing. Funding staff work with clients to solve technical and business questions. Program staff uses their experience and connections to bridge gaps for North Carolina's job-creating companies. Professional communications and library staff advise small companies in areas where many cannot afford their own staff. These connections promote industry growth and contribute to the success of funding activities.

The Center's human resources staff has processes in place to review job descriptions annually. Each job is also reviewed as turnover occurs to assess whether the position is critical or could be covered by other staff members. Each vacancy is filled through a competitive process based on skills and expertise of the candidates.

The Board also looked for redundancy across staffing positions. Of NCBiotech's 64 positions, 54 have unique job descriptions. To further evaluate for duplication, the Board mapped staffing to the diagram (figure 3-1). In this format, it is clear that each position has specific goals that are not redundant with other positions.

Staffing Reductions

As a part of the 27 percent state appropriation cut, NCBiotech cut a number of funding and program activities (question 1). The staffing for funding, programmatic and support positions was also downsized as a part of that process. Throughout 2013, NCBiotech staff was reduced by 26 percent, from 86 in January to 64 in December. Ultimately, this will save \$1.6 million in personnel costs.

The savings are slightly less for FY 2014 as reductions were made after the fiscal year started.

Conclusions

Upon review of the current organizational structure at NCBiotech, in concert with the staffing diagram, the Board finds no areas of staffing duplication. Previous reductions in staff were made in calendar year 2013, and calendar year 2014 is a transitional year to assess these changes and continue upon this path.

In addition, the Board notes that NCBiotech's ability to achieve its mission relies on expert staff to implement funding and program activities. Each job requires specific knowledge, contacts and the ability to connect the parts of the technology development continuum. This capacity to make connections sets North Carolina's life science development apart from other states.

Actions

- During 2013, NCBiotech staff has been reduced from 86 to 64. The reduction still allows NCBiotech to operate programs efficiently.
- No staff additions or further reductions are recommended by the Board at this time. To coordinate with program and industry growth, the Board will continue to be apprised of staffing needs via formal report to the Board.

Connecting with Novartis

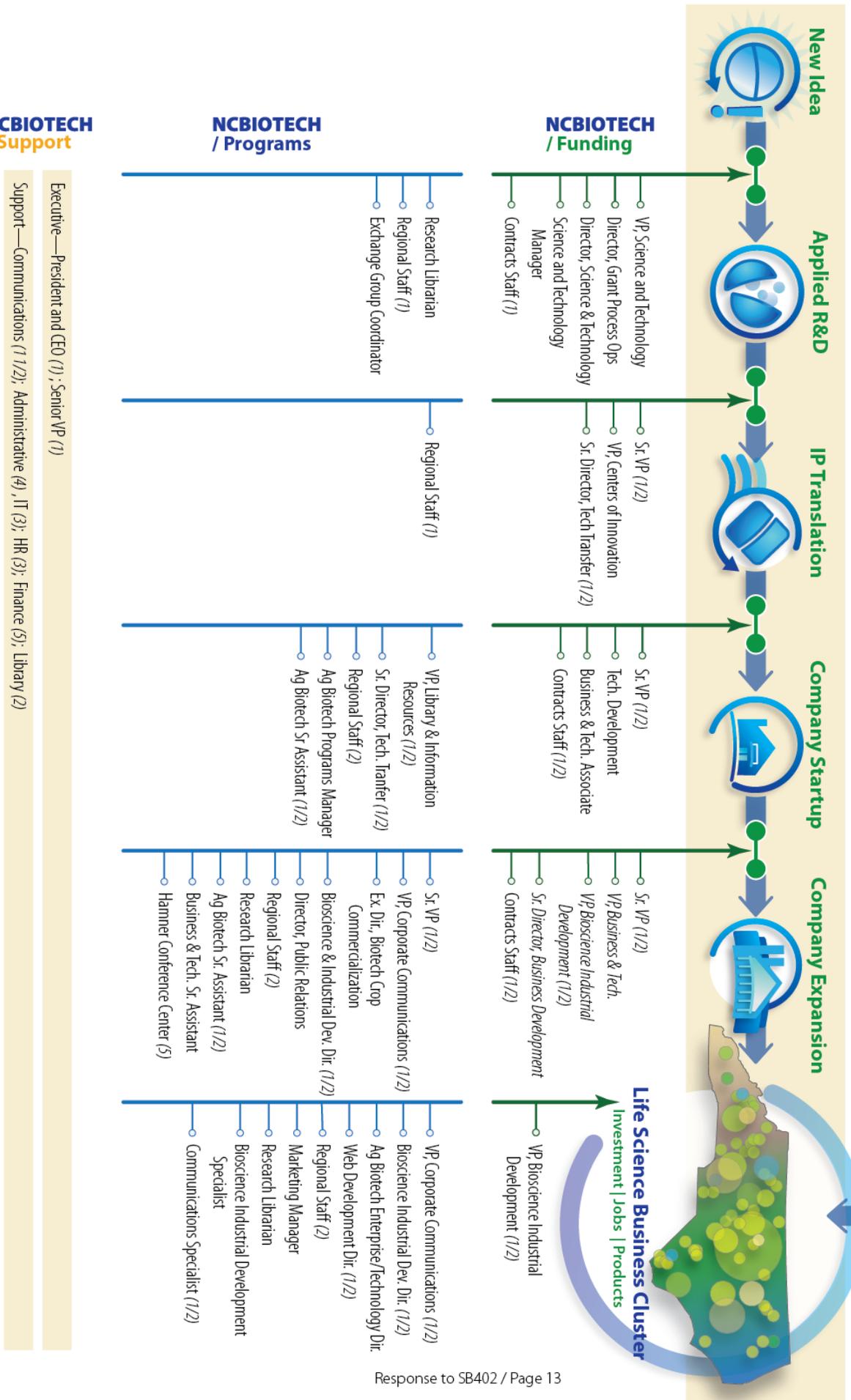
The NCBiotech Pharma Partnering Program links multinational companies with NC-based research. Company representatives typically meet with a dozen NC companies or academic centers during a visit. The ultimate goal is to spark collaborations that accelerate innovation and job creation here.

By all accounts it's working. Participants have included Eli Lilly, J&J, Abbott, Celgene, Novartis, Novo Nordisk, Daiichi Sankyo, and Sinopharm.

"You have a very good system in place...It is very important for us in big pharma to have a point of contact who understands what we are looking for," – Novartis participant.

Figure 3-1 NCBIOTECH/Staffing for Business Development for N.C.

As of 12/31/2013, NCBIotech has 64 positions distributed as follows:



Grants and Loans vs. Staffing

4

*The board shall review ... Whether State funds would be better used to **provide additional grants and loans rather than to support current staffing levels** and whether reducing current staffing levels to increase the amount of funds available for grants and loans would provide a positive return on investment. The Center shall determine the appropriate percentage of State funds that should be distributed for grants, loans, and staff to maximize the return on State funds appropriated to the Center.*

Response

NCBiotech grants and loans work with and rely upon the many other Center activities that grow the life science industry in North Carolina. The Board examined and restructured activities to retain the funding, program and support activities that are most important to growing the state's life science industry and creating high-paying jobs. This restructuring will fund grants that drive innovation and company start-up activity; expand impact of the small-company loan program; provide staff expertise to evaluate funding requests; and execute programs that help the grant and loan programs succeed.

The Board believes that this distribution of funding, programs and support is the correct infrastructure for moving forward. To give one example, this infrastructure has awarded small-company loans that have been critical to catalyzing nearly \$3 billion in external funding. This infrastructure is necessary to ensure taxpayer dollars are spent well, and it is capable of awarding more dollars.

Discussion

As part of the restructuring, five funding programs and numerous other activities were canceled (question 1). These program closures led to a reduction in NCBiotech personnel from 86 on January 1, 2013 to 64 on December 31, 2013. As shown in figure 4-1, the resulting fiscal 2015 budget will allocate 64 percent of the \$12.6M state appropriation to funding activities, 20 percent to programmatic activities and 16 percent to support for these funding and programmatic activities.

The Board believes that this refined infrastructure more tightly targets jobs creation. It could easily and effectively award more state dollars, further increasing the state's return on investment.

NCBIOTECH /Spending Breakdown
FY 2015 projected

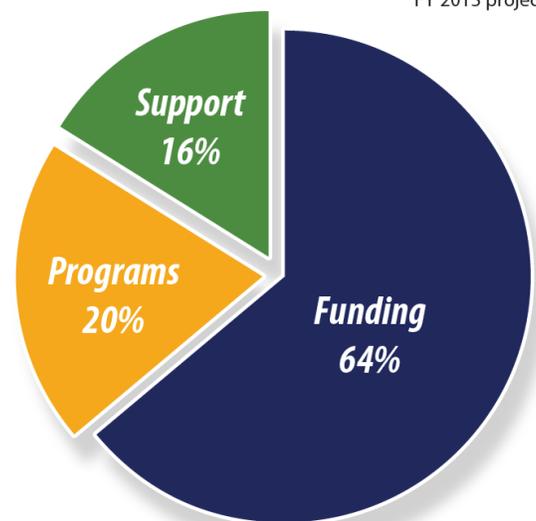


Figure 4-1

Grants and Innovation

NCBiotech grants are foundational to strengthening innovation and demonstrate that creativity and innovation are critical components of economic growth. This encourages researchers to develop ideas with commercialization as a focus. NCBiotech's grant programs:

- Directly support university-company partnerships
- Help N.C.-based university researchers compete more effectively for federal funding
- Focus attention on promising life science sectors such as marine biotechnology, nanotechnology and personalized medicine
- Provide support for university technology transfer offices to develop technologies so they are ready for licensing to an existing company or new start-up

Quantitative results for grant programs range from \$4 to \$73 in external follow-on funding per state dollar depending on program. The overall average for research grant programs is \$28. These figures include additional investment into these funded projects, such as federal and commercial dollars. (Appendix O) Other results include scientific publications, patents, and start-up company formation.

Both Grants and Loans go to projects of commercial significance that lead to further job creation and wealth for North Carolinians.

Grants (Appendix N) are awarded to universities and other non-profit organizations. These awards are not repaid.

Loans (Appendix L) are awarded to promising emerging companies at specific stages. These awards are repaid with interest.

Loan Successes

NCBiotech loans are critical to life science company start-up and job growth in North Carolina. Only North Carolina-based biotechnology companies are eligible for these loans, and NCBiotech employs a thorough due-diligence process in reviewing loan applications. Most companies selected for funding by NCBiotech have no other funding options. (See Bridging the Gaps, http://www.ncbiotech.org/sites/default/files/BridgingtheGaps_0.pdf) Private

Most companies selected for funding by NCBiotech have no other funding options

investors such as venture capitalists and angel groups typically avoid investing in such early-stage companies, independent of how promising they might be. This is because the technology has not gone through proof-of-concept studies, often funded by NCBiotech. As constituents frequently note, NCBiotech loan funding "is the only game in town." Without this loan funding, many promising start-ups would not have the opportunity to emerge and complete the early

product testing required to attract follow-on external funding and drive company growth. In conjunction with other Center activities, these loans give N.C.-based companies a springboard to funding from venture capital firms, angel investors, foundations, federal sources and strategic partners. (Appendix P)

Quantitative metrics substantiate the importance of NCBiotech loans to company growth and job creation:

- **One NCBiotech loan dollar is followed by \$117 in external funding:** For every \$1 in loans awarded, companies have received \$117 in subsequent funding from external sources such as venture capital (VC) and angel investors, strategic partners and foundations. Over the past 24 years, the Center's \$25 million in

loan awards have led to an additional \$2.9 billion in external funding for these companies. This funding is documented in appendix M.

- **For every \$2,079 in net loan disbursements, companies create a new job:** Subsequent to the Center’s loan awards, 2,952 N.C.-based jobs have been created at loan portfolio companies and, on average, these high-paying jobs are in place for more than 10 years.
- **In the past three years, NCBiotech loans were key to the startup of 18 companies:** All of these companies remain in business in North Carolina today. A large number of companies also achieve significant milestones each year. A sampling of 2013 successes is in Appendix P.
- **Loan payoffs exceed write-offs by a 4:1 ratio:** Despite making loans to high-risk, early-stage life science companies when little to no other funding is available, the Center has a high loan repayment success rate. The ratio of principal payoffs to principal write-offs is 4 to 1. In addition, interest payments and warrant benefits have exceeded the amount of principal written off. This reflects thorough due diligence and the impact of NCBiotech programmatic activities (including VC and strategic partner connections that lead to external investments).

Expert Review

Proper assessment of the grant and loan applications requires an understanding of biotechnology concepts that can only be gained by years of studying disease mechanisms and evaluating different treatment methods. The Center’s grant and loan evaluation team includes eight members with Ph.D.s, and six members with significant biopharmaceutical industry experience. For larger grants and loans, external experts, who have specific experience in the field of the applicant, add another layer of review. Finally, all grant and loan applications above \$75,000 must be approved by designated subcommittees of the NCBiotech Board.

This process (question 5) ensures that the state’s funding is awarded to the applicants that have the highest likelihood for success in shepherding innovations that drive job creation, increase state tax dollars and improve patient outcomes. The grant and loan program metrics show clearly that this process is working.

Reducing the size of the evaluation team has three potential impacts:

- 1) Fewer grants and loans awarded, or
- 2) Less due diligence per grant or loan application, diminishing the quality and impact of the grants and loans.
- 3) Fewer complementary programmatic activities.

Program Activities

NCBiotech balances the need for direct funding of grants and loans with the need for other, non-funding activities that create the right environment for life science industry growth. Experts on the grant and loan evaluation team

Connections and Funding Fight Cancer

NCBiotech’s loan evaluation team members began working with CivaTech Oncology’s management team in 2010 and awarded the company a Small Business Research Loan in 2012. The company is developing its CivaString and CivaSheet products for cancers including prostate and breast cancer.

“They have helped us in a lot of ways, not just in terms of the funding, but in terms of collaborations and referring us to people in the industry.”

CivaTech CEO Suzanne Babcock
Triangle Business Journal, June 7, 2013

help grant and loan recipients leverage their Center funding, or provide needed support for companies that have not received Center funding. Staff may provide:

- Advice on strategy, presentations, documentation, and funding opportunities
- Connections to external funding sources such as VC, angels, foundations, crowdfunders and federal agencies
- Connections to strategic partners such as large pharma, biotech or medical device companies
- Connections to service providers and potential employees

In addition, NCBiotech runs a number of non-funding programs that promote industry growth. The Bioscience Industrial Development team develops recruitment prospects and works on in-state expansion. Ag Biotech efforts, from large-company connections to universities to startup support, are coordinated by the AgBiotech Initiative staff. And numerous events, job matching services, market research reports and other supporting activities are provided by NCBiotech staff. (Figure 3-1) The Board affirms that this comprehensive effort is critical to the success of grant recipients, the small-company loan portfolio and the overall life science community.

Small Companies Get Funding and More

Two NCBiotech loans helped Ridge Diagnostics commercialize its first-in-class blood test for major depressive disorder. The 2007 and 2009 loans helped Ridge leverage more than \$7M in funding.

“This was crucial for our development and it is why we were able to equip and staff a commercial diagnostic laboratory in RTP,” said Ridge CEO John Bilello, who added that NCBiotech support was key to the company’s ability to stay in North Carolina.

“However, while early funding was and is critical, that is not all we have gained from our interaction with the NC Biotechnology Center. Through its educational programs and business network we have forged a number of key relationships and interactions between other business entities both small and large.”

Connections made by NCBiotech staff members can be as important to the success of the state’s companies and universities as grants and loans. In fiscal 2013 alone, loan evaluation team members were responsible for 316 company-investor introductions, 85 foundation introductions and 161 partner introductions. These connections lead to further external funding; for instance, connections made by NCBiotech team members at our Angel Summit Lunches in 2013 have recently led to two angel fund investments in presenting North Carolina-based life science companies. A full list of these activities is in Appendix Q.

Summary

The success of NCBiotech grant and loan programs depends on expert evaluation during the pre-award process. Without these experts, state tax dollars would leverage fewer company investments, and ultimately create fewer jobs. These evaluation teams must remain intact.

Second, the staff dedicated to program activities has a significant impact on the life science community. These programs strengthen the overall sector and give the funding recipients more chance to succeed. Program activities also create a vibrant community to attract companies, employees, investments and jobs to North Carolina. The two depend on each other and would not have the same success alone.

Two Board committees evaluated NCBiotech's funding and program activities and staffing in 2012 and 2013. The Strategic Oversight Committee considered industry growth, changing needs, and activities needed to drive future growth. The Corporate Leadership Committee considered staffing needed to lead that growth. As a result of this process, the Board sees the need for several new programs. These should be funded with additional support from the state.

New Programs

New Industrial Public-Private Partnership Grant: Building a culture of entrepreneurship at the universities is crucial. While the pursuit of knowledge for its own sake can yield unexpected breakthroughs, a more applied approach can also have economic benefit. However, resources are often scarce for universities to build strengths in this area. North Carolina's universities have tremendous expertise in the life sciences; providing additional resources will accelerate mobilizing this expertise to foster key relationships with industry. This new NCBiotech program, the Industrial Public-Private Partnership Grant, is proposed to directly foster university-company collaborations with the goal of stimulating large-scale long-term partnerships. These funds will be seed funds, with a required match (proposed to be 3X) from both industry and university partners, to multiply the funds. The focus will be on incentivizing and strengthening strategic relationships between universities and industry as an economic development tool for the state.

New \$500,000 Loan: With an increase in the loan program budget, NCBiotech would be able to offer a \$500,000 loan to help more advanced companies bridge the gap. Current Center loans range in maximum size from \$50,000 to \$250,000. A loan of this size, which would require a matching investment from institutional investors or partners, could be used to fund higher-cost projects and would be limited to companies with clear proof-of-concept from earlier studies. Life science companies at this stage of development are often approaching the point when significant new hiring would be required; as such, these larger loans would be expected to have an even greater impact on job creation than current NCBiotech loans.

Expanded Economic Development Award: Life science companies must overcome unique technical, business and financial hurdles to succeed. The existing Economic Development Award (EDA) leverages NCBiotech's expertise and resources to extend its grant and loan program impact to attract and grow new jobs in North Carolina. The EDA program fills a gap where existing state, regional and local financial support and incentive programs fail to adequately address the unique profile of life science companies. Expanding this program will allow N.C. to compete more aggressively with other states pursuing new life science jobs and have an even greater impact on company attraction to, and expansion in, North Carolina.

Agricultural Biotechnology Leadership: NCBiotech launched its AgBiotech Initiative in January 2010. Ag biotech is key to meeting the global demand for food, fuel, medicine and sustainable materials. North Carolina has a strong position, with five of the six world leaders in ag biotech, as well as Novozymes, a global enzymes producer. In all, 80-plus ag biotech companies employ more than 8,100 people in North Carolina.

So far, the AgBiotech Initiative has launched the Biotechnology Crop Commercialization Center to develop new or enhanced crops for N.C. agribusiness. The project has saved about \$30 million for the swine industry. The Initiative has also promoted growth of the state's early-stage companies through events, networking, and connections to investors. Finally, since 2010, eight ag biotech companies have announced more than \$279 million in prospective investments. NCBiotech has leveraged \$1.5M in private dollars for this initiative, and additional state dollars are needed to increase the impact of industry support.

Additional state funding will enhance the projects of the Crop Commercialization Center; implement programs to catalyze growth of entrepreneurial companies; promote understanding and acceptance of technology in ag; and attract more ag and ag biotech businesses to North Carolina. Ultimately, the goal is to solidify North Carolina's position as a leader in agricultural biotechnology. North Carolina has done well to wrest this title from the Midwest, and St. Louis, Iowa, Kansas and others are working aggressively with state programs to win it back.

Biodefense and other life science related sectors: Military and homeland biodefense development is a critical need for our nation and is also an area that has potential spillover impacts to other commercial areas of biosciences. This seems like a natural fit for the state since North Carolina hosts a major military presence as well as a strong life science sector. However, despite this potential synergy our universities have relatively low levels of Department of Defense funding. There is little to no comfort level with the DoD funding process – a distinctly different funding mechanism than that used by the NIH. The UNC System and some universities have recognized this issue and are working toward improvement, but with few resources. More broadly, this has a trickledown effect to North Carolina's start-up companies who also do not receive much funding from DoD. (Full report Appendix R.)

This new funding will be used through the Centers of Innovation (COI) grant program. NCBiotech created the COI program to make innovation and commercialization a strategic priority. The individual COI initiatives focus on accelerating the growth of targeted industry sectors. In considering biodefense opportunities through the Centers of Innovation Program, NCBiotech will take a broad view to include three areas of opportunity: Bioterrorism and emerging infectious diseases, including detection and countermeasures; DoD strategic biomedical interests including traumatic brain injury, combat casualty care and warfighter restoration; and Veterans Administration R&D activities, as there is already a network of medical research activities aligned with universities.

Actions

- Adjusted the funding, program and support funding ratio by cutting or curtailing funding and program activities, and reducing staff. This maximizes the return on state funds.

The Board recommends creation of the following programs with additional state funding:

- Initiate a new academic grant program to spur university-company collaborations
- Initiate a new loan program focused on a larger \$500,000 loan to drive additional job growth by playing a larger role in bridging companies across the early-stage funding gap
- Enhance the existing Economic Development Award program to strengthen job recruitment
- Leverage ag biotech strengths to stake North Carolina's leadership in the sector
- Allocate additional funds for grants to new Centers of Innovation to drive sector growth

Grants and Loan Efficiency

5

*The board shall review ... and evaluate the administration of grant and loan programs funded in any way with State funds to **ensure that the programs are conducted in a cost-efficient manner.***

Response

NCBiotech runs a suite of targeted grant and loan programs designed to strengthen N.C.'s life science sector. In-house scientists and external experts evaluate applications. A Board committee approves the best proposals. From 218 applications requesting more than \$20 million, NCBiotech made 151 grants and loans for \$10.7 million in FY2013. (Appendix S)

The Board looked at performance in four key areas to analyze cost efficiency in administration of grant and loan programs: labor from life science experts at minimum cost, use of technology and process, maximization of benefits from targeted investments, and commitment to good stewardship and compliance. The Board concludes that NCBiotech oversight is among the strongest in grant and loan programs across the state.

Discussion: Expert labor at minimum cost

Proper evaluation of complex life science projects requires specific scientific expertise and knowledge targeted to the topic of each proposal. NCBiotech's award programs rely on life science experts in N.C. and nationwide for an objective review that ensures state dollars are spent wisely.

NCBiotech staff provides initial review and evaluation for all funding requests. This work leverages many volunteer hours from external experts, recruited by NCBiotech's trained technical staff. This approach minimizes the employee time and maximizes technical expertise and objectivity at little or no cost. In the few cases where an honorarium is provided, it is generally below market rate. Examples of 2013 projects are included in Appendix S.

The Board found that professionals with the required sector expertise will donate many hours, because of overall interest in the sector, support for the Center's mission, and high levels of trust in the Center's track record. In fiscal year 2013, 285 life science experts collectively donated almost a half a year to the Center for proposal evaluation, resulting in a conservative estimate of \$38,000 in scientific expert consulting services at no cost.

Technology and Process

The Center uses grants administration software, SOPs, and other best practices in conducting administration of the state's investment.

- Electronic proposal and review systems streamline personnel time and resources to handle the multiple stages of proposal processing; this system is integrated with the post-award grants-tracking system.
- The electronic grants-tracking system increases efficiency of post-award management.
- Processes and SOPs guide pre- and post-award procedures and functions, optimizing staff time spent on review.

Maximizing Benefits from Targeted Investment

Center staff and funding activities are aligned and designed to leverage taxpayer dollars. As documented in question 4, NCBiotech grant and loan recipients raise more dollars following their funding, creating a strong return to the state. This process to maximize benefits from targeted investments is built on six pillars:

1. Community Need: The Board, through its Science, Education and Technology and Equity Investment committees, annually assesses needs of organizations with life science interests and projects. As the community changes, so do the programs. (Guidelines in Appendix N.)
2. Community Readiness: NCBiotech staff, including regional staff, ensures that applicants know about the programs and understand how to develop a proposal that will benefit the state.
3. Consultations on specific projects allow NCBiotech to enhance the success of North Carolina scientists and business persons seeking funding for innovative ideas. All applicants are encouraged to consult with program staff regarding their specific project prior to submission.
4. Competition: Demand far exceeds funding available; only the highest quality projects receive an award. In 2013, more than \$20 million was requested through Center programs, but less than \$11 million was awarded. Requests were nearly double available funds.
5. Expert Review: Proposals submitted to the Center are reviewed by business and scientific experts nationwide. The science behind these requests is very technical, as opposed to the programmatic grants that may be more common in economic development. (Appendix S)
6. Prove It: NCBiotech monitors awards for years after funding has been disbursed. This follow-up allows us to evaluate which activities yield maximum benefit. Results range from \$4 to \$117 in additional funding, as well as company launches, patents and publications. Programs with less impact were curtailed or eliminated following the recent budget reduction. (Appendices M and O)

Good Stewardship/Compliance

NCBiotech has processes, procedures, and trained staff that ensure compliance. Annually, an independent audit firm audits the financial statements and has reported no weakness in internal controls. Last year, the Center underwent a successful state audit. Two minor recommendations were addressed immediately. (Appendix T).

Conclusion

NCBiotech's award performance is strong. The staff costs leverage significant volunteer hours for high-quality proposal review, which yields an awardee portfolio that attracts significant follow-on funding and return to the state. The Board concludes that NCBiotech funding infrastructure is cost-effective and could efficiently award more dollars with minimal administrative cost.

Action

- No further action is suggested at this time.

Cash Balances

6

The board shall review ... any and all **cash balances on hand** to determine ways in which those cash balances can be used quickly to make grants and loans.

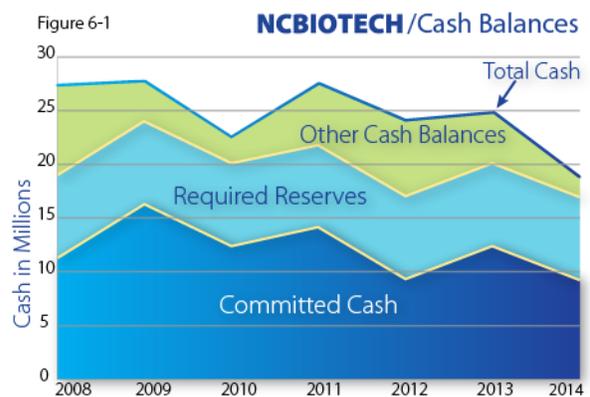
Response

Cash balances are defined as cash that is on hand. NCBIotech maintains three types of cash balances, two of which are created by its due-diligence policies for awarding state tax dollars. The first is cash for grants and loans that will be made in the current fiscal year. The second is cash committed by contract for grants and loans made in previous fiscal years. The third is cash for operating reserves. Any cash balances that do not fall into these three categories (other cash balances) will be re-allocated toward goals for which state funds are appropriated, currently estimated at \$2 million.

Discussion: Mandatory cash balances

The first type of cash balance is planned for use in the current fiscal year's grant and loan programs. NCBIotech plans to award \$6.8 million this fiscal year. Awards are staggered throughout the year as staff due-diligence, external review and Board approval processes are completed. All funds are committed by the end of the fiscal year, with contracts that outline the criteria for disbursing awards.

The second type of cash balance is funds that are contractually committed for grants and loans made in previous fiscal years (committed cash). This amount is currently nearly \$12 million. Since cash is disbursed to awardees only when award milestones are met, this can create the appearance of available cash. However, these funds are distributed over a contracted period of time that can extend several years as milestones are met. It does not mean that this committed cash is available for other uses; using this cash for other purposes could mean defaulting on signed contracts. (These two types of cash balances are represented in figure 6-1 as committed cash. This figure graphs commitments at the end of each fiscal year. All award dollars for the current fiscal year are contractually committed in this snapshot in time.)



The third category of mandatory cash balance is operating reserves. These funds cover the period between the beginning of the fiscal year and the date when state funds are received. These reserves also promote business continuity in case of emergency, crisis or natural disaster. These funds include personnel costs, operating expenses, and any new grants and loans made prior to receipt of state funds. This approach ensures programs will continue, a strategic goal for nonprofits recommended broadly by independent experts. (Appendix U)

Based on those best practice documents, NCBiotech determines the operating reserves by multiplying the average monthly expenses by a conservative estimate of the number of months between the beginning of the fiscal year and the month in which state funds will be received. This period has recently ranged from four to seven months. As a result of this process, NCBiotech is implementing a policy to set the operating reserves at five months of expenses, or \$7.5 million. This is actually fewer than the six months that the Center recommends to its portfolio loan companies.

Other cash balances

Cash balances outside of mandatory cash balances discussed above result from investment and interest returns to the Center. These returns come from the accumulation of years of small returns which include but are not limited to interest on cash investments, interest repaid on loans and warrant payments.

When this type of cash balance grows beyond a certain point, the additional funds have historically been used in accordance with the goals for which state funds are appropriated to the Center. For example, in both 2012 and 2013, the Board's Executive Committee allocated \$1.2M and \$1.1M, respectively, to grants and loans mid-year.

To date, the amount and timing of these re-allocations have been handled at the discretion of the Executive Committee. Moving forward, a new Board policy will be created that states that when funds in this category reach the level of 20 percent or more of operating reserves it will trigger a decision in the current or immediately following fiscal year to award or invest those funds in a manner consistent with the goals for which state funds are appropriated to the Center.

The Center currently has approximately \$2 million in this type of cash balance. It is the plan for these funds to be handled in the manner discussed above. However, since this has been an unusual year for the Center, with some disruption in the normal flow of business due to the decrease in the state appropriation, it has resulted in some timing delays. Therefore, these additional dollars will be re-allocated and awarded or invested in either the current (2014) or following (2015) fiscal year to allow more time to evaluate opportunities that create benefit for the State.

Actions

- The Board will continue with its plans to invest the estimated \$2 million of reserves into programs that will create return on investment to the state.
- The Board will formalize the Executive Committee's current practice that designates the amount of operating reserves as \$7.5M and that any funds that exceed this amount by 20 percent or more will be allocated to the grant, loan, and other investment programs in the following fiscal year in a manner consistent with the goals for which state funds are appropriated to the Center.

Board Size

7

*The board shall review ... The **size of the Board and the overall governance of the Center** to determine whether changes in either or both can be made to make the Center more cost-efficient and effective in providing grants or loans.*

Response

NCBiotech's volunteer Board includes 40 members appointed through a mix of ex-officio positions, elected official appointments and at-large appointments. The Board exercises its oversight through standing and ad hoc committees. The breadth of NCBiotech activities across the technology-based economic development continuum (figure 1-1) requires a diversity of academic, business, policy, and regional expertise for proper oversight. These Board members serve on a volunteer basis, and operational costs total approximately \$18,000 annually.

This review identified several advantages of the current Board structure, which effectively administers funding and programs. The Board will appoint a committee to study options for reducing board size and the impact on effectiveness. This committee will report its findings by June 30, 2014.

Discussion: Current Board Structure and Committees

NCBiotech's by-laws state that the Board of Directors (Appendix F) shall be comprised of 40 individuals:

- 9 *ex officio* appointees or their designees
 - Secretary of Commerce
 - President of the UNC System,
 - President of the NC Community College System
 - Chancellors from UNC Chapel Hill, NCSU, and ECU
 - President or Chancellor of Duke University
 - President and CEO of Wake Forest University Health Sciences
 - President and CEO of the North Carolina Biotechnology Center
- 12 state elected official appointees (3 each from the Governor, Lt. Governor, Senate President *Pro Tempore*, and the Speaker of the House)
- 19 at-large appointees as recommended by the Board's nominating committee to the full Board for confirmation. These appointments fill gaps in business, financial and scientific expertise on committees that have financial oversight.

All *ex officio* directors (or their designees) serve as long as they hold their office. All other directors serve two-year terms.

Board oversight of NCBiotech operations is largely provided by six standing committees (Appendix G). All standing committees have one or more members who also serve on the Executive Committee. The standing committees:

- Executive Committee
- Science, Education and Technology (SET) Committee

- Equity Investment Committee (EIC)
- Audit Committee
- Nominating Committee
- Management Development and Compensation Committee (MDCC)

Occasionally, time-limited, ad hoc committees have been established and later dissolved to provide oversight for specific NCBiotech activities. Two examples are the Strategic Oversight and the Corporate Leadership committees mentioned in question 4.

In addition, various advisory committees can be established by the Board. Presently, NCBiotech has established regional advisory committees to provide guidance to each of the five regional offices. These are comprised of regional scientific, business and community leaders.

The full Board meets quarterly as do the Executive, SET and Equity Investment committees. The Audit and Nominating committees as well as the MDCC meet less regularly as duties require.

Operations

All NCBiotech programs and activities are overseen by the full Board. Specifically, the Board approves the budget, the election of officers and appointment of new Board members as well as any significant changes in NCBiotech programs or activities. Most remaining oversight functions have been delegated to the standing committees, thereby drawing upon the expertise of individual Board members for more technical or detailed oversight functions.

The duties of the standing committees are:

- The Executive Committee (10 members) Responsible for implementing direction, approving new programs, approving Center of Innovation funding as well as approving changes in existing grant or loan terms. The Executive Committee acts on behalf of the Board when needed.
- The Science, Education and Technology (SET) Committee (9 members) All hold either a Ph.D. or M.D. degree and have been (or are) practicing scientists. This is an important point since the grants approved for funding by the SET Committee represent highly complex and innovative proposals at the beginning of the technology development life cycle. All members are employed by or hold emeritus appointments at N.C. universities. Most serve as the Chancellor designate to the Board and hold the position of Vice Chancellor for Research at their respective universities. The SET Committee has authority for all research grant approvals up to \$350,000 per grant. The SET Committee also has the authority to adjust budget lines within an approved grant budget. However, the Committee cannot authorize expenditures that exceed the Board-established budget for grants.
- Equity Investment Committee (EIC) (5 members) All come from the financial or life science industries. All have served in executive management or C-level positions. The EIC has authority for all business loan approvals up to \$350,000 per loan. The EIC Committee also has the authority to adjust budget lines within an approved loan budget. However, the Committee cannot authorize expenditures that exceed the Board-established budget for loans.
- Audit Committee (4 members) All have significant finance, senior management and/or legal experience. Each year NCBiotech undergoes a full external audit. The Audit Committee's responsibilities include: i) oversight of accounting controls, ii) selection of the independent auditors, iii) review of the annual audit plan with the independent auditors and iv) review of the annual audit with the independent auditors. In

addition, the Audit Committee oversees the completion of annual tax documents, including the Form 990 for nonprofits.

- Nominating Committee (5 members) The committee develops and maintains a list of potential Board members and considers candidates who represent a balance of scientific expertise, business experience and regional representation, to fill the at-large seats. The Nominating Committee recommends to the Executive Committee and then to the full Board a slate of candidates for election to fill Board seats that have opened. All Board members who are appointed by elected officials, as well as any changes in the *ex officio* directors or their designees, are reported to the full Board by this committee.
- Management Development and Compensation Committee (MDCC) (5 members) The committee is chaired by the Board chair and all five members serve on the Executive Committee. The MDCC is responsible for the professional development of senior management and for setting compensation of NCBiotech officers.

Evaluation

NCBiotech requires a Board of Directors with significant life science business and technical expertise to oversee NCBiotech's complex activities and operations. The Board has broad regional representation with 35 percent from outside the Research Triangle area. Most directors have research or industry expertise. This expertise is viewed as significant asset, especially important for appointment to the SET and EIC where grant and loan funding decisions are made. Based on this analysis, the review and decision-making processes that support NCBiotech funding activities are highly efficient and cost effective. Overall, the Board is well organized and has distributed the work duties and oversight responsibilities among a limited number of standing committees. All Board members serve on a volunteer basis. These unpaid directors expend significant time working on behalf of NCBiotech. (Appendix K).

The financial cost of the Board is minimal. As noted, Board members are unpaid; however, they can request travel-related expense reimbursements. In addition, meals are usually provided for the full Board. Other costs charged to the Board include mailing fees, IT or phone conference lines for members not attending in person, and costs related to bringing NCBiotech partners to Board meetings for formal presentations. In FY 2013, Board-related expenses totaled approximately \$18,000.

The current Board of 40 members is well managed and provides balanced representation of the many constituencies served by NCBiotech. Engagement is high, with at least three-fourths of Board members routinely in attendance at full Board meetings. In addition, the oversight of an organization with the many complex functions of NCBiotech requires a sufficient number of directors with the technical and business expertise to make strong fiduciary decisions and to provide informed strategic guidance.

A significant reduction in Board size may make NCBiotech less effective in providing grants, loans and programs to the life science community. Too few directors could create gaps in knowledge needed to effectively evaluate funding proposals. Still, other options to meet these needs exist, and the Board will appoint a committee to consider the options and their impact.

Action

- The size of the Board will be reviewed by a committee of the Board. The proposed committee would assess the appropriate size of a Board that can effectively balance regional, government, academic and industrial representatives with appropriate knowledge to guide NCBiotech's operations. Findings will be reported to the full Board by June 30, 2014.

Life Science Competitive Grants

8

*The board shall review ... whether it would be beneficial to the State if the funds that might be appropriated to the Center for the 2014-2015 fiscal year, and any funds that might be appropriated to the Center in future fiscal years, were instead appropriated to the **Department of Commerce for purposes of establishing and implementing a competitive grants process.***

Response

The Board does not see the benefit of recreating NCBiotech’s funding programs in the Department of Commerce. This would require Commerce to create new programs and hire additional staff with scientific and financial expertise already present at NCBiotech (figure 1-1). The companies targeted by these new funding programs would be much earlier-stage than Commerce typically engages with to support business growth. Additionally, the Center’s benefits to the state go beyond simply providing grant and loan funds. Failing to recreate NCBiotech’s broad approach to company growth would diminish the impact of investments in the sector.

Discussion

Life science product development has a long timeline. Companies that successfully navigate technology transfer and startup activities must then conduct discovery research, pre-clinical studies and multi-phase clinical trials before a product comes to market. They do this over several years with no product revenue, which creates a unique funding dilemma.

NCBiotech funding, program and support activities address specific gaps and company needs across this timeline (figure 1-1). These activities require a deep understanding of the strengths of the technology, its market potential and its risk profile. Any funding for early-stage activities must have a mechanism to help companies over these hurdles. Otherwise, effectiveness of the grants is diminished.

Program Effectiveness

Other sections of this document discuss the outcomes of NCBiotech funding programs. The rigorous due diligence on these awards is a key factor in producing these results (Appendix B). A study of approaches to company and economic development found that NCBiotech’s mediated approach was the most successful and a best practice (Appendix V). Commerce currently does not provide this type of support.

Company Startup and Long-Term Growth

Life science economic development, for reasons previously discussed, is a longer-term proposition than building an IT company or recruiting a services company. NCBiotech has developed funding and support programs to accelerate early-stage growth at many different points. These programs have an economic development component in that they keep small companies in North Carolina, when other states offer them incentives to relocate.

Several NCBiotech programs also engage directly with the universities and their technology transfer offices. This partnership, along with the Technology Enhancement Grant, Company Inception Loan and BATON network of service providers, accelerates company creation and removes common obstacles to early growth. The result is that companies startup and grow in North Carolina and create jobs more quickly. NCBiotech has worked to develop and align these programs over the last decade, and these activities are currently outside Commerce’s scope.

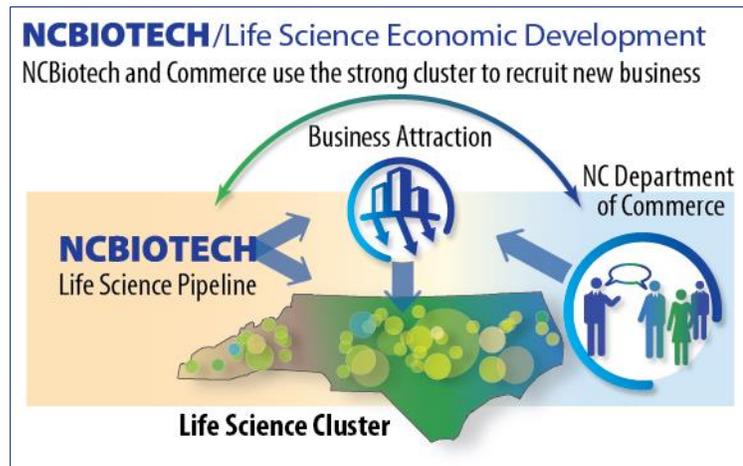
Early-Stage Support

The results of NCBiotech’s programs align well with a department of commerce. However, NCBiotech activities address needs of earlier-stage companies than economic development activities at North Carolina’s Department of Commerce. NCBiotech’s award programs could be recreated and added as a function in Commerce. However, moving these existing functions away from an established and well-known entity would create several setbacks for the state.

First, NCBiotech serves as a neutral third party that connects industry, academia and government. Moving funding to Commerce would remove that neutrality. Second, NCBiotech executes its activities as a private entity, giving it more flexibility than state government.

Recreating the functions of NCBiotech in a state agency would remove flexibility to respond quickly to changing needs. Finally, NCBiotech is recognized as an international best practice (Lowe), and North Carolina benefits from recognition of the established NCBiotech brand.

The Board recognizes that the state’s approach to economic development is changing. As responsibilities are shifted to the Economic Development Partnership of North Carolina and realigned at Commerce, the Board will remain open to opportunities to streamline these connections.



Action

- The Board will evaluate opportunities for partnership with NC Commerce and/or the Economic Development Partnership of North Carolina to maximize resource efficiency and job outcomes.

Action Steps and Funding Requirements

The Board of Directors of the North Carolina Biotechnology Center has been thorough and diligent in its response to the state budget and the requirements of SB402. The Board and its committees regularly review funding performance, program activities, regional office accomplishments and cash balances. In addition, the Board's Strategic Oversight Committee began a long-term planning process in 2012 to align activities with the changing industry. Because of this committee and the Board's regular review, NCBiotech was able to implement the following changes in summer 2013, after state budget cuts.

Actions already taken

- Reduced or eliminated six funding programs and multiple programmatic activities judged less critical to job creation. Implemented measures to optimize efficiency of remaining activities. Total savings is \$3.5 million.
- Eliminated 22 positions related to these program cuts and efficiency measures, saving \$1.6 million.
- Reallocated \$409,820 from regional office budgets to cover budget cuts. Combined oversight and office director positions; eliminated two administrative positions; reduced rent expenses. This is the equivalent of closing more than one office.

In addition, in response to the review and examination of each aspect of the Center's operations to determine ways in which efficiencies and cost savings can be achieved, as required in SB402(a), the following actions will be taken to implement continued changes to Center operations.

Actions planned

- The Board will review the Center's education and workforce mission, objectives, and purpose to consider new activities that have an even stronger focus on understanding and improving the workforce available to employers.
- The Board will continue with its plans to invest the estimated \$2 million of reserves into programs that will create return on investment to the state.
- The Board will formalize the Executive Committee's current practice that designates the amount of operating reserves as \$7.5M and that any funds that exceed this amount by 20 percent or more will be allocated to the grant, loan, and other investment programs in the following fiscal year in a manner consistent with the goals for which state funds are appropriated to the Center.
- The size of the Board will be reviewed by a committee of the Board. The proposed committee would assess the appropriate size of a Board that can effectively balance regional, government, academic and industrial representatives with appropriate knowledge to guide NCBiotech's operations. Findings will be reported to the full Board by June 30, 2014.
- The Board will evaluate opportunities for partnership with NC Commerce and/or the Economic Development Partnership of North Carolina to maximize resource efficiency and job outcomes.

Funding Requirements

Moreover, SB402(b) further required that this report include the Center's anticipated funding requirements from the General Assembly. In response to this, the Board recommends that Center funding be increased by \$7.3 million to \$19.9 million. This increase is for new programs, described in question 4 and included below. This recommendation builds on the work of the Strategic Oversight Committee.

The Board has taken the step of recommending this increase in funding for the following reasons: Throughout this report, metrics, case studies and independent analysis demonstrate NCBiotech's success in accelerating life science industry growth in North Carolina. As shown in figure 8-1, NCBiotech acts at an earlier stage than Department of Commerce activities, to provide a foundation that has developed North Carolina's life science industry into one of the leading and fastest-growing in the nation. The state's 23.5 percent job growth over the last decade is 3.5 times the national average. Tax revenues generated by the sector are \$1.7 billion annually, and direct employment has reached 60,000 highly compensated jobs at more than 600 company locations.

Massachusetts, Texas, New York City and others have created investment funds with hundreds of millions of dollars using a combination of public and private dollars. These funds invest \$10 million or more in promising life science companies. (A full list of state programs is in Appendix C starting on page 18.) This is a competitive risk for North Carolina and must be addressed. The Board's position is that NCBiotech has a strong infrastructure to deliver funding and program services that meet life science sector needs, and must be leveraged to do more for North Carolina. The Board proposes the following plan of new and expanded programs to accelerate company growth, investment and job creation for North Carolina.

1. **Launch New Industrial Public-Private Partnership Grant:** This new program will accelerate development relationships between universities and industry. The program goal is to stimulate large-scale long-term partnerships. These funds will be seed funds, with a required match from both industry and university partners, to multiply the funds. The focus will be on incentivizing and strengthening strategic relationships between universities and industry as an economic development tool for the state. \$3.4M
2. **Initiate a new loan program** featuring a larger \$500,000 loan to drive additional job growth by playing a larger role in bridging companies across the early-stage funding gap. \$1.5M
3. **Expand the Economic Development Award:** Life science company expansion projects face a unique set of funding challenges. This award program has been used to fill gaps in life science expansion/recruitment projects and attract additional jobs and investment to the North Carolina. \$0.8M
4. **Solidify North Carolina's leadership in agricultural biotechnology:** Additional funding will enhance the projects of the Crop Commercialization Center; implement programs to catalyze growth of entrepreneurial companies; promote understanding and acceptance of technology in agriculture; and attract more ag and ag biotech businesses to North Carolina. Ultimately, the goal is to solidify North Carolina's position as a leader in agricultural biotechnology. North Carolina has done well to wrest this title from the Midwest, and St. Louis, Iowa, Kansas and others are working aggressively with state programs to win it back. \$0.5M
5. **Develop biodefense and other life science related sectors:** This funding, distributed through the existing Centers of Innovation program, would provide for dedicated attention to developing strategic life science sectors for the state. \$1.1M

The following charts illustrate the point about infrastructure being able to award more dollars. On the left is the current projected allocation of the Center’s resources. The right diagram shows the allocation if more state funding is allocated to NCBiotech. The percentage shift reflects nominal additional staff to increase activities and award more dollars.

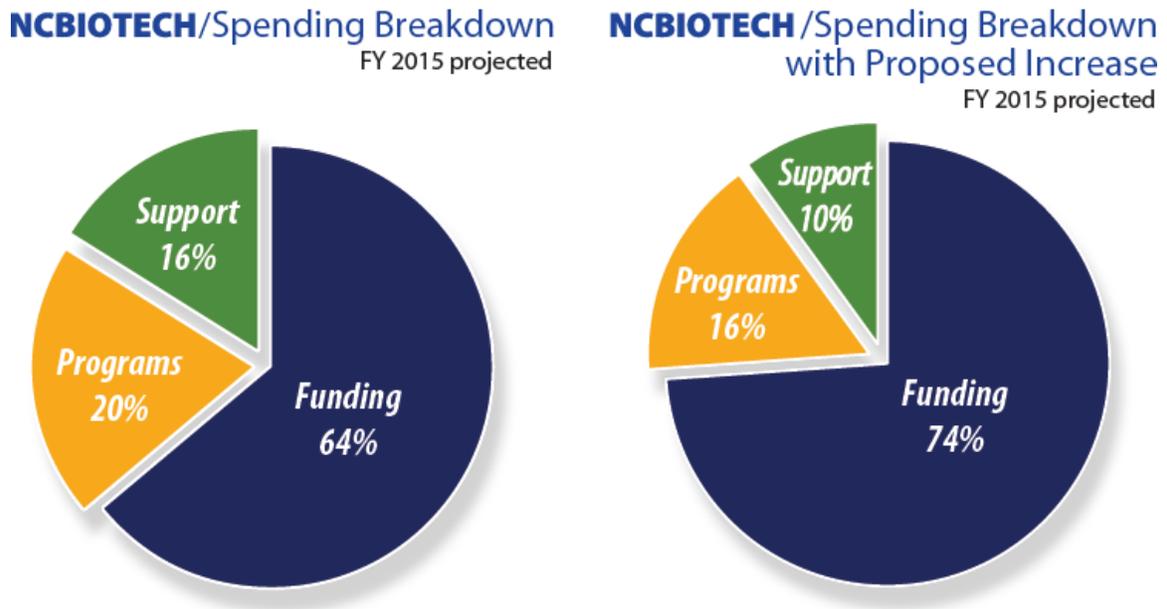


Figure AC-1

Funding Summary

The Board recognizes that competition for life science jobs is fierce. North Carolina competes well for these high-paying jobs even though other states provide larger incentives. By providing funding at critical times, connections to needed resources, and program support, NCBiotech provides a unique and cost-effective support mechanism for this valuable industry. It is a competitive advantage for North Carolina.

The Board regularly reviews and will continue to review the broad range of activities at NCBiotech, looking for ways to be more efficient and effective. Because of this strong oversight, success metrics and the competitive landscape, the Board encourages the state to expand NCBiotech funding by \$7.3 million to \$19.9 million. Doing so will provide a long-term return to the state in the form of company investment and jobs.

Success Metrics for Life Science in North Carolina

North Carolina's life science sector employs 60,000 people at more than 600 locations statewide.

Its economic activity is \$59 billion:

- Yielding \$1.7 billion in taxes for state and local governments
- Indirectly supporting a total of 237,000 jobs

From 2001 to 2010, North Carolina's life science employment grew by 23.5 percent

- 3.5 times the national rate
- Faster than North Carolina's private sector, which lost jobs
- Faster than all top-tier states for biotechnology

The North Carolina Biotechnology Center is a private, non-profit corporation supported by the N.C. General Assembly. Its mission is to provide long-term economic and societal benefits to North Carolina by supporting biotechnology research, business, education and strategic policy statewide.

The Biotechnology Center serves as the hub for this vibrant sector, making connections among academic, business and civic leaders. The Center delivers a spectrum of technology-based economic development programs to spur innovation, education, commercialization and job creation.

The Center's success metrics include:

- An average of \$28 in additional funding per \$1 in research grants,
- \$117 raised per \$1 loaned, and
- 31 company expansion projects since 2008.

Learn more at www.ncbiotech.org.

