

Preliminary Business Plan

North Carolina Advanced Medical Technologies Center

Vision

Within the next five years establish and grow the North Carolina Advanced Medical Technologies Center (AMTC or AMT Center) into a financially self-sustaining non-profit organization recognized nationally for the products, programs, and services it delivers to support North Carolina's advanced medical technology (AMT) community.

Mission

The AMT Center's mission is to promote the growth of North Carolina's statewide advanced medical technologies community.

Background

This document presents a preliminary business plan (Plan or Business Plan) for the North Carolina Advanced Medical Technologies Center (AMTC or AMT Center). This Plan is intended to be considered in conjunction with the Preliminary Organizational Plan for the AMTC, which is being submitted to the North Carolina Biotechnology Center as part of the North Carolina Bioscience Organization's application for the initial tranche of Phase II Center of Innovation program funding for the AMTC.

North Carolina's Advanced Medical Technologies Industry. In its report, *North Carolina's Strategic Plan for Advanced Medical Technologies (Strategic Plan)*, the North Carolina Biotechnology Center (NCBC) concluded that North Carolina is home to a nascent but robust advanced medical technologies cluster. In all, the State's advanced medical technologies industry consisted of approximately 404 establishments with 9,165 workers that collect an average annual wage of \$46,986. Between 1999 and 2006, medical device and advanced medical technology companies in North Carolina collectively raised more than \$545 million in private and public equity from investors. Advanced medical technology companies represented the second largest category of life science investments during the period, exceeded only by investments in drug-based therapeutic technology companies.

North Carolina's Strengths and Challenges. The *Strategic Plan* found that North Carolina has a variety of significant assets to support advanced medical technology companies. These include strong university biomedical engineering programs, a cluster of existing medical device and device component manufacturing and prototyping companies, several early stage incubators with medical device focus, and a supportive medical device vendor community. Most importantly the State is well positioned to support the convergence of medical devices with other technologies of potential importance to health care, including biotechnology, engineering, nanotechnology, chemistry, photonics, materials engineering, computer science, regenerative medicine and other relevant disciplines.

Despite these strengths, the *Strategic Plan* also found that North Carolina must address significant challenges and needs if the State is to accelerate the growth of its advanced medical technologies industry. The most important of these challenges include development of talent pools surrounding market intelligence, reimbursement and payment, manufacturing and regulatory compliance, capitalization and commercialization. To accomplish these tasks, the *Strategic Plan* recommended that North Carolina create a new Advanced Medical Technologies Center to (i) increase its AMT talent pool, (ii) create a supportive community for AMT start-up companies and (iii) improve access to AMT resources outside of North Carolina.

Center of Innovation Planning Grant. Based on the findings of the *Strategic Plan*, the North Carolina Biotechnology Center invited the North Carolina Biosciences Organization (NCBIO) to apply for a Centers of Innovation Phase I Planning Grant to develop plans for and Advanced Medical Technologies Center of Innovation. The Centers of Innovation initiative is designed to support the accelerated commercialization of biotechnology-related technologies and products. Given the expected convergence between biotechnology, medical devices, and other related technologies, the COI program is well-suited to addressing North Carolina's AMT opportunities.

NCBIO applied for the Planning Grant in the late fall of 2007 and was awarded the grant in 2008. NCBIO next assembled a Project Steering Committee composed of representatives from a diverse group of stakeholders, many of whom expressed support for NCBIO's COI Planning Grant Application. Under the guidance of the Steering Committee, NCBIO assembled a smaller Business Plan Committee to provide ongoing input and feedback to the business planning process and recruited a Project Senior Executive to lead the Organization's business planning team.

Benchmarking. The planning team began its work by assessing AMT support programs in other states to ascertain best practices of organizations similar to the proposed AMT Center. Ten organizations were identified in regions with an established and emerging medical technology industry. Initial research was conducted on these organizations. Five organizations (Pittsburgh's Life Sciences Greenhouse, Boston's Center for Integration of Medicine & Innovative Technology, Cleveland's BioEnterprise, New York's NYSTAR, and the BioBusiness Alliance of Minnesota) for more extensive research. Site visits were made to two organizations, the Center for Integration of Medicine and Innovative Technology (CIMIT) in Boston, Massachusetts, and BioEnterprise in Cleveland, Ohio.

Goals and Strategies. Based on its benchmarking work, the goals of the COI program, and the recommendations of the *Strategic Plan*, the planning team developed the following preliminary goals and strategies for the proposed AMT Center.

1. Goal: Improve Access to AMT Talent and Services
 - 1.1. Strategy: Help Companies Recruit Qualified Employees
 - 1.2. Strategy: Help Companies Find Qualified Vendors
 - 1.3. Strategy: Provide Coaching by Experienced Executives
2. Goal: Attract Outside Investors and Companies
 - 2.1. Strategy: Brand North Carolina as an AMT Hotbed
 - 2.2. Strategy: Raise the Visibility of North Carolina AMT with National Investors and Partners

3. Goal: Stimulate Creation of New Companies
 - 3.1. Strategy: Promote Communications and Collaboration between Clinicians, Researchers, and Entrepreneurs
 - 3.2. Strategy: Provide Grants and Loans to Support Early Commercialization Activities
 - 3.3. Strategy: Encourage R&D Partnerships

For each strategy, the planning team developed one or more example activities that the proposed AMT Center might execute in order to advance the strategy and relevant goal.

Stakeholder Interviews. The planning team next sought feedback from North Carolina's AMT community by conducting a survey and series of personal interviews with nearly fifty key stakeholders across North Carolina's medical technologies community. The survey and related interviews found that there is strong support for the proposed AMT Center across all regions and AMT interest groups. The proposed goals for the AMTC were unanimously supported by all respondents. Although levels of support differed marginally between goals and among stakeholder groups, all goals were substantially supported by all interest groups. Detailed results and analysis are of the stakeholder survey and interview results are available in the *Report on Proposed AMT Center Stakeholder Interviews* completed on October 7, 2008.

Strategic Vision

Based on the findings of its planning process, the planning team identified three goals for the proposed AMT Center -- (i) improving access to AMT talent and services, (ii) attracting outside companies and investors, and (iii) stimulating the creation of new AMT companies in North Carolina, especially through support of interdisciplinary collaboration in the development of new AMT product concepts.

These goals both address the key challenges to the State's AMT sector growth as identified in the *Strategic Plan* and are consistent with the COI program purpose of accelerating commercialization of new biotechnology-related technologies. Improving access to AMT talent and services focuses directly on the AMT talent shortage identified in the *Strategic Plan* and works to assure that innovators and entrepreneurs seeking to commercialize new AMT technologies will have access to the talent and services to do so. Attracting outside companies and investors will further deepen the State's AMT talent pool and help connect innovators and entrepreneurs with financial resources necessary for product commercialization. Stimulating the creation of new AMT companies directly accelerates the conceptualization and commercialization of AMT technologies, thereby providing the impetus for job creation and a more robust demand for AMT development services.

Improving Access to AMT Talent and Services. To improve access to AMT talent and services, the AMT Center will serve as a market-maker for innovation services among AMT community participants. In its role as an innovation-services market-maker, the proposed AMT Center will serve to match innovators to existing in-state innovation service providers to improve the efficiency with which proof-of-concept and product development activities are completed, while at the same time assuring that dollars spent

on these activities remain within North Carolina's AMT community.¹ By assuring that, whenever possible, local AMT service needs are fulfilled by local providers, the AMT Center will continuously strengthen in-state innovation service capabilities.

The AMT Center's role as an innovation-services market-maker will involve three functions – (i) identifying users of innovation services (i.e., AMT companies and innovators), and (ii) identifying providers of innovation-related services (i.e. AMT vendors), and (iii) efficiently and effectively matching innovation service users to providers.

AMT Company Database. The primary users of innovation services will be AMT companies. Therefore, the AMTC will create an AMT Company Database that will help innovation service providers identify and connect to potential customers. The database will also help individuals seeking work in North Carolina's AMT cluster to identify potential employers and evaluate the depth of future employment opportunities in the State. Finally, the AMT Center will work with its institutional partners, particularly technology transfer offices, to identify researchers, faculty and other AMT innovators in need of AMT-related innovation services. Because of its importance to supporting recruitment of new AMT talent, the company database is a near-term priority of this Business Plan.

Vendor Database. The AMT Center will develop a comprehensive database of innovation service providers. The database will serve as a catalog of North Carolina AMT service providers, including vendors with capabilities or expertise in prototyping, clinical and preclinical testing, intellectual property, reimbursement, AMT regulation, marketing, and other important commercialization functions. The database will include equipment and services available at North Carolina universities and other research institutions. Although initial development of the proposed vendor database will focus on in-state service providers, attention will also be given to identification of out-of-state providers of services not readily accessible within the State. Because of its importance to matching AMT development services to innovators and entrepreneurs, the vendor database is a near-term priority of this Business Plan.

Matching Companies and Vendors. The AMTC will assist innovation service users in identifying required service needs. This support will initially be provided by AMT Center staff. Later, the AMT Center's coaching program will assist companies and innovators in determining what commercialization services are needed and how they can be secured. Over the long term, the AMT Center may ask vendors to provide AMT Center clients standardized terms or other protocols that make it easier to finalize service contracts.

¹ To the extent that required innovation services are not available, the AMT Center will also develop connections to out-of-state innovation service providers. These connections will be used as necessary to assure that commercialization activities are not stymied for lack of access to critical support functions.

Attracting Outside Investors and Companies. In addition to fostering the growth of North Carolina's existing AMT assets, the AMT Center will market North Carolina's existing AMT assets to attract new talent and resources as rapidly as possible. The AMT Center's work in marketing North Carolina's AMT community will focus on raising the visibility of the State's AMT capabilities among out-of-state AMT companies and investors. This activity will be synergistic with the proposed AMT Center's role as a market-maker, since an essential element of both tasks will be cataloging and characterizing relevant AMT assets. The AMT Center's marketing activities will therefore include – (i) collaborating with state, regional and local economic development organizations, (ii) hosting an annual AMT conference/venture fair, and (iii) publishing an annual report on North Carolina's AMT community.

Economic Development Assistance. Economic development officials contacted as part of the planning team's stakeholder interview process identified a need for information to support AMT-targeted economic development marketing activities, including technical assistance with target company identification and messaging. To address these needs, the AMT Center will provide -- (i) a comprehensive listing of AMT companies, vendors and institutional assets, including public and private research and engineering programs; (ii) staff assistance for economic development organizations in the development of AMT recruitment materials, web pages and other marketing materials; (iii) staff or volunteer assistance in identifying recruitment targets; and (iv) staff or volunteer assistance with recruitment calls or representation of North Carolina at national AMT conferences and events. Because of its importance to raising North Carolina's visibility as an emerging AMT location and its potential to deliver value to key potential funders of the AMTC, economic development technical assistance is a near-term priority of this Business Plan.

Annual AMT Networking and Venture Conference. The Council for Entrepreneurial Development (CED), which has traditionally hosted an annual advanced medical technologies conference, has informed NCBIO that it intends to discontinue the program in 2010. The AMT Center will therefore assume responsibility for organizing a similar conference in future years. The conference will include a venture-fair or other venue for matching AMT innovations to investors. The AMT Center will focus its resources on developing content for the conference and attracting high-quality speakers, investors and other participants. Conference management services, such as registration and logistics will be contracted to a third-party vendor. This configuration will maximize synergies between the annual conference and the AMT Center's operational emphasis on data-gathering and AMT technical assistance. To the extent that its resources permit, the AMT Center will also support AMT conference offerings by other state or local hosts, including assistance with content development, recruitment of participants, speakers, and AMT investors.

Annual Report. The AMT Center will publish an annual report summarizing North Carolina's AMT assets, significant developments in the AMT community and notable activities of the AMT Center. This function will be synergistic with the AMTC's data-gathering, marketing and economic development technical assistance activities. Because of its importance to raising the visibility of the AMT Center and measuring its progress against its goals, the Annual Report is a near-term priority of the Business Plan.

Stimulating Creation of New AMT Companies. The AMT Center will undertake two activities in support of new company creation – (i) a coaching program and (ii) sponsorship of interdisciplinary symposia to support new product conceptualization.

Coaching Program. As noted above, the *Strategic Plan* reported a serious “lack of senior-level expertise across the range of functions and skills required to successfully commercialize advanced medical technologies” in North Carolina. However, the *Strategic Plan* also noted that a surprising number of senior medical technologies industry executives are retiring to North Carolina. The business planning team’s research confirms this trend.

The AMT Center will establish a panel of seasoned industry executives to provide management coaching to AMT innovators and less experienced managers of AMT start-up companies. The AMT Center will work with the entrepreneurial community and investment community to identify individuals who may serve as coaches. These individuals will have previously demonstrated success in the launch or management of AMT ventures and will be well connected to resources that can assist other businesses achieve success. All individuals in this program will be required to provide references for character and accomplishments. Responsibilities, time commitment, and expectations will be documented in advance of assignment. Participating coaches will be paid small monthly or quarterly stipends and will have access to typical office infrastructure such as work space, computer access, and part-time administrative support. Coaches will agree to protect the confidentiality of client business information, but will not be prohibited from entering into subsequent independent contracting or employment arrangements with client companies.

The coaching program will work with university technology transfer offices to help research faculty and clinicians with AMT product concepts (i) evaluate the commercial potential of innovations, and (ii) project an appropriate pathway for bringing commercializable innovations to market. Participating coaches will be matched by the AMT Center’s professional staff with business administration and professional-masters students from North Carolina universities, who will provide research support for the program. The AMT Center will not seek carried interests in innovations supported by the coaching panel.²

Because of its importance to accelerating commercialization of AMT technologies, as well as its potential to deliver value to key potential funders of the AMT Center, development of the coaching program is a near-term priority of this Business Plan.

Interdisciplinary Product Conceptualization. The *Strategic Plan* concluded that the most important strategic advantage of North Carolina’s emerging AMT community is its strength in potentially convergent technologies. The AMT Center will therefore work to

² Several of the AMT support entities interviewed by the planning team as part of its benchmarking process had negative experiences with taking carried interest in their client companies. Generally, it was suggested that by these entities that such carried interest created conflicts of interest and other tensions that impaired the ability of the entities to be fully supportive of client companies. This business plan therefore does contemplate the AMT Center taking equity, licenses or other carried interests in its client companies or related technologies.

foster interdisciplinary collaboration between North Carolina's diverse technology communities with potential relevance to advanced medical technologies.³

At a minimum, these technologies will include those identified in the *Strategic Plan* -- biotechnology, biomedical engineering, information technology, materials and coatings, and nanotechnology. In addition, it is believed that an interdisciplinary collaboration platform would benefit from the participation of other health system stakeholders, including clinicians, patients and payers. Initially, the AMT Center will use its database of companies and AMT innovators to encourage collaborations. In the longer term, the AMTC will host symposia designed to bring together technical, regulatory, clinical, reimbursement and patient expertise to consider solutions to health care problems at the point-of-care level.

Market Analysis⁴

The activities of the AMT Center will provide benefits to entities throughout North Carolina's AMT community, including -- (i) AMT companies, (ii) universities, research institutions and teaching hospitals, (iii) AMT vendors and service providers, (iv) economic development organizations, (v) patient groups, and (iv) health care payers.

AMT Companies. As reported in the *Strategic Plan*, North Carolina is home to a growing number of advanced medical technology companies of all sizes. These include established research, development and manufacturing operations of large corporations; smaller companies, including many engaged in product development and related activities; and incubator/accelerators focusing on medical technologies.

Among the State's *large and midsized AMT companies*, the primary benefits of the AMT Center will be improved access to talented employees. The AMT Center's database and marketing programs will improve North Carolina's visibility as an advanced medical technologies location and help prospective employees better understand the depth and breadth of the area's employment opportunities. Large companies conducting product development in North Carolina may also benefit from the AMTC's vendor database, including improved access to university programs and assets. The AMTC's partnership with academic medical centers will facilitate large company access to these institutions. The AMT Center's connections with patient groups will improve opportunities to partner in clinical testing programs, and provide a platform to involve patients in regulatory and reimbursement decision-making.

Early stage and start-up AMT companies engaged in product development and related activities will benefit from the AMTC through improved employee recruitment

³ Support for interdisciplinary product conceptualization is a key operational venture of Massachusetts' Center for Integration of Medicine and Innovative Technologies (CIMIT), which was one of the programs investigated by the planning team as part of its benchmarking activities. CIMIT is primarily focused on supporting collaboration between clinicians at Boston's world class medical centers and engineers at the Massachusetts Institute of Technology.

⁴ The nature of North Carolina's advanced medical technologies community is well characterized in NCBC's *North Carolina Strategic Plan for Advanced Medical Technologies* and is briefly summarized in the Background section of this business plan, *see supra*, at 1. This Market Analysis concentrates on identifying potential users or beneficiaries of the AMT Center's programs.

opportunities, efficient access to vendors and support services (including university and academic medical centers), networking opportunities, and enhanced visibility among potential investors and corporate partners. The AMTC's coaching program, in particular, will provide low-cost access to industry expertise that will be very valuable to start-up companies seeking advice regarding technical, regulatory, reimbursement and similar matters.

Innovators and entrepreneurs with new product concepts and technologies will benefit from the AMT Center's market-making activities and coaching programs. These stakeholders, who frequently lack significant experience in AMT business, will receive help with identifying commercializable technologies, identifying potential partners, developing business plans, efficiently identifying vendors and service providers, and accessing start-up capital through networking and AMTC-sponsored investment fairs.

Universities, Research Institutions and Teaching Hospitals. North Carolina is home to a large community of universities, other research entities and academic medical centers with rich AMT resources. There are expected to be strong synergies between the AMTC and these entities. Universities, research institutions and teaching hospitals are often presented with very early stage technologies in need of market knowledge. The AMTC will be in a position to provide market knowledge necessary to identify commercializable technologies and chart preliminary pathways to market – thus advancing its key mission of accelerating commercialization.

The AMT Center's coaching program has particularly strong potential to enhance both the bandwidth and expertise of existing technology transfer offices' review of AMT innovations. Commercialization of even a small number of additional technologies could result in substantial increases in licensing revenues for these institutions. The AMT Center's programs could be of special value to research institutions with major federal translational research grants.

Universities and research institutions will also benefit from the AMT Center's market-making activities. These programs will make it easier for AMT companies to identify and connect to useful university resources, including joint research opportunities, faculty consulting arrangements and testing or prototyping services.

Vendors and Service Providers. Vendors and service providers include business consultants, commercialization experts, regulatory and reimbursement resources, contract manufacturers, prototype developers, attorneys, accounting firms and other similar entities. Through its vendor database, vendor referral service and coaching programs, the AMTC will act as a market-maker for innovation services and will assist companies in identifying and connecting with qualified vendors and service providers. Vendors will benefit from the AMT Center's work through increased referrals and access to the AMT Center's AMT company database.

Economic Development Entities. Several of North Carolina's regional and local economic development entities have expressed strong interest in the AMT industry. The AMTC will provide economic developers with information necessary to effectively market North Carolina as a location for new AMT research, manufacturing, and corporate headquarters units. In addition, the AMT Center will assist developers in identifying recruitment targets and in meeting with target company executives to discuss North

Carolina's AMT assets. The AMT Center's Annual Report will also be a useful tool in positioning North Carolina as a location for AMT business activities.

Patient Groups. The AMT Center will collaborate with patient groups to identify point-of-care quality of life issues potentially addressable by advanced medical technologies and bring them to the attention of AMT companies, innovators and payers. These activities will accelerate commercialization of beneficial technologies and assure more immediate access to innovations and new products.

Health Care Payers. The AMT Center will work with health care payers to identify point-of-care cost drivers and bring these issues to the attention of companies, innovators and patient groups. For payers, accelerated commercialization of technologies designed to address cost drivers will mean reduced reimbursement costs. The AMT Center's interdisciplinary product conceptualization support activities will also offer payers a technology-driven platform for educating patients and clinicians about health care cost drivers and improving the quality of care available to covered individuals.

Collaboration and Partnering Plan

It is anticipated that the AMT Center will be located in the Research Triangle area, but will work closely with other entities interested in the growth and development of North Carolina's AMT community. Therefore, in addition to the strategic activities outlined above, the AMT Center will work with other supporting, partnering and other allied organizations to minimize potential duplications of effort and maximize in-kind support for the AMTC's activities. Opportunities for collaboration will include joint funding efforts, as well as sharing of (i) AMT information and subject matter expertise, (ii) information technology and information resources, including servers, databases, libraries, and job board resources, (iii) conference and event management services, (iv) grant and loan program management resources, (v) public policy research and government relations expertise, and (vi) human resource and accounting support services.

Joint Fundraising. Although the AMT Center's coaching and interdisciplinary product conceptualization initiatives will greatly assist in identifying commercializable technologies and mapping paths to market, innovators and start-up companies will still require financial resources to fund proof-of-concept and early product development activities. Increasing start-up ventures' access to this funding will be critical to the AMTC's mission of accelerating product commercialization. The AMT Center will therefore work with various partners to improve AMT innovators' access to funding resources.

An important opportunity for improving AMT companies' access to commercialization funding will be collaboration with NCBC. Many AMT companies and innovators are already eligible to apply for commercialization-supporting grants and loans from NCBC. The AMTC will be ideally positioned to market these NCBC programs to AMT companies, assist companies in preparing applications for NCBC grants or loans, and to help NCBC identify subject matter experts to evaluate grant and loan applications. Such collaborative activities could substantially accelerate commercialization of AMT innovations already eligible for NCBC programs.

In addition, the AMTC will encourage NCBC to expand its grant and loan programs to include any AMT innovation, whether or not directly related to biotechnology. As noted in NCBC's report, *Strategic Plan for Advanced Medical Technologies*, North Carolina's existing AMT companies are likely to be only "the harbingers of future technology-driven economic growth" based on the convergence of biotechnology, classical medical technologies and other disciplines. These synergies argue strongly for a broad program of grants and loans to support commercialization of emerging advanced medical technologies. At a minimum, the AMT Center and NCBC should collaborate in seeking new sources of commercialization-supporting grant and loan funding including (i) expanded State appropriations, (ii) federal grants, (iii) grants from foundations, including philanthropic interests in entrepreneurship, (iv) disease or health condition-specific grants from patient groups, and (v) grants from health care payers.

It is believed that the AMT Center will also be an effective partner to other public and private non-profit research institutions seeking government or philanthropic funding for AMT translational research and commercialization. In such partnerships, the AMT Center would be not only a source of expertise in identifying and articulating targets for such funding, but a helper to partners seeking to account for technical, regulatory and market realities in the deployment of such funds. Synergies between the AMT Center and these partners will be a compelling feature of joint funding applications.

AMT Information and Subject Matter Expertise. The AMT Center will ask its participating companies, vendors and research institutions to be prepared to provide brief or high-level technical advice to AMTC staff, coaches and interns for the purpose of aiding client companies and other members of the AMT community. The purpose of this information sharing will be to aid in connecting AMT community members with appropriate information resources. Once specific resource or information requirements are identified, AMTC clients will be expected to contract or otherwise arrange for direct consulting, information sharing or similar collaborations.

Although the *Strategic Plan* concluded that strengthening North Carolina's AMT vendor and service community will be a key factor in growing the community here, there are already a number of companies providing very competent service to the AMT community. These law firms, accounting firms, contract manufacturers, consultancies, and other service providers will benefit from introductions to AMTC client companies that allow both parties to more fully understand the needs and capacities of the other. By increasing the number of such interactions, the AMTC can effectively strengthen not only North Carolina's many AMT start-ups, but also assure that area vendors and service providers achieve volumes of business that allow them to continuously upgrade and expand their AMT-related offerings.

Information-sharing collaborations also will accelerate AMT-related discovery and commercialization. For example, AMT Center companies will enjoy improved access to clinical expertise at North Carolina teaching hospitals. Faculty innovators will more readily connect with vendors or entrepreneurs with legal, regulatory, reimbursement and other areas of expertise. Students will be linked to knowledgeable mentors in businesses and clinical institutions. Large AMT companies will more easily access patients and health care providers interested in participating in clinical trials. Patient groups will get better information about on-going research and clinical innovations.

Information sharing between AMT Center partners will be a key element of the AMTC's market-making activities, but will also increase opportunities for collaboration between participating institutions or community participants separated by geography, institution, or scientific discipline. By promoting such collaborations, the AMT Center will advance its mission of improving the efficiency of AMT-related innovation and commercialization throughout North Carolina.

Information Technology & Information. The AMT Center will seek opportunities to share or piggy-back information technology infrastructure and information resources with partners and allied entities. These opportunities include collaborative use of information assets as well as technology infrastructure.

The most important information sharing opportunities will involve the AMT Center's company and vendor databases. It is likely, for example that both these databases will overlap with existing databases at the North Carolina Biotechnology Center, directories of State, regional or local chambers of commerce or other economic development entities, as well as other Centers of Innovation established by NCBC. Access to technical libraries, such as journals and other databases maintained by NCBC or libraries of institutional partners will also be fertile ground for collaboration. The AMT Center will work with its partner entities and allies to identify information-sharing opportunities that lower costs and reduce the data gathering and maintenance burdens of the AMTC and collaborating entities. These efficiencies will allow all partners to devote more energy to promoting commercialization of new technologies.

Although the AMT Center will necessarily operate some technology infrastructure of its own, it will seek opportunities to share other infrastructure. The AMTC's proposed job board, for example, may leverage existing infrastructure already used by private providers, or by NCBC for its job board. Another potential information resource partner will be North Carolina State University, which has already developed a database of local AMT companies, vendors and resources. The AMTC will also seek opportunities to share internet-based infrastructure such as video conferencing or teleconferencing facilities, or systems for archiving and downloading of AMTC programs or other content.

Regional Outreach. The AMT Center will seek partnerships with regional entrepreneurial support entities such as the Ben Craig Center in Charlotte, the Nussbaum Center in Greensboro, and the CED in Research Triangle Park. It is anticipated that these organizations will help connect the AMTC with innovators and entrepreneurs in their communities. In addition, these partners may serve as platforms for organizing or supporting regional AMT coaching networks that will augment the core AMTC management coaching network described earlier.⁵

Conference and Event Management. Although the AMT Center will host an annual networking and venture conference, it will partner with other entities to manage logistical, registration and other administrative activities associated with this event. The planning team has had preliminary discussions with CED regarding this matter. CED has a long track record of experience with the development, marketing and execution of such conferences, and it is expected that CED's established network of venture contacts would

⁵ See *supra* at 6.

allow the AMTC to quickly identify and attract more local funding opportunities for commercialization of its clients' technologies. It is expected that the AMT Center will also explore conference support arrangements with other non-profit and for-profit partners.

Grant and Loan Program Management. The AMT Center will avoid establishing its own grant and loan management infrastructure by partnering with NCBC or other institutional allies that offer grant and loan programs.⁶ These partnerships may be integrated with the joint fundraising activities described above. By eliminating or reducing grant and loan administration overhead, the AMT Center will be free to focus more resources on its core mission of accelerating commercialization of new AMT products.

Public Policy. It is expected that the AMT Center will partner with NCBIO, as well as its institutional partners, in the development of public policy recommendations for advancing the growth of North Carolina's AMT community. NCBIO has a strong history of innovation economy advocacy before state and federal officials. Bringing the needs of North Carolina's AMT communities to public leaders will be an important first step in shaping state and federal tax structures and program funding to better support AMT product commercialization.

Human Resource and Accounting. The AMT Center will explore opportunities to piggy-back the human-resource and accounting systems of the North Carolina Biotechnology Center or other institutional partners. While the planning team has not had specific discussions with potential partners in this activity, we are aware of at least one other non-profit life science organization in the area that has partnered with Duke University in such an arrangement.

Preliminary Financial Independence Strategy

This Business Plan is premised on the assumption that the AMT Center will receive \$2.5 million in Phase II Centers of Innovation funding from the North Carolina Biotechnology Center during its first four years of operation. An initial tranche of \$250,000 will be made available to NCBIO to fund launch-related activities for the new entity. Subsequent tranches will be paid by NCBC to the AMT Center to offset operating expenses. Table 1 shows projected aggregate income and expenses for AMTC in its first five years of operation. Detailed budget estimates for Year1 and Year2 are included in the Pro Forma Budget included with NCBIO's Phase II AMT COI application.

The AMT Center will derive sustaining income from the following sources: (i) support payments from partnering institutions and economic development entities, (ii) sponsorships from supporting companies, (iii) subscriptions from AMT businesses and vendors, and (iv) event revenues.

Partners. Principle funding for the AMTC will be derived from partnering research institutions and economic development entities.

⁶ The planning team has had preliminary discussions with NCIDEA about cooperative management of grant programs.

Table 1 AMT Center Pro Forma Income Statement					
Financing/Source of Funds	Yr1*	Yr2	Yr3	Yr4	Yr5
NCBC Award	\$750,000	\$650,000	\$600,000	\$500,000	\$0
Subscriptions	\$15,225	\$47,850	\$78,566	\$94,280	\$113,135
Events	\$0	\$80,000	\$125,000	\$165,000	\$264,750
Sponsorships	\$0	\$100,000	\$125,000	\$200,000	\$250,000
Partners	\$0	\$150,000	\$200,000	\$300,000	\$450,000
Total Revenues	\$765,225	\$1,027,850	\$1,128,566	\$1,259,280	\$1,077,885
Operating Expenses					
Communications/Marketing	\$56,500	\$18,540	\$19,096	\$19,669	\$20,259
Payroll/Benefits	\$225,000	\$564,000	\$592,200	\$621,810	\$652,901
Recruiting	\$61,500	\$0	\$0	\$0	\$0
Tech Ops/Services	\$124,931	\$80,508	\$48,000	\$48,360	\$50,923
G&A	\$135,700	\$211,354	\$236,992	\$271,818	\$296,165
Total Operating Expenses	\$603,631	\$874,402	\$896,288	\$961,657	\$1,020,248
Net Operating Expense	\$161,594	\$153,448	\$232,278	\$297,623	\$57,637
Cumulative Cash Reserve	\$161,594	\$315,042	\$547,321	\$844,943	\$902,580
* Year1 income and expenses include \$86,000 of initial Phase II tranche monies and related expenses paid to or by NCBCIO. All other Phase II monies will be paid to the AMTC.					

Institutional Partners. The primary value proposition of the AMT Center will be the accelerated commercialization of innovations developed within North Carolina's universities, academic medical centers and other research institutions. The AMT Center's programs will provide a vertically integrated array of assistance designed to help move AMT-relevant innovations from laboratory to market. As noted above, these services will include: (i) assistance in identification of commercializable innovations, (ii) assistance in charting appropriate commercialization pathways, (iii) matching of innovators and start-up businesses to necessary AMT talent and services, and (iv) development of new sources of financial assistance to support commercialization.

Institutional partners will derive new revenues from royalties or other carried interests associated with commercialized innovations. While the AMT Center will not, itself, take carried interests in technologies or companies that it assists, it will look to its institutional partners to ultimately reinvest a portion of their incremental commercialization-derived revenues to support the AMT Center. Institutional partners will not be asked to provide

their full pro rata share of support revenues immediately. Instead, Phase II Center of Innovation Grant revenues will substitute for a substantial share of the financial support responsibilities of institutional partners in the early years of the AMT Center's operation. Only after the AMTC has proven its utility as an AMT innovations accelerator will institutional partners be asked to provide their full pro rata share of the AMT Center's financial support requirements.

Economic Development Partners. A second principle value proposition of the AMT Center will be its ability to improve local and regional economic development outcomes in the AMT sector. This value proposition will be supported by the AMT Center's information and technical assistance offerings to North Carolina economic development entities. As discussed above, these offerings will include (i) accurate and timely information regarding the nature and size of North Carolina's existing AMT community, (ii) assistance in identifying AMT recruitment targets, (iii) assistance in development of recruitment and retention messaging, and (iv) direct personnel support for AMT recruitment activities. Partnering economic development entities will be asked to provide funding support to the AMT Center commensurate with the value of these services. The planning team has had favorable discussions with several economic development entities concerning this proposition. It is hoped that these discussions will quickly mature into early funding opportunities from for the AMTC.

Sponsorships. As noted above, large North Carolina AMT companies will benefit from improved access to talented employees and other support resources. The AMTC's partnerships with academic medical centers, patients and payers will improve opportunities to partner in clinical testing programs, and provide a platform to involve patients in regulatory and reimbursement approval decision-making. It is expected that that most large AMT companies doing business in the State will conclude that these benefits merit sponsorship support of the AMT Center. Preliminary discussions with several of North Carolina's major AMT companies suggest that these firms could be an early source of funding for the AMTC.

Subscriptions. The AMT Center will offset the cost of its database, coaching, and vendor matching programs by charging subscription fees to participating AMT companies and vendors. These subscriptions may be structured either as membership dues, fees for service, or a combination of these. Revenue estimates in Table 1 assume annual subscription/memberships of \$300 per year for early-stage companies and up to \$3000 per year for later-stage start-up companies.

Event Revenues. The AMT Center will host two categories of events, each of which will be designed to generate some revenue in excess of costs. These events will include the AMTC's (i) annual networking conference/venture fair, and (ii) interdisciplinary product conceptualization symposia. The planning team anticipates the proposed networking conference/venture fair to produce most of the AMTC's event-related revenues in the near term and some later-year revenues from the proposed interdisciplinary product conceptualization programs.

Annual Conference. The AMT Center' annual networking conference/venture fair will be similar to the Council for Entrepreneurial Development's (CED) annual MedTech conferences held in 2008 and 2009. As noted above, CED has notified NCBIO that it

plans to discontinue its hosting of the Medtech conference, but is amenable to collaborating with the AMT Center to provide logistical, registration, marketing and other support services for future similar events. As with the MedTech conferences in 2008 and 2009, it is expected that revenues substantially in excess of costs can be derived from conference sponsorships and registrations. By underwriting the financial risk of future conferences, the AMT Center can be expected to capture net revenues that can be applied to support other AMTC operations. Because of its dedicated focus on AMT, the planning team expects that the annual conference will attract out-of-state sponsorships and registrations that contribute not only to funding of the AMTC, but expansion of North Carolina's AMT community.

Interdisciplinary Product Conceptualization Symposia. As explained above, a longer term initiative of the AMT Center will be to host symposia designed to bring together technical, clinical, reimbursement and patient expertise to consider solutions to health care problems at the point-of-care level. It is expected that patient groups and health care payers will be amenable to supporting such symposia as a means of accelerating AMT innovations that improve quality of life or address health care cost drivers. It is expected that financial support for these conferences will be available to offset expenses associated with their development and hosting. Additional revenues may be derived from commercial sponsorships or publication of symposia proceedings.

Annual Goals and Milestones

Specific goals and milestones for the AMT Center's first two years of operation are set out below. More generalized timelines for subsequent years follow.

In addition to the work plan set out below, it is assumed that NC BIO will conduct the following pre-launch activities using funding from an initial tranche of \$85,000 in Phase II monies – (i) incorporation of the AMT Center as a non-profit, tax exempt, legal entity, (ii) development of initial branding concepts, (iii) recruitment of an initial Board of Directors, and (iv) recruitment of the AMTC's founding President. A fuller discussion of these activities is set out in the Operational Plan included with NC BIO's Phase II AMT COI application.

First Year Goals and Milestones. Goals for the first twelve months of the AMTC's operation will be (i) networking, fundraising and education, (ii) recruitment of staff and Advisory Committee members, (iii) infrastructure development, (iv) communications and marketing, and (iv) launch of initial products, programs and services.

Networking, Fundraising, and Education. The President of the AMT Center will conduct a series of local and regional meetings with key stakeholders throughout the State of North Carolina. If possible, these meetings will begin with a dinner for AMT community leaders at the MedTech 2009 conference scheduled for May of 2009. Based on the stakeholder meetings, the President will develop revisions to the AMT Center's business plan and begin seeking financial commitments from sponsors and partners.

Recruitment of Staff. The President will first hire the Executive Assistant, followed by the Communications & Marketing Resource (targeted for the third-quarter of operations), and the Client Services Resource (targeted for the fourth quarter of operations). The

President and Board of Directors will also establish an initial Advisory Committee within the first six months of operation.

Develop Infrastructure. Infrastructure activities will include securing office space; selecting and implementing technology infrastructure; and engaging vendors or establishing partnerships to support payroll, accounting, human resources, telecommunications and information technology support. Legal counsel to the AMTC will be retained during this period.

Communications and Marketing. Initial communications and marketing activities will include registration of a domain name for the AMT Center, development of the AMTC's website, and distribution of news releases announcing these and other newsworthy activities of the AMTC. During this period the AMT Center will also begin planning for the 2010 AMT networking conference/venture fair.

Launch of Initial Products, Programs and Services. The AMTC will create and begin populating its databases of AMT companies and vendors.

Second Year Goals and Milestones. In its second year of operation, the AMT Center will focus on (i) building out its suite of products, programs, and services and (ii) raising the visibility of North Carolina's AMT community.

Products Programs and Services. The AMTC will expand its AMT company and vendor databases, begin providing vendor referral services, and create or collaborate in the creation of a North Carolina AMT job board. Second year program activities will also include commercialization support for institutional technology transfer offices, and launch of the coaching program. During this period the AMTC will also collaborate with its partners and allies to begin developing new commercialization funding resources for North Carolina AMT companies. Because of the relatively complex nature of the proposed interdisciplinary product conceptualization program, the planning team also expects that the AMTC staff will begin multi-party discussions regarding the program in the second year of operations.

Branding, Communications and marketing. Second year branding, communications and marketing activities will include launch of an online newsletter, hosting of an annual AMT networking conference/venture fair, economic development support activities, and publication of the AMT Center's inaugural annual report.

Third and Fourth Year Preview. During this period the AMT Center will continue to (i) refine and expand its product, program and service offerings and (ii) collaborate with partners and allies to expand commercialization funding resources. In addition, the AMTC will plan for and hold one or more interdisciplinary product conceptualization symposia.

Appendix A

AMT Center Planning Teams

AMT Project Executive Committee

Greg Davis, President and Chief Executive Officer, Tryton Medical, and AMT COI
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Dan Pelak, Resource Group Member, Welsh, Carson, Anderson & Stowe

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Samuel Taylor, President, The North Carolina Biosciences Organization (NCBIO), and
AMT COI Award recipient and administrator

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Colin Bishop, Ph. D., Wake Forest University Baptist Medical Center, Institute for Regenerative Medicine

Mitzi Bond, Vice Chancellor for Research, North Carolina A&T State University

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