



# On the offensive

*With all the right pieces in place, North Carolina's biotechnology leaders look for ways to expand into the national biodefense sector.*

**WITH MORE THAN 600 LIFE-SCIENCE COMPANIES,** North Carolina is known for its biotechnology industry. Some see opportunity for expansion by pairing life science with national defense — known as biodefense. *BUSINESS NORTH CAROLINA* gathered a panel of biotech and biodefense leaders to discuss ways to attract more projects and funding from the U.S. Department of Defense.

#### **PARTICIPANTS:**

**Chris Brown**, vice president for research and graduate education, UNC System Office of General Administration

**Luke Burnett**, chief science officer, KeraNetics LLC, a Winston-Salem-based medical-research company

**Doug Edgeton**, president and CEO, N.C. Biotechnology Center and moderator of this discussion

**Corey Russ**, founder, Combat Medical Systems LLC, a Harrisburg-based maker of battlefield medical supplies

**David Saravitz**, partner, Williams Mullen, a law firm with 10 offices in North Carolina, Virginia and the District of Columbia

**Kathie Sidner**, defense applications engineer, UNC System

**Mary Beth Thomas**, vice president, Centers of Innovation Program at N.C. Biotechnology Center

The North Carolina Biotechnology Center sponsored the discussion, which was held at its office in Durham. Williams Mullen provided additional support. The transcript has been edited for brevity and clarity.

#### **How would you define biodefense?**

**Thomas:** This is something that we thought a lot about when we started considering this issue: How do we match up the different resources and assets that we see in the life-sciences sector with the needs and demands that are clearly present within the Department of Defense and the military and homeland-security sectors? Because we weren't sure when we started this process exactly where North Carolina had its strengths, we left the definition of biodefense very broad.

We include in our definition three areas of opportunity. The first is what we consider critical countermeasures: things to protect soldiers, biohazard containment, detecting biohazardous materials. We also capture other medical and health-related things. So the biotech center also looks at how to foster more work with the DOD Defense Medical Research and Development Program. The third thing, which is hardly ever considered, is what's happening within the Veterans Affairs Department. North



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#### **CHRIS BROWN**

vice president for research and graduate education, UNC System Office of General Administration

Carolina has a very large population of returning veterans, given our military installations. And the VA has a lot of research and development going on within their medical research institutes. That broader definition was very strategic, because it allowed us to be much more inclusive in what we brought into this sector and allowed us to explore more opportunities.

**Brown:** I would like to suggest that it be even broader: for example, the intersection of biotech and agriculture, or remote sensing or environmental issues. One of the big issues worldwide is scarcity of resources, like water or arable land, which can cause instability. That’s a little bit farther afield. I think it’s pretty important that we have the capacity here in the state to tackle those issues.



Participants  
in the  
Biotechnology  
Round Table



David Saravitz



Mary Beth Thomas



Corey Russ



Kathie Sidner



Doug Edgeton



Chris Brown



Luke Burnett

**Saravitz:** What Chris brought up touches on how biodefense really includes homeland defense too. I mean, protecting our livestock and plants — what we call our kill crop. Our industries face serious dangers that are very destructive. And so we need to protect these things. The military needs food and water to be successful as well.

**What's the economic impact of the biodefense industry in North Carolina?**

**Thomas:** The military accounts for 10% of the state's economic activity, which makes it one of the largest economic sectors in North Carolina. It currently supports more than 540,000 jobs in the state. I think that's a substantial piece of not just economic activity but citizen activity. People who live in North Carolina are present within the sector, and I think we do ourselves a disservice if we look past it and don't consider how biodefense can relate to it.

**Edgeton:** The Department of Defense prime contracts for the 2012 fiscal year were \$3.43 billion in 18 counties of North Carolina. That's a fairly substantial invest-

ment in our state. We think there's room for improvement on that.

**Sidner:** I would like to comment about that \$3.43 billion in contracting. I don't have the exact numbers, but I know that the majority of that is in services. So it's not just in research and development, and maybe that's an area where we can help swell the tide and bring more research and development dollars to North Carolina. The state has every industry.

**Brown:** Within the university, the impact is fairly large. For research last year, we had over \$1.2 billion at public universities. We sponsored projects and research. About 3% was DOD in all facets. That's still much smaller than it could or should be. The potential parties to the solution probably are here. Our job is to get them together and get them to be able to communicate with each other.

**Edgeton:** We talked about defense, but I'll give you just a little stab of the overall picture of bio. In the state of North Carolina, we have 600 life-science companies, and they bring in about \$73 billion in economic kickback. That's 61,000 people. The average salary for those jobs is \$81,000

a year. So when we look at where we have gone as a state, we continue to outpace the country in growth, jobs and life sciences. We're right now at 30.9% growth in biotech since 2006 and the rest of the country is at 7.4%. Merging these two — bio and defense — together is an important element and where those overlapping points might occur. And then another important part is the college system. The overall higher education system in North Carolina is big. It's a large amount of money that's coming into the state.

**What's keeping researchers in the state from landing military contracts, and how do we fix that?**

**Sidner:** We've come around to some campuses and listened to folks who said they have interest in working with DOD but don't know how to open that first door to get started. It's this completely unknown world, and everything is about relationships. You have to actually talk to a program manager in advance. It's very important that we try to educate our researchers who are not familiar with the DOD on how to do that.

**Russ:** You have to be in the early part of the conversation and shape the need, the wants, the requirements, the parameters that would make it a good idea for the DOD. Then you get a proposal. We've stated many times in these types of events that you can't just sit — or you're behind the curve.

**Burnett:** A lot of people I talk to say, "How can I get DOD funding for my lab?" Well, you can if your lab is working on something that fits within a DOD requirement. They're not going to fund what you're interested in if it doesn't fit their needs.

**Brown:** And I think that's a really excellent point. The middle ground is to help the researcher figure out how his or her work fits or solves that problem. Sometimes it's just reconnecting a few different dots.

**Sidner:** Or helping the researcher convince that program engineer that there's a different way to do things beyond the way the DOD requirement is written. They



Anthony Atala, M.D., Director, Wake Forest Institute for Regenerative Medicine

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want to get the people way out in left field but who actually have a solution. Talking with the program manager will shape their vision of what that program is and could change the requirements.

**Brown:** One thing I wanted to share about connecting research to need is that it could be more palatable to the researcher to find the dual-use or more than dual-use opportunity. You're studying this thing, and it's applicable to your agriculture, your environmental studies, your social-science work. And, oh, by the way, it can solve this defense problem.

**Burnett:** That is a great point because that is where the Department of Defense is going. They are finding ways to do many things that are single use and that are not the same in the marketplace. So you have to make something that is sustainable in the civilian marketplace that can also have a use in the military world. That's where we find the integration.

**Edgeton:** When you apply for funding, you have a program manager, you have a requirement document and you make your budget. If you can't name a program manager, you're not sure what the requirement document reads like and you don't know the budget line, you're really in the concept stage. That's where companies face the same challenge. You really want to be in the top tier of mission

essential or mission critical, and then your scientists have to shape that discussion and be part of it.

**What makes North Carolina attractive to the biodefense sector?**

**Brown:** It seems that there's a bit more emphasis and enthusiasm from the governor for bringing this together. So that's a reason. I think the time is right.

**Thomas:** Well, I think we're tapping into a time where there's a lot of change going on within the Department of Defense. They are trying to address these medical issues that they see within the older population and now with the veteran population that's coming back. And they will continue to move funds toward that. When we are not engaged in an act of war, money will be redirected to other means. We're just trying to become more aware of how that money is redirected. We have not watched how the DOD is moving its money toward life-science work, medical and health care-related things.

**Burnett:** Promoting North Carolina is an easy case. All of the universities we have — top five, top ten in the country — and we've got some of the best biotech in the world located here, along with clinical trials. The entire spectrum is located right here. We just need someone to help us.

**How are the universities working together on these projects?**

**Sidner:** I've seen a lot of examples of smaller scale projects that are collaborative between the universities. For example, in the analytics area, there's a lot of opportunity for collaboration between Duke University and UNC Chapel Hill. And maybe there's an opportunity to do that in a biotech or biodefense area.

**Brown:** The universities do collaborate. N.C. State and UNC Chapel Hill have a joint department of biomedical engineering. North Carolina A&T and UNC Greensboro have the Joint School for Nanoscience and Nanoengineering. So there are these formalized opportunities that draw into universities. One thing that I think would help in this area is a Web-based tool that allows researchers, program officers, companies and others to tap into what's going on at the universities. If I'm interested in a particular vaccine, I can type that in, find out who's working on it and who they're working with, and then go from there. I know we have not utilized that nearly to full capacity.

**Saravitz:** I wonder if it's easy getting universities to work together outside the UNC System, or if we need some sort of grant to promote that. These folks are working within the same area. They're not going to want to give their best secrets up. If there's a reason to work together, then maybe we can help that.

**Do we need a prime government contractor in the state to compete?**

**Thomas:** Well, we realize North Carolina does not have a prime contractor, and maybe we don't have a lot of issues. We can't claim every industry. But I think what's so important, and what I don't think people fully appreciate, is how important the prime contractor is within the Department of Defense system. So much of the business that the DOD does is repeat business with people that they know and people that they've had contracts with before. So not having a prime contractor or a large presence of one in



“So much of the business that the DOD does is repeat business with people ... they’ve had contracts with before. So not having a prime contractor ... in North Carolina is significant.”

**MARY BETH THOMAS**  
vice president, Centers of  
Innovation Program at  
N.C. Biotechnology Center

the state of North Carolina is significant because it means that we never get looked at for those large awards. And I think we need to establish more foundations or relationships with some of these prime contractors. That will require us to go to them.

**Edgeton:** Well, we have the Department of Commerce. And now they have the public-private partnership. Has there been a concerted effort by Commerce to recruit that kind of company — the prime contractors? We want the big car manufacturers and so forth. But this is different, maybe a different kind of sales job?

**Thomas:** It absolutely is. The challenge is these contractors are very large, multinational companies, and they have many, many different units. What we have to tap into is the business unit that is most directly related to what we're interested in. GE Healthcare, which would generally be considered a prime, has a very specific health care and life-science unit, and we



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**LUKE BURNETT**  
chief science officer,  
KeraNetics LLC

need to bring the right set of people here and make sure that they're aware of what we do in North Carolina. We just don't have that connection right now.

**Russ:** My experience has been in selling devices and not necessarily the research side, but I don't know that the

prime is a make-or-break moment. I think writing proposals is probably much more important than the prime itself. Understanding their requirement, what they deal with in the field and where they're going to use your technology will really help you slingshot forward and

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“You have to be in the early part of the conversation and shape the need, the wants, the requirements, the parameters that would make it a good idea for the DOD.”

**COREY RUSS**  
founder, Combat Medical Systems LLC

building new facilities, they might come here and get some folks on the ground.

**How do we take it to the next level?**

**Brown:** From a university perspective, I think we need to continue our great research. And an important thing that we have talked about is communication. Communicating to the outside world: This is what we do, this is what we have, this is what we can offer to you. But really important, too, is the communication inside, amongst ourselves, so that the universities understand what the opportunities and special parameters are that they need to meet. It’s not, “I need to fund my lab,” but rather, “What problems can I solve for you?” And so communication is key. Then the last thing, which we also talked about, is getting an understanding of the relationship aspect of doing DOD research. It’s a person-to-person kind of approach, different from what many are used to.

**Sidner:** Part of that is supporting travel to conferences and different events. I talked to one professor of computer science at UNC Chapel Hill who told me that it took him probably 15 trips before he finally made the right connection to a DOD program leader who would listen to him. Now, 99% of his lab is funded by DOD. It took that face-to-face contact, so we’re trying to encourage folks to travel to things like the Army Medical Research, Development and Acquisition conference in March.

**Thomas:** Within the Department of Health and Human Services is BARDA — the Biomedical Advanced Research Development Authority. BARDA has made a lot of news lately because of the Ebola outbreak in Africa and has been one of the lead agencies in coordinating the federal funding and activities that are happening there. But North Carolina has not engaged BARDA very much. I think that’s something that we’ve also been trying to get a little bit more delved into, developing the relationship with these other agencies that do not know very much about us. I think understanding

adapt it and make sure that you’re at least part of the conversation.

**Saravitz:** Getting back to the point about getting Commerce to try to target some primes, maybe we need to start smaller than that. Get a company like GE

Healthcare to consider building a new lab. Talk to them about bringing it here in North Carolina to one of our capsules at N.C. State or a research campus or somewhere like that. Just make them aware of us — those primes — so that when they are considering



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how agencies like that work and how they move their money around and where it's going is a key element of trying to tap the funding they have and meet the needs they have. But I think something that will continue to come up is this focus on solutions. If they are trying to develop a therapeutic vaccine, that is very, very targeted. It's about understanding what they need, and developing applications to meet that need.

**Burnett:** In my company's experience, we have 12 actively funded government contracts. Ten are DOD. We raised over \$50 million in research and development efforts that are funded by the government. So we've had a ton of success with understanding and working on DOD problems. I talk to academic faculty all the time who say, "I really want to do what you guys do. I want to get some DOD money." But if you want to get DOD money, this is what you have to do. The faculty don't understand how to work that process. Too often when they come up with the new technology, they don't think about how this might be dual-use.

**Russ:** I agree. Just like business, it's a question of width and depth. To the extent it could be done, we should have more resources with a smaller target. But I think good proposal writing does a few things. It gives you a higher probability, and it saves you time and energy. I think we would do more if we knew that there was a good category of people reaching out to get proposals.

**Burnett:** And the startups here can take an idea and make it work. There are units within our universities that are denying proposals. Usually they're focused on either helping faculty get started, or they're setting up to help the biggest proposals — to get the big center grants and things like that. I want to comment on putting resources toward the few we expect to be winners. If we knew which projects were going to be the winners, that would be great. There are a lot of great projects out there that don't get funding. ■

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Funding from the NC Biotechnology Center, the NC Department of Commerce, and Federal Government and Department of Defense granting agencies allows us to develop products for advanced trauma and regenerative medicine—so we can continue to give back to those who have given us so much.

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