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The next frontier

Inside the Triad's vision to be
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Dr. Adnan Mjalli

The next frontier

Inside the Triad's vision to be a world leader in biotech research and why it may happen sooner than you think

By Michael J. Pallerino

The 150-mile I-85/I-40 stretch from the Research Triangle Park to Charlotte is becoming one of the country's premier biotech corridors. In the offices and conference rooms and labs in the companies that sit along that stretch, there is groundbreaking work being done – the kind of research and analysis that is changing the way (and how) we live. In the heart of this corridor sits the Piedmont Triad – the 12-county area anchored by the cities of Greensboro, High Point and Winston-Salem. More than 1.5 million people call the area home – good enough to make it the 36th-largest metropolitan area in the United States.

The Triad area also is good enough to make it a renowned incubator for the growing biotech and life sciences industries. The companies are many: Laboratory Corporation of America; TransTech Pharma; Cook Medical; Ameritox; Targacept; Banner Pharmacaps; Novartis Animal Health; and Syngenta Crop Protection, just to name a few. Their impact on the region – the world, really – is still evolving. Today, the Piedmont Triad generates more than \$4 billion in biotech and life science revenue annually.

The Tar Heel State has made the growth of this flourishing industry one of its

highest priorities, including raising the commitment to workforce development and training, college educational programs, technology transfer from state universities

“Innovation is a primary success factor for a biotechnology company”

and colleges, tax incentives and aggressive company recruitment.

From where Nancy Johnston stands, these are good days of opportunity in the Triad. As the executive director of the North Carolina Biotechnology Center, she has a clear view of some of the most intriguing groundbreaking research and technologies in the world. The long-time marketing executive came to the Center in May of last year, tasked with helping it provide long-term economic and societal benefits to North Carolina through support of biotechnology research, business, education and strategic policy statewide.

With the state's traditional tobacco, textile and furniture markets beginning to erode, biotech was on the cusp of becoming a new industry in 1984 when then Governor Jim Hunt and other state leaders established the Biotechnology Center to capitalize on its economic promise. The Center – a private non-profit organization supported by the N.C. General Assembly – was created to be the world's first government life science jobs engine.

The concept has worked. North Carolina is not only one of the top three states in bioscience employment, but its biotech base is one of the fastest growing among major biotech states. Today, North Carolina's biotechnology sector is a \$64.6 billion industry, employing close to 60,000 people in more than 500 companies.

And that's just the beginning. There are those, Johnston among them, who feel the Triad will significantly contribute to North Carolina further becoming the world's premiere destination for bioscience research. It already is the country's leading hub for contract research and testing companies, as well as a world leader in vaccine research and manufacturing.

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TransTech Pharma, High Point

Dr. Adnan Mjalli, Chairman, President & CEO



TransTech Pharma is a clinical-stage pharmaceutical company focused on the discovery and development of human therapeutics to fill unmet medical needs. Its mission is to utilize its innovative technology to rapidly translate the functional modulation of human proteins into safe and effective medicines. The company has a pipeline of small molecule clinical and pre-clinical drug candidates for the treatment of a wide range of human diseases including central nervous system disorders, cardiovascular disorders, type I/II diabetes, obesity and cancer. It built its product candidate portfolio through internal discovery, advancing its product candidates through in-house research and development efforts. In addition, strategic collaborations with leading pharmaceutical and biopharmaceutical companies have contributed to our portfolio of product candidates. *Business Leader* recently sat down with Dr. Adnan Mjalli, chairman, president and CEO of TransTech Pharma to get his comments on who the company is, where it is going and what the future holds. Following is what he had to say.

Tell us a little about what your company does.

We are a clinical-stage pharmaceutical company focused on the

discovery and development of human therapeutics to fill unmet medical needs. Our mission is to utilize our innovative technology to rapidly translate the functional modulation of human proteins into safe and effective medicines. We have a pipeline of small molecule clinical and pre-clinical drug candidates for the treatment of a wide range of human diseases including central nervous system disorders, Type VII diabetes, cardiovascular disorders, obesity and cancer.

TransTech Pharma was founded in 1999 with one man and one vision. The vision has grown to more than 200 employees with 12 programs at different stages of development with over 1,000 patent and patent applications, and eight key strategic, national and international partnerships, including Novo, Pfizer, Forrest, Cephalon, BI, SIGA, and Merck. TransTech Pharma has four divisions, basic research, preclinical development, manufacturing, and clinical research.

How did you get started?

My start began in 1999 when I submitted my resignation as chief scientific officer of a previous Biotech company. From the attic of

my home I began by writing a business plan and developing a vision that included, raising capital, finding a location, setting up lab and the recruitment of talent to execute the business plan.

What product and/or service do you provide?

This vision has been realized in the discovery and development of 12 different novel medicines, that treat life threatening diseases with high unmet medical need, at various stages of development.

How has this added to your success?

These medicines, along with the talent we have recruited and retained, in addition to the jobs we have created have augmented my goal of discovering new medicines to reach millions of sick people globally in many disease areas.

Talk about the future. What are your plans for the next 18 months?

The future is very bright. In the next 18 months we will continue to execute and advance closer to the market, these new therapeutics that treat diseases with high unmet medical need.

How has being based in the Triad helped your business?

The Triad is an ideal place to work, live and educate. It offers good access to top talent and tertiary institutions within close proximity. We have been successful in recruiting many employees from all over the United States as well as foreign countries to work in the area. It is geographically convenient and provides convenient access to other pharmaceutical/biotech regions both within and outside North Carolina.

How has the Biotech Center helped your business?

TTP was the first biotechnology company in the Triad, prior to the establishment of the North Carolina bioregional location in the Triad. We didn't realize how important the NC Biotech center in the Triad would be in helping us recruit talent and encourage relocation of other Biotech companies to a point where this region is becoming a biotech hub.

How did you started in this profession? What were your inspirations?

It started during my Ph.D. research. The inspiration was to use research to help mankind by discovering new therapeutics.

Give us a story that helps define what your company is all about.

There is a success story behind each of the 12 drugs we have in development, ranging from identifying a gene and a treatment for Alzheimer's disease; a gene and treatment for food intake, obesity, and depression; a gene and treatment that controls healthy aging; a treatment for cancer; and identifying a gene and treatment for type 2 diabetes, where glucose is controlled and the pancreas preserved.

All these stories have been recognized as success stories both nationally and internationally on various levels. Our Alzheimer's drug candidate, targeting RAGE was featured as one of the top 12 innovative worldwide programs at the national Bioconference in Boston in 2007. A video presentation about this program was aired at the keynote luncheon featuring speeches by Sen. Ted Kennedy and Michael J. Fox. TransTech also received the first ever the Economic and Development award from the NC Department of Commerce during this national conference.

Targacept, Inc., Winston-Salem

J. Donald deBethizy, Ph.D., Founder, President & CEO



Targacept, Inc. is a biopharmaceutical company engaged in the design, discovery and development of NNR Therapeutics, a new class of drugs for the treatment of multiple diseases and disorders of the nervous system. The NNR Therapeutics selectively target neuronal nicotinic receptors – or NNRs, which are found on nerve cells throughout the nervous system and serve as key regulators of nervous system activity. The company currently has a robust clinical-stage product pipeline and multiple preclinical product candidates. Its most advanced product candidates are in development for major depressive disorder, attention deficit/hyperactivity disorder, Alzheimer's disease and cognitive dysfunction in schizophrenia. *Business Leader* recently sat down with president and CEO J. Donald deBethizy, Ph.D., to get a look who they are, what they are doing and what's on the horizon. Following is what he had to say.

Tell us a little bit about what you do.

Targacept is developing a diverse pipeline of innovative NNR Therapeutics™ for difficult-to-treat diseases and disorders of the nervous system. NNR Therapeutics selectively modulate activity of specific neuronal nicotinic receptors, a unique class of proteins that regulate vital biological functions that are impaired in various disease states.

Our lead program, TC-5214, is being co-developed with AstraZeneca and is in Phase 3 clinical trials as an adjunct treatment for major depressive disorder (MDD). Targacept

leverages its scientific leadership and proprietary drug discovery platform Pentad™ to generate novel small molecule product candidates to fuel its pipeline and attract significant collaborations with global pharmaceutical companies.

We currently have a robust clinical-stage product pipeline and multiple preclinical product candidates. Our most advanced product candidates are in development for major depressive disorder, residual phase schizophrenia, attention deficit/hyperactivity disorder, Alzheimer's disease and inflammatory disorders.

How did you get started?

We trace our scientific lineage to a research program initiated in 1982 by R. J. Reynolds Tobacco Company (RJR), a Fortune 100 consumer products company, in which scientists studied the chemistry and biology of nicotine. During our incubation within RJR, our researchers published hundreds of scientific papers and abstracts. Many of the publications focused on neuronal nicotinic receptors, which we refer to as NNRs, a unique class of molecular targets in the body that modulate and regulate nervous system activity.

The findings from this work, as well as numerous investigations into the biological effects of nicotine reported in the scientific literature, suggested a role for NNRs in the treatment of human disease and led to the creation of Targacept as a subsidiary of RJR in 1997.

We became independent in August 2000 in a spinout hailed in the *Harvard Business Review* as a Best Practice for corporate spinouts. The key factor contributing to that success was the recognition that Targacept had to be completely independent. In other words, we had to cut the umbilical cord with RJR.

What product or service do we provide?

We are a development-stage biopharmaceutical company, meaning that we discover new small molecules that we refer to as NNR Therapeutics™. NNR Therapeutics target neuronal nicotinic receptors in various tissues of the body and have the potential to treat diseases and disorders of the nervous system. We discover these molecules using varying techniques, including sophisticated computer-based molecular modeling and laboratory synthesis. We then test these potential therapeutics in the lab in test tubes and preclinical disease models, before proceeding to human clinical trials.

Larger pharmaceutical companies are always looking for innovation in drug development, providing us with the opportunity to license our promising product candidates to these companies. We have done just that with TC-5214. We are co-developing TC-5214 with AstraZeneca as an adjunct treatment for major depressive disorder.

The revenue derived from these licensing deals can provide much needed capital that allows us to invest in additional research and build a pipeline that could potentially be licensed to another company or developed to the market by our company.

Biotech investors like to invest in development-stage companies like Targacept because the commercial opportunities for a safe and effective drug for treating patients with diseases such as Alzheimer's disease and depression can be enormous and very few companies can successfully innovate to make a meaningful difference in the lives of patients.

What are the plans over the next 18 months?

We have a very exciting 18 months in front of us. Our most advanced program, in MDD, is in the last stage of clinical development before filing for approval, known as Phase 3. The four RENAISSANCE efficacy studies, ongoing with AstraZeneca, are expected to give us a much better understanding of how our innovative therapeutic, TC-5214, will perform in a large sample of patients with MDD who do not respond adequately to initial treatment.

In addition, we expect to learn whether AZ will license TC-5619, our promising therapeutic for treating some of the symptoms of schizophrenia, and to get the next stage of its development underway.

How has the Triad helped our business?

We are fortunate to be located in such a supportive region of the state and country. Our employees tell us that the quality of life in this part of the country is outstanding. We also enjoy the support of Wake Forest University and its commitment to building one of the largest urban biotech parks in the country. In addition, Winston-Salem is in the midst of its own renaissance and our employees enjoy being an important component of that evolution.

How has the Biotech Center helped your business?

It has been instrumental in putting North Carolina and Triad biotech on the map. The Battelle studies commissioned by the center have highlighted how important biotech has been for job growth over the last several years. There now are 539 biotech companies in the state that have contributed a 29.1 percent job growth rate from 2001 to 2008, or 500 percent of state's overall private sector growth. The Triad now has more than 15 percent of the biotech companies in the state and is fueled by the development of PTRP.

How did you get started in this profession?

I was always interested in technology and was truly a product of the space race in the latter part of the last century. As a youngster, I thought my future was in car mechanics but somehow I turned this natural interest in how things worked to biology.

Fast forward through my Ph.D. and postdoctoral fellowship and I became a scientist working in applied science. I liked seeing practical outcomes from fundamental research. This eventually led me to RJR where I learned that my real talents were with helping people be successful in collective efforts.

I was inspired by talented mentors along the way. From my public school teachers who encouraged me to follow my dreams to hard headed mentors who taught me that you had to deliver on the promises you made.

Give us a story that helps define your company.

Our latest success story is around our recent positive results seen in schizophrenia patients. Some of our chemists, I recall Anatoly Mazurov specifically, but there were others as well, kept focusing on the potential application of a particular form of the nicotinic receptor, alpha 7, to treating schizophrenia, ADHD and AD. These scientists worked with little funding to discover TC-5619. Our biologists ran with it and found it to have one of the best preclinical profiles for a potential new drug that we have ever discovered. Our recent Phase 2 outcomes may be just the beginning to a story of discovery and development of drugs that we believe have the potential to change how schizophrenics are treated.

(Continued from page 11)

“There is no single story that defines the success of the Triad, but more of a compilation of diverse milestone successes – large and small – that makes a difference from an academic, industry and economic impact perspective,” Johnston says of the area’s success. “Biotechnology development is about community development. Our regional office strives to make meaningful connections and communicate the importance and impact of biotechnology. We collaborate to bring jobs to the community.” Johnston believes the state of North Carolina looks to the Triad region to be the next generation model of Research Triangle Park, which today serves as an international icon of North Carolina’s forward-thinking and strategic leadership. “The community is intensely focused on moving forward in the new technology economy,” she says.

Leading the charge

When Johnston was named executive director last May, her vision was to bring a new “set of eyes” and perspective to the already growing biotech landscape. That meant listening and learning, and being a collaborative spirit.

“The Center and its leadership have garnered great respect across the state through its outreach to regional hubs of activities,” Johnston says. “The support and engagement of the advisory committee for biotechnology in the Piedmont Triad has been incredible. I’ve been impressed and encouraged by the high level of commitment. A select group of executive level volunteer leaders have invested a great deal of time in strategic planning sessions to build upon past successes.”

Johnston says the collaborative spirit of the Triad reveals itself every day. For example, during a recent statewide advisory leadership retreat that included the chair and vice chairs for various statewide committees, a strong emphasis was placed on the value of the Center’s continual engagement in the local community with its statewide office model. “It was not a surprise or revelation but a pride point for me as

our regional office works diligently to represent the Piedmont Triad and the N.C. Biotechnology Center in concert with our statewide colleagues,” Johnston says.

Of the 500 companies in the state, close to 100 exist in the Piedmont Triad. The area employs more than 10,000 people in the 12-county region. The Center is focused on energizing and engaging the community and continues to drive economic impact through emerging technologies in areas such as regenerative medicine and nanobiotechnology.

“There is no single story that defines the success of the Triad, but more of a compilation of diverse milestone successes.”

Among the Center’s many allies is its 24 member Advisory Committee for Biotechnology in the Piedmont Triad, which includes representation from industry leaders, research universities, community colleges, economic developers and research parks. Collectively, these leaders have an interest in building a biotechnology community to help create job opportunities. The volunteers serve as the “pulse of the community,” helping to educate and promote biotechnology, and offer strategic guidance, among other contributions that include Triad BioNight, a bi-annual celebration, scheduled for later this year.

The Triad is as diverse as it is successful. Companies range in size from a local early stage entrepreneurial start up, to a multi-national brand with regional headquarters or operations. Career opportunities range from Ph.D.-educated scientists, to a workforce transitioning

from traditional industries through our strong community college system.

Johnston says the region also has a dynamic entrepreneur group, from a life sciences executive round table, to one of the largest centers for entrepreneurship in the Southeast – a quality she hopes will continue to grow and attract more executives to help commercialize the technologies coming out of the region’s four research universities – Wake Forest, UNC Greensboro, N.C. A&T and Winston-Salem State, as well as two research parks, which include Gateway University Research Park and Piedmont Triad Research Park.

The Triad’s growing biotechnology sector includes three major areas that continue to show increases over the past few years: medical and diagnostic labs (50 percent); research and development (36 percent); and pharmaceutical and medical manufacturing (25 percent).

With academia and industry working in nearly every area of biotechnology, from pharmaceuticals and food safety, to bio defense and medical devices, the Triad is uniquely positioned for future growth in areas of world-class healthcare institutions and research in regenerative medicine and nanotechnology; agricultural biotechnology; medical devices and biopharmaceuticals. In addition, there are several hundred companies that serve the industry, including investors, patent lawyers, staffing relocation firms, among others.

And innovation abounds. “Innovation is a primary success factor for a biotechnology company,” Johnston says. “The industry is globally competitive, and the ability to bring impactful ideas to market requires the ability to leverage brainpower and resources. The term ‘bench to bedside’ is often used to define success, as a key driver is to bring technologies to help better humankind.

“What makes all this ‘tick’ is the intense interest in implementing innovative ideas and the desire to attract further investment to the region. What makes it work is an energized community of creative and collaborative minds.” □



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