
**Denver Magazine** / January 2010 / The New Health Technology

# The New Health Technology

## The face of the bioscience industry is changing rapidly and nowhere more so than in Colorado.

By Barbara T. Zimmerman, Ph.D.
Rob Hammer/photography

A 578-acre campus devoted to biomedical education, patient care, and drug development rises in Aurora on the site of an historic U.S. Army hospital. New construction in Boulder and Fort Collins facilitates the transfer of university technologies to the marketplace. A multitude of medical device, biotech, and green fuel companies dot the Front Range of the Rockies. This is the bioscience industry in Colorado today.

When people think of Colorado, the image is one of snowcapped mountains; first-class ski resorts; and healthy, active people. Economic drivers have historically included telecommunications, transportation, tourism, mining, agriculture, aerospace, and energy research. Denver is also a regional headquarters for government agencies and a financial center. What is not mentioned is that Colorado is becoming one of the most prominent venues in the United States for the rapidly growing bioscience industry. In 2008, Colorado was ranked at the forefront of bioscience initiatives by several noted indices, including the Milken State Technology and Science Index, which gauges the intensity of the state's technology and science workforce and assets that can be leveraged to promote economic development. The Milken Index placed Colorado among the top five in all five of its assessment categories. Given the independent and entrepreneurial spirit pervasive in the American West, these facts shouldn't be surprising but need to be publicized beyond the world of scientists and those who support their endeavors.

### A Definition and Brief History

The bioscience industry is comprised of biotechnology and pharmaceutical companies, medical device manufacturers, health care providers, research institutions, and businesses that provide critical services and products to them. It includes academicians and scientists, technology transfer professionals, entrepreneurs, and financiers. The biotechnology industry took off in the 1980s when scientists learned to manipulate DNA and develop industrial applications. For example, research by the University of Colorado's Marvin Caruthers, using small molecules called oligonucleotides, led to the development of new drugs for clinical applications, diagnostics and therapeutics. Caruthers co-founded Amgen in 1980, which has grown into one of the world's largest biotechnology companies. Others have succeeded and been merged, bought out, or brought public, and medical device firms were founded as outgrowths of this bioengineering research.

Colorado has had prominent research institutions, but the biosciences industry was not a major economic driver in the economy until recently. The academic world generally focused on research for its own sake rather than commercial potential. Graduate students were trained to become professors who would train the next generation of young scientists. Although some newly minted Ph.D.s "defected" to industry, the practice was discouraged. The rewards of a career in science were publications, successful grant applications, and managing a "productive" laboratory.

In the past decade, there has been a tremendous shift in direction as academic scientists realized their observations could be the basis for patents and commercialization. Technology transfer professionals became increasingly knowledgeable and aggressive in pursuing, protecting, packaging, and licensing to business the intellectual property generated in academic research laboratories. Discoveries led to new drugs and other products that are now widely used. Similar activity occurred in other states, especially on the east and west coasts. According to John Collar, CEO and president of the Colorado BioScience Association (CBSA), Colorado is now competitive with many of these states and internationally and is positioning itself to make the bioscience sector a major player in the state's economy.

**Why Colorado?**

Colorado is a prime location to develop the bioscience economic sector. The state has a uniquely entrepreneurial population and a highly educated workforce. Its geographically central location places it in an advantageous position for future economic development and growth. The scenery and lifestyle attract top-quality talent. Most importantly, Colorado has a vision for the future.

In 2003, the Governor's Office of Innovation and Technology, supported by a group of public and private interests, including Amgen, the Colorado Institute of Technology, and the Denver Metro Chamber of Commerce, presented an action plan designed to distinguish Colorado as a preeminent life science and healthcare center and to create a vibrant cluster of bioscience companies. Within five years, the state had made significant progress in investing in the bioscience sector and necessary supporting infrastructure, and discoveries were increasingly leading to new applications and products for medical treatments, new energy sources, and new biomaterials. In 2008, the CBSA, a nonprofit corporation that shapes policies and develops programs to help bioscience companies grow and prosper, collaborated with the Colorado Office of Economic Development and International Trade, local research institutions, industry partners, and economic development organizations to assess the progress made since 2003 and create a plan to position the bioscience sector as a key driver of the economy.

This 2008 Roadmap envisions Colorado delivering solutions for regional, national, and global health needs through its leadership in research, education, and clinical medicine. With its robust cluster of bioscience companies and a highly talented workforce, Colorado is positioned to develop innovative products that address health care, environmental, clean energy, agricultural, veterinary, and national security needs.

Although much progress had been made since 2003, the report states that to fully achieve this vision, Colorado will have to increase the availability of investment capital for bioscience companies and related infrastructure; develop a stronger bioscience technology commercialization network that provides support to bioscience entrepreneurs, start-ups, and emerging companies; ensure development, attraction, and retention of a population with the skills and education needed; and strategically focus on technology areas that distinguish Colorado in a globally competitive industry.

**Are We Succeeding?**

The general consensus is that Colorado has the vision, talent, and skills to continue to develop the bioscience sector. According to the CBSA, the industry employs 20,000 Coloradoans directly and more than 100,000 indirectly. Forty new companies were started from 2001 to 2007 based upon technologies from Colorado research institutions. In 2009, Colorado was among the top five in the country for getting venture capital investment in life sciences, and eighth for funding the medical device industry.

The legislature recognizes the potential of supporting developing technologies that began in the research institutions. It created the Bioscience Discovery Evaluation Grant Program in 2006 to support business development. House Bill 1001, passed in 2008, provides $26.5 million to extend the program for another five years. It supports technology transfer offices to accelerate commercialization of bioscience technologies, early stage companies that have licensed a technology from a state research institution, and partnership efforts between the bioscience industries and research institutions to build necessary infrastructure, which has helped technology transfer grow exponentially and streamlined the commercialization process. Colorado has also developed a number of job creation performance incentives and tax refunds/exemptions to encourage further development.

**Progress and Changes**

The past decade has seen tremendous change in research-oriented medical centers. The 2008 Roadmap states that from 2002 to 2006 Colorado academic medical research and development grew more than 72 percent, nearly twice the national rate. Much of this activity was spurred by the relocation of the former University of Colorado Health Sciences Center to the site of the closed Fitzsimons Army Medical Center in Aurora where a new state-of-the-art campus was built. Following a consolidation, the institution is now known as University of Colorado Denver-Anschutz Medical Campus (UCD-AMC). It was designed to reflect the new medical practice paradigms. The University of Colorado Denver has 13 schools and colleges on two campuses, the Denver Campus and the AMC in Aurora. The School of Medicine is affiliated with other research institutions; University of Colorado Hospital; and clinics in integrated educational, research, and clinical zones. Academic programs have been shifted from relative isolation to multidisciplinary, team-driven, collaborative learning experiences, encouraging relationships between students of different disciplines, researchers, and physicians.

According to Jacque Montgomery, director of PR at AMC, the project is now the largest medical development in the country. UCD generates more than $376 million from grants and contracts and is sixth in the country in terms of National Institutes of Health (NIH) grant support. The Anschutz Medical Campus employs 16,000 people and expects that number to eventually grow to 60,000. The campus integrated education, research, and clinical care and is home to the University of Colorado Denver's health sciences programs, the University of Colorado Hospital, and the University of Colorado Cancer Center.

In recent years, the NIH has shifted its funding focus to "translational" medicine, which emphasizes taking research discoveries to patients' bedsides. This trend brings basic scientists together with clinicians in a team approach and has encouraged the creation of the Colorado Clinical and Translational Science Institute to train both physicians and scientists to become clinical investigators.

UCD-AMC boasts specialized centers such as the Charles C. Gates Regenerative Medicine and Stem Cell Biology Program. Dr. Dennis Roop was recruited to direct the program with the goal of transforming CU into one of the country's premier stem cell research centers. The program was initially limited by the legal restrictions on use of embryonic stem cells. Now, a new technology, induced pluripotent stem cells, can effectively "reprogram" adult cells to behave like embryonic cells and holds tremendous promise for future therapies without the legal and ethical drawbacks of embryonic material. Roop collaborates widely with investigators in other disciplines who can benefit from stem cell technology.

The new models of interdisciplinary collaboration function across institutional as well as departmental lines. The Children's Hospital (TCH) relocated to the former Fitzsimons campus. Dr. Stephen Daniels, pediatrician-in-chief and chair of pediatrics, is also a professor of pediatrics and preventive medicine at UCD School of Medicine. He feels the move strengthened the hospital's clinical and research programs by facilitating traditional and entrepreneurial collaborations that can benefit the children. TCH clinicians hold appointments at the university, and their grants come through the university as well. In Daniels' view, research contributes to the clinical practice of the future. TCH plans a major financial investment to increase its research program.

**An Arduous Path**

In traditional research institutions, scientists propose a hypothesis and design experiments to test its validity. If the data are convincing, the information is published in a peer-reviewed journal. When enough preliminary data is collected, the scientist writes a grant proposal to the NIH or other agency to continue funding the research.

In contrast, scientists involved in drug development begin their quest with a vision of the end product. They then work backward to design technologies that meet that goal and are safe and effective. It is only in recent years that research universities in Colorado have encouraged the type of activity in which the aim is a commercial product. The change has been accelerated by the shift in funding to translational and personalized medicine, which uses up-to-date technologies to design drugs that work for an individual patient rather than the "one-size-fits-all" model. There is no formal training for scientists to learn how to commercialize their observations, and graduate training generally follows hypothesis-driven methodologies. Only some UCD-AMC faculty members choose to engage in commercialization, but the number is growing.

Scientists whose observations could potentially lead to a commercial product are urged to meet with the Technology Transfer Office (TTO) before publishing to begin the application for a patent. This action protects the intellectual property (IP) even after the discovery is published and put into the public domain. TTO personnel guide the scientist/inventor along the complex path to commercialization, a process known as product translation. The TTO matches the scientist with an advisor who helps develop a commercial roadmap, including such

milestones as providing proof of concept, demonstration by a significant amount of pre-clinical data that the proposed IP might actually be successfully commercialized. If promising, the technology is licensed to a company for further development with the expectation of beginning clinical trials by a certain date. Royalties are paid as the product reaches certain developmental junctures.

Assuming the product passes the requisite clinical trials, it must then follow strict manufacturing and marketing procedures. There is extensive FDA oversight and many potential points of failure. According to Dr. Rick Silva, director of technology transfer for UCD, only one in 20 to 30 will succeed. It takes approximately two million dollars and up to three years to bring a drug to clinical trials. The average successful new drug takes 10 to 12 years and $100 to $200 million to come to market. The TTO tries to take the product to a point where it will be attractive to major funding sources such as venture capitalists. At CU, royalties on patents are split four ways: 25 percent goes to the inventor; 25 percent to the inventor's laboratory; 25 percent to the chancellor, who filters the money to the dean and department head to further education and research. The TTO takes the remaining 25 percent. According to Silva, this is its only source of income, so it is to everyone's benefit that the product be developed successfully and the IP protected.

**Campus Life**

The remainder of the Fitzsimons campus is owned by the Fitzsimons Redevelopment Authority (FRA) and is now known as the Fitzsimons Life Science District. It houses the Colorado Science and Technology Park whose Bioscience Park Center building serves as an incubator for new start-up companies. More established companies are housed in a separate building, and a third is expected to break ground in the coming year. The physical proximity of the Science and Technology Park to UCD-AMC facilitates the transfer of technology.

There is no shortage of entrepreneurial scientists at UCD-AMC or potentially marketable products. The major problems are a lack of funding at the early stage and the lack of an infrastructure to support technological maturation. Most funding sources are too risk-adverse to put money into an early project that may fail. To fill the gap, Dr. Richard Duke and Kevin Smith created CID4, the Colorado Institute for Drug, Device and Diagnostic Development. CID4 identifies and funds potential opportunities, matches new treatments and cures with the right investors, develops realistic business plans, and promotes economic development in Colorado by getting more companies started and thriving. According to Duke, the University of Colorado campuses currently spin off 10 to 13 new companies per year.

The FRA sponsors Fitzsimons BioBusiness Partners (FBBp), directed by Dr. Michael Artinger. FBBp mentors tenant start-up companies in business strategy and finding appropriate management teams. It matches the company with a commercial "driver" who is familiar with the technology and helps identify funding sources, such as highly specialized federal grants for promising early-stage innovations.

Other universities have their own programs for commercializing new technologies. UC-Boulder is building a new facility for the Colorado Initiative in Molecular Biotechnology, headed by Dr. Leslie Leinwand and Nobel laureate Dr. Thomas Cech, which applies different disciplines to the biosciences and has spun off new companies. Colorado State University in Ft. Collins has three Superclusters that promote alliances between academic researchers, economists, and business experts. It is currently building a Research Innovation Center for the Infectious Disease Supercluster and its enterprise arm, MicroRx. CSU has also established the Biopharmaceutical Manufacturing and Academic Resource Center for training students in product translation and clinical trial methodologies, and the university spins off three to five new companies per year.

**Future Considerations**

There is no question Colorado has a critical mass of talented, entrepreneurial investigators who are willing to take the tremendous risks necessary to drive the bioscience sector forward. They comprise a solid community with excellent technologies and a strong spirit of collaboration. They sincerely believe in the necessity for biomedical research, both basic and applied, for the economic well-being of the state and the health of its residents. What they need most is investment capital to achieve their vision.

Even for companies that have overcome the difficulty of finding solid funding sources for early-stage technology, venture capital firms have become extremely risk adverse. The state has its own budget deficits and is not in a position to commit the amount necessary to be fully competitive with other states. Some companies are still doing well, but others have left the state, and some have folded. There is also the big unknown concerning pending health reform legislation. The drive is there to personalize medicine for a healthier population, but will the diagnostics and therapies be affordable?

This article appears in the January 2010 issue of Denver Magazine