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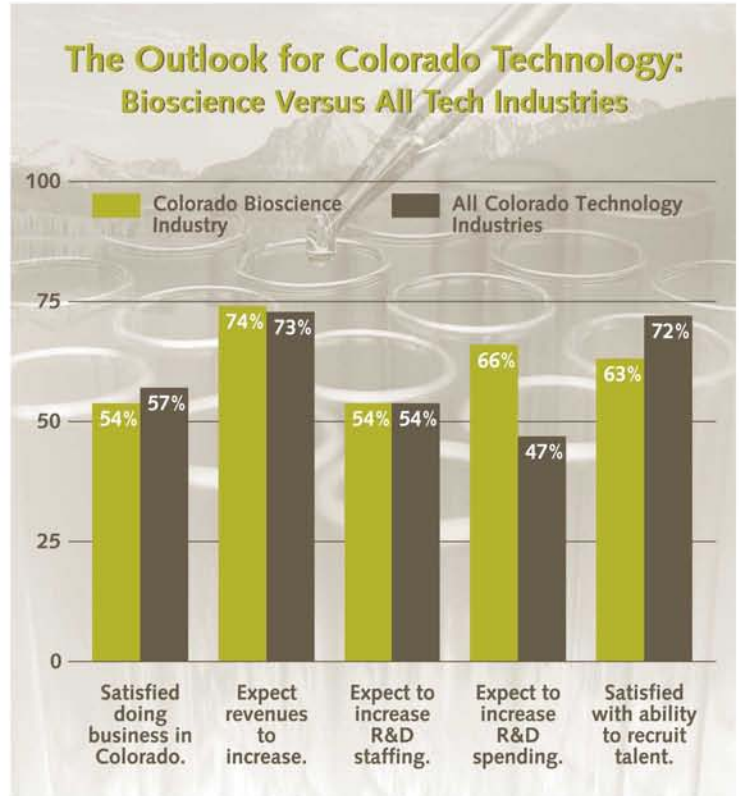
SURVEY SHOWS INCREASE IN NEW PRODUCT DEVELOPMENT

A recent survey focused on technology in Colorado shows bioscience companies plan to invest more money and human capital in research and development during the first six months of 2005.

The survey was conducted in January and February by the Colorado Software and Internet Association and ccintellect, a market research firm. A total of 242 professionals responded, representing over 215 companies. Of those who responded, 54 were from the bioscience industry, 22 percent of all respondents.

A majority of the bioscience companies who responded said they expected to increase budget spending in the area of research and development. About half of the respondents also said they plan to increase their research and development staff. This early stage investing could signal new confidence in future and current research and development projects.

Compared to the total for all technology industries, the bioscience sector was more upbeat about research and development than other industries – with 66 percent saying they intend to spend more on research and development compared to 47 percent of all sectors.



"There's a clear sense of increased optimism in our bioscience industry. Most companies plan to accelerate testing of current products in development and put more products in the development pipeline," says Denise Brown, CBSA executive director.

Other significant findings included:

- Nearly two-thirds of respondents said revenues were up in the second half of 2004 and they expect profits to continue to rise in the first six months of 2005.

- 54 percent of respondents said they were satisfied doing business in Colorado.
- Only 9 percent of companies were satisfied with incentives from state and local governments.
- 54 percent were satisfied with the talent pool and 63 percent were satisfied with their ability to recruit in Colorado.



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## COMING EVENTS

CBSA hosts an ongoing series of educational seminars and training programs for our members. Please visit our Web site for more details or to register for upcoming events: [www.cobioscience.com](http://www.cobioscience.com)

### April 14th

CBSA Annual Member Meeting - featuring National Jewish Medical and Research Center

### April 27th

Bio Breakfast at Fitzsimons

### May 3rd

Seminar

### May 12th

Longmont Life Science Thursday

### May 25th

Bio Breakfast at Fitzsimons

### June 7th

BioScience Larimer County

### June 9th and 10th

Bio Bootcamp

### June 15th

Bio Breakfast at Fitzsimons

## SAVE THE DATE

### September 19th

Annual CBSA Golf Tournament

### November 8th and 9th

BioWest

### November 8th

CBSA Annual Dinner

Watch your e-mail for event invitations and check the CBSA Web site frequently for additional programs.



Ralph Christoffersen, PhD  
Chair, CBSA  
Partner, Morgenthaler Ventures

## IT IS MY PLEASURE TO PRESENT THE INAUGURAL CBSA FOCUS.

It's been in the planning stage for some time, so we hope you find this new member benefit informative and interesting. The CBSA staff looks forward to your comments and suggestions.

CBSA is now 300 members strong, thanks to you and others who view a vital bioscience industry group as essential to

our Colorado economy. During 2005, we have over 40 programs and events planned, all aimed at enhancing your networking, education, and training opportunities. Please plan to attend our annual meeting on April 14th at the National Jewish Medical and Research Center and participate in the governance of your Association. Remember, every member has a vote.

CBSA actively works on industry legislation, including tax and fiscal policy proposals, economic development initiatives, reimbursement issues, and agricultural policy matters. Last year, we helped create the new State Venture Capital Authority (a \$50 million investment fund for early stage companies). In 2005, we plan significant action on legislation to allow medical device and biotechnology companies to sell net operating losses. Please watch for details in the weekly reports from our lobbyists, Tomlinson and Associates.

We continue to advocate for technology transfer, and we are hard at work on BioWest, the 2005 golf tournament and membership development. In May, you will receive the second annual *Bioscience Colorado* magazine, including an updated and improved directory of Colorado companies.

I encourage you to visit the new CBSA office in the Advance Colorado Center at 1625 Broadway, Suite 950. CBSA shares space in an exciting new collaborative with other technology business organizations. The space is rent-free and comes with program and technical support from the Governor's Office of Economic Development and the University of Colorado. We still maintain our offices at Fitzsimons and in Fort Collins, too.

I look forward to seeing you at the annual meeting.

# BioWest 2005

The Rocky Mountain Region's premier medical device and biotechnology conference returns on November 8 and 9 at the Colorado Convention Center.

Highlights include:

- Over 700 expected to attend
- Exhibit hall featuring 80 exhibitors open entire two days
- 15 expert panels
- 5 breakout tracks
- 4 keynote sessions

- 10 companies in venture showcase
- Technology transfer poster session
- Two receptions and two lunches included in registration fee
- Discounts for dual registrations to the conference and the November 8 CBSA dinner

For exhibit space contact:

Jessica Emmet at  
[Jessicae@burnsmarketing.com](mailto:Jessicae@burnsmarketing.com)  
or 970-223-4060.

For sponsorship information:  
Christine Shapard, Colorado Director of Biosciences and Emerging Technologies:  
[Christine.Shapard@state.co.us](mailto:Christine.Shapard@state.co.us)  
or 303-892-3859. Online registration begins in June at: [www.biowestconference.com](http://www.biowestconference.com).



# McKinley Medical Carves Out a New Niche in Pain Management



The ACCUFUSER® Post-Op Pain Control Pump features a unique bolus-dose button that patients can activate to relieve breakthrough pain after surgery.



The ACCUFUSER® Post-Op Pain Control Pump with bolus-dose button and McKinley Saturation Catheter™.

Aesthetic surgery is booming in America, thanks to extensive media coverage that gives the public an eye-opening view of what plastic surgeons can do. As the population ages, people seem determined to stay youthful and lean as long as possible, and many of them are opting for appearance-enhancing procedures.

A Colorado medical device company is taking advantage of this trend. McKinley Medical, LLC, based in Wheat Ridge, with a facility in Blackpool, Lancashire, England, provides infusion therapy for post-operative pain management. A leader in pain management systems for general and orthopedic surgery, McKinley currently targets three popular aesthetic or reconstructive procedures: abdominoplasty, breast augmentation and breast reconstruction.

According to the American Society of Plastic Surgeons' most recent statistics, 101,000 abdominoplasties, 254,140 elective breast augmentations and 68,000 post-breast surgery reconstructions were performed in 2003.

"It makes sense for us to be in the aesthetic surgery market. We have carved out a nice niche in this field with our product and distribution strategies," says Richard "Randy" Hoffman, Pharm.D., McKinley's president. "Plastic surgeons are very approachable and it is a smaller market segment not aggressively pursued by other pain management companies."

Hoffman, with more than 20 years experience in the infusion pump and health care industries, has been with McKinley since the privately held company's inception in 1995 and was appointed president in 2001. Prior to joining McKinley, he helped Columbus, Ohio-based Medex, Inc., create European and Asia-Pacific business development and product development programs that established Medex as a leader in ambulatory infusion therapy in the United States.

His clinical and management expertise improved McKinley's operational efficiencies and helped the company develop manufacturing relationships for products like the ACCUFUSER® Post-op Pain Control Pump. The non-latex, disposable pump provides clinical benefits and

increased patient satisfaction during recovery following cosmetic and reconstructive surgery.

Inserted intraoperatively at the surgical site, the McKinley Saturation Catheter™ connects to the ACCUFUSER® flow control tubing. When the pump is activated, the catheter delivers a continuous infusion of local anesthetic to the surgical site for up to five days. The device allows patients to control their own pain relief with a bolus-dose button, a feature that is especially beneficial in the first few days after surgery. Controlling infusion via a patented piston system also prevents sub-therapeutic dosing or toxic over infusions.

McKinley sees liposuction and bariatric surgery (gastric bypass to treat morbid obesity) as emerging areas of interest where the ACCUFUSER® could benefit patients post-surgically. Liposuction is the most popular of all cosmetic surgery procedures with 320,000 surgeries performed annually and represents significant opportunity for the company.

Hoffman says Colorado's medical device community is a forward-thinking arena in which to do business. "Colorado has an outstanding resource pool of research, development, product engineering and support services."



## New FDA Rules

### TISSUE PRODUCTS

The new set of FDA regulations designed to improve the safety of human cellular and tissue based products (HCT/P's) takes effect in May. The regulations expand the requirements on tissue products previously regulated under 21 CFR 1270, and also bring a variety of tissue products under regulation that were previously completely unregulated by the FDA.

The new regulations, while based on the authority of the Public Health Services Act and not the Federal Food Drug and Cosmetic Act, are similar to the quality system regulation for medical devices, and include many common elements: quality audits, corrective and preventive action, process validation, software validation, and environmental control and monitoring. While distinctly crafted around control of communicable diseases and disease agents, the new regulations dramatically increase the level of control and extent of quality systems needed by this industry for ongoing compliance.

For the first time, facilities manufacturing reproductive tissues, including semen, oocytes, and embryos will be inspected by the FDA. This includes not only sperm banks, but also in-vitro fertilization (IVF) centers and clinics that manage the donation process and determine donor eligibility. For these newly regulated facilities, developing and implementing formal quality systems that meet FDA expectations is a major undertaking. Although the new regulations have been under development since 1997, many of those affected



are unaware of the implications and ill prepared to operate in an environment regulated by the FDA.

While the implications for reproductive medicine are significant, tissue product manufacturers that were regulated under the limited requirements of 21 CFR 1270, could also face a significant challenge to upgrade their current systems for compliance with the requirements of 1271.

Colorado's bioscience industry includes a strong group of manufacturing companies, tissue procurement facilities, and IVF centers that work in the HCT/P industry. CBSA is committed to helping them meet these new regulatory challenges. Navigating the regulatory maze is a difficult task for even the most mature organizations. CBSA has the resources and the knowledge to help.

**"...THE NEW REGULATIONS DRAMATICALLY INCREASE THE LEVEL OF CONTROL AND EXTENT OF QUALITY SYSTEMS NEEDED BY THIS INDUSTRY FOR ONGOING COMPLIANCE."**

#### SPONSORS

CBSA is proud to announce our 2005 corporate sponsors. We honor their outstanding commitment to bioscience in Colorado and encourage you to thank them for their generous support.

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# Colorado's Triple Threat

## Dr. Michael Bristow

CLINICIAN, RESEARCHER AND ENTREPRENEUR



**"IF YOU WANT YOUR DISCOVERY TO TURN INTO SOMETHING USEFUL, YOU HAVE TO BECOME AN ENTREPRENEUR."**

From the university medical lab where he worked as a young student, to a distinguished career as a clinician and entrepreneur, he is still driven by the same spark – discovery research in cardiology.

Dr. Michael R. Bristow is a professor of cardiology at the University of Colorado Health Sciences Center, co-director of the University of Colorado Cardiovascular Institute, and founder of Myogen, one of Colorado's best bioscience success stories. "Everything I do," he says, "is designed to develop new approaches for the treatment of heart failure."

He graduated from the University of Illinois - Chicago with a combined MD degree and a PhD in pharmacology. Perhaps it is this ability to blend fields of study and areas of expertise that allows Bristow to enjoy success even when straddling the often conflicting worlds of science and business. In any case, to Bristow it's all academic.

"If you want your discovery to turn into something useful, you have to become an entrepreneur," he says. It helps if the entrepreneur also thinks like a clinician. "You have to understand the needs of your patients because that's where you get your insight. Out of the blue, something will click that you haven't thought of before."

Coming up with a new paradigm is not for the faint of heart. "Science is a highly skeptical business," says Bristow. "The typical response to a new idea is massive rejection."

Bristow founded the University of Colorado Cardiovascular Institute in 1998 with Leslie Leinwand to attract top talent to CU. They developed a world class molecular genetics program now housed at the bioscience park at Fitzsimons. To generate revenue for the institute, Bristow decided to commercialize their research by starting a separate company with partners Leinwand, Eric Olson, and Ben Perryman.

The new biopharmaceutical company became Myogen, a Colorado success story whose stock is now traded on NASDAQ. Myogen has three cardiovascular drugs in late stage development that were in-licensed by leveraging Bristow's intellectual property. It also has an extensive preclinical drug discovery program in partnership with pharmaceutical giant Novartis. It can take 10 years or more from target discovery to drug approval, so licensing-in something that already went through the early phases of clinical trials is an attractive model for starting a biopharmaceutical company.

In 2004, Bristow founded ARCA Discovery, a company that uses

a version of this model to develop drug therapy targeted at cardiovascular gene variants that are important in serious cardiovascular diseases.

Every business decision he makes is motivated by saving lives and improving outcomes for patients. "The best way to save lives is to keep getting new and effective products to patients," says Bristow. "It took us 25 years to develop beta blockers for heart failure but now it's the most effective single therapy for the most important chronic cardiovascular disease in industrialized societies."

Bristow sees a bright future for Colorado biotechnology. He believes the entrepreneurial spirit is ingrained in Colorado's frontier culture, and that its quality of life, talented workforce, and savvy venture capital companies give the state an edge.

### BRISTOW'S ADVICE

Budding entrepreneurs need to believe in themselves. Don't worry about rejections and be tenacious. Find a reliable investment partner and keep moving forward, even when everyone says it won't work.

"When I hear people being irrationally negative I know I must be on to something good," says Bristow. "It makes me more determined."

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## NEWS BRIEFS

### Careers Page on CBSA Web Site

CBSA is pleased to offer a new career placement service to our members. Bioscience companies can now post job openings on our new career page with a link to their Web site. To post a position, please send your company name, contact name, Web site link and job description to Amanda Starbuck: [astaruck@cobioscience.com](mailto:astaruck@cobioscience.com).

### NEW BIO Business Solutions Partner – Airgas, Inc.

As part of CBSA's partnership with the Biotechnology Industry Organization (BIO), we are proud to announce that Airgas, Inc., a CBSA member, was selected to participate in the BIO Business Solutions program. This program offers discounts and enhanced benefits on partner company products and services.

Please visit the BIO Web site for more information on how to tap this member-only benefit: [biobusinessolutions.com/states/co.asp](http://biobusinessolutions.com/states/co.asp).

### BIO Mid-America Venture Forum to include Medical Device Companies

The Colorado BioScience Association, in partnership with BIO and eight other state associations, is presenting the BIO Mid-America Venture Forum. For the first time, the forum is open to medical device companies as well as biotech. The BMA conference will be held in Minneapolis on September 21st–23rd. Stay tuned for nomination details.

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