THE CBSA FOCUS SUMMER 2005

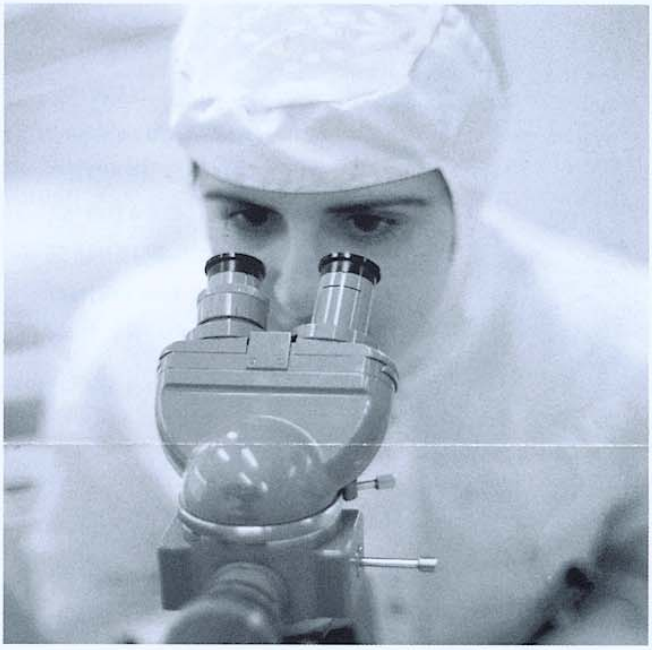
A QUARTERLY LOOK AT COLORADO'S MEDICAL DEVICE AND BIOTECHNOLOGY INDUSTRIES

IN THIS ISSUE

Referendums C and D

CRITICAL TO COLORADO'S BIOSCIENCE INDUSTRY

In November, Colorado voters will be asked to approve two ballot questions that address the state's fiscal crisis. These referendums could have a significant impact on the quality of Colorado's workforce and the state's infrastructure, key components of a sustainable climate for the bioscience industry.



Referendum C would allow the state government to keep and spend all revenues collected from existing state taxes for the next five years, and sets a new revenue cap at the highest level of state tax revenue reached between now and 2011.

The proposal requires that surplus revenues kept under the new cap be spent for health care, public schools, state colleges and universities, and transportation projects.

Referendum D authorizes the state to issue up to $2.07 billion in new, multi-year bonds to speed up funding statewide for a variety of projects including: transportation improvements, pension funds for firefighters and police officers, and repairs for schools and universities. Referendum D takes effect only if Colorado voters also approve Referendum C.

"It is important these referendums pass to ensure an economic environment that supports growth and maintains a healthy bioscience industry," said Denise Brown, CBSA executive director.

The recent recession cost Colorado thousands of jobs and forced the state to cut more than $1 billion in services. Current spending limits mandated by the TABOR amendment make it extremely difficult for Colorado to dig itself out of this hole. If C and D fail, business leaders expect even more cuts in the 2006-07 budget. The majority of these cuts will most certainly come from higher education.

"What that could mean for the bioscience industry is the loss of a highly educated workforce, little collaboration with universities and no modern infrastructure," Denise Brown said.

"We strongly urge our constituents to vote yes on Referendums C and D," she said. "Doing so will help Colorado balance its budget and provide essential support for higher education and other critical state services."

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FITZSIMONS BIOSCIENCE PARK

FORT COLLINS TECHNOLOGY INCUBATOR

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

July 27th
Bio Breakfast
Fitzsimons

August 11th
Life Science Thursday
Longmont

August 24th
Bio Breakfast
Fitzsimons

September 7th
Bioscience Larimer County
Fort Collins

September 19th
BioScience Bogie, Omni Interlocken Golf Course
www.cobioscience.com

SAVE THE DATE

Watch for the **2nd Annual Wine Tasting Event** in LoDo in early August - co-sponsored with Colorado Software and Internet Association

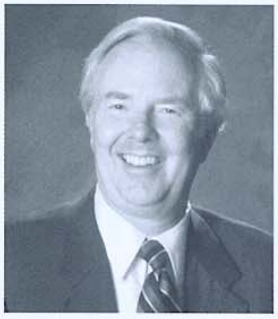
November 8th
CBSA Annual Awards Dinner

November 8th and 9th

2005 BIOWEST
Reserve your booth now
www.biowestconference.com

Check the CBSA Web site frequently for additional programs.

EXECUTIVE REPORT



Ed Wood
Chairman, CBSA

AS CBSA'S NEW CHAIRMAN, I'M PLEASED TO REPORT THAT COLORADO'S BIOSCIENCE BUSINESS SECTOR IS GROWING STRONGER EVERY DAY.

The state now has 160 medical device companies and 150 biotech companies. A third of them are members of CBSA and five new companies join us every month. We are proud of the role we play in ensuring the industry's continued good health.

One of the ways CBSA does this is through our educational programs. Our program committee, led by Derek Cole and Bonnie Vivian and aided by dozens of other volunteers, has sponsored over 24 programs since January, with 15 more planned by the end of 2005.

CBSA programs are not just for C-level executives or specially invited guests; they can also provide a valuable and inexpensive continuing education program for any employee. As we increase our focus on member communications, we hope to encourage more companies to take advantage of this important membership benefit by promoting CBSA programs deeper within their organizations.

This newsletter is part of that increased communication effort. We hope you will also frequently visit our Web site, www.cobioscience.com to catch up on the latest news, including legislative updates, coming events, and career opportunities.

To make sure we fulfill our mission and provide maximum value to our members, we expect to complete work on our new strategic plan and unveil it by the end of this year. Between now and then, our board members and committee volunteers will examine our past efforts and brainstorm new ideas to incorporate into the strategic plan that will guide us for many years to come. The board began this process last December and has already implemented several changes. We look forward to your input as we continue our progress.

As I begin my term as Chairman, I know we have a great deal of work to do to fulfill CBSA's promise. I'm ready for this exciting challenge. I hope you are too. I'll need your support during the next two years as we work together to build a strong bioscience industry and association we can all be proud of.

Committee Plays an Important Role in CBSA's Public Policy Process

CBSA's public policy positions come from the ground up. Just ask the members of the Government and Public Affairs committee, who play an important role in CBSA's decision-making process.

The committee, chaired by Richard Duke of GlobeImmune, meets monthly to discuss and recommend positions on a variety of issues that impact CBSA stakeholders. All members are welcome to join the committee.

When a bill or legislative issue is debated, the committee discusses the impact it could have on the bioscience industry and votes on a plan of action to either support or not support a bill or position. The committee's recommendation is passed to the executive committee and the board makes a final decision on what action should be taken.

Working closely with lobbyists Danny Tomlinson and Erin Silver, the committee and board make sure CBSA's voice is heard in the legislature. During 2004, the committee worked hard to ensure the passage of the state law that created the new Colorado Venture Capital Authority.

Meetings are held the first Tuesday of every month at the downtown CBSA office; all members are welcome to attend. For more information, members should contact CBSA at 303-592-4073 or CBSAInfo@cobioscience.com.

PR Pharmaceuticals

FORT COLLINS COMPANY MAKING ALL THE RIGHT MOVES

THE EXECUTIVE TEAM AT A COMPANY CALLED PR PHARMACEUTICALS (PRP) HAS A KNACK FOR MAKING THE RIGHT MOVES.

That talent may soon reap huge benefits for millions of patients with diabetes and heart disease.

PRP is the result of a 1998 merger between Micrel Limited, an Arizona drug delivery company founded by PRP's CEO Steve Howe, and the Fort Collins based Wildlife Pharmaceuticals. Today PRP is a privately owned company that develops and manufactures innovative sustained release drug delivery technologies for human and animal health.

Howe says the decision to come to Colorado was easy. The Front Range, with its highly educated workforce, was ideally suited to a growing bioscience business. "We compete with the Bay Area and Boston for high level talent," says Howe. "The Colorado lifestyle and our lower cost of living are two big advantages in our favor."

With 55 employees and 25,000 square feet of state-of-the-art manufacturing facilities, PRP uses its proprietary controlled delivery technologies to make an existing drug work better. The idea is to develop its own product pipeline by bringing the discovery through Phase I or Phase II trials before licensing it out to a partner for commercialization. Howe says this model is the inverse of a typical drug discovery model.

"We already know the drug works, so the risk of late stage failure is minimal," he explains. "The risk is on the front end, not in Phase III."

Insulin is a good example. PRP's sustained delivery system can deliver a week's worth of insulin in one injection, allowing diabetics to go from daily use to weekly use. The company's InsuLAR™, is a weekly basal insulin injection expected to enter Phase I clinical trials next year. "This will be a revolutionary change for millions of patients," says Howe.

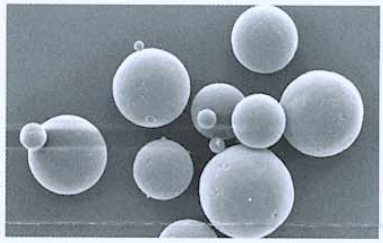
Another drug in development is PulmoLAR™, designed to be delivered every 30 days for patients with a pulmonary arterial hypertension – a dramatic shift in the way patients are currently treated. In April, the FDA granted orphan drug status to PulmoLAR™, an important step that recognizes the drug's potential based on encouraging results from pre-clinical studies.

PRP leverages its technologies to attract collaborations and partnerships. For example, a strategic alliance with one of the world's largest animal health companies, Merial, allows PRP to develop and manufacture new animal health products using PRP technologies, while Merial markets the products worldwide.

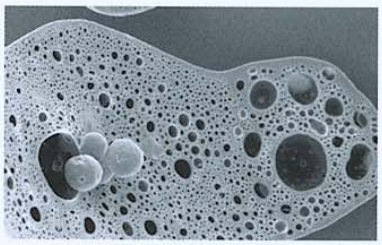
After investing more than $25 million in its Fort Collins manufacturing infrastructure, PRP expects to see significant employee growth in the next several years. "We have a lot going on here," Howe says. "We have a great team and very little turnover."

Like its leadership, it seems that PRP is making all the right moves.

PRP invested millions in its processing facilities in Fort Collins.



Insulin microspheres - PRP's drug delivery systems may change the lives of millions of patients with diabetes.



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Compliance as a Competitive Advantage

BY CLAY ANSELMO

For many veterans of FDA regulated industries, regulatory compliance and quality systems are necessary costs of doing business. Regulatory enforcement activities in the form of a warning letter or a consent decree are prime motivators driving quality systems development and compliance.

While many medical companies still take this approach, the most successful ones are adopting an integrated approach that satisfies the FDA's regulatory requirements and distinguishes the company's products as truly outstanding. Remember that the mission of the FDA (as well as the intent of their regulations) is to ensure that only safe, effective medical products are available to the public. These regulations should be consistent with the mission of every medical products company.

The challenge comes in how organizations implement the requirements of the regulations. If the organization considers them simply an "add on" to its normal business processes and performs the required activities only to satisfy the FDA, it wastes an opportunity to differentiate itself from its competition.

Regulated companies of all sizes need to begin to think of strong, efficient systems that combine business requirements and regulatory requirements as fundamental to future success. The direct costs of redundancy and layers of business and quality systems are exceptionally clear. What many fail to consider is the inherent difficulty of maintaining product quality and compliance in an overly complex system.

Most of us understand the potential impact of regulatory enforcement and product recalls. The problem is we very rarely articulate it or consider it during planning activities. For example, consider how the following scenarios could change a company's bottom line:

- Failure to deliver products to the marketplace and the corresponding loss of sales revenue
- Costs associated with remediation activities including increased staffing and consulting services
- Civil and criminal penalties and their impact on a company's brand and reputation
- Increased future scrutiny from regulatory bodies
- The impact on other organizational initiatives due to re-prioritization of activities.

Considering the tangible costs of layering systems and the potential impact of regulatory enforcement, it is clear that a fear motivated approach to quality systems is unlikely to meet long-term organizational goals and result in sustained compliance. Whether you run a small company just beginning to develop its business systems or a large company struggling to achieve a balance between compliance and costs, it is time to change the way you think about business and quality systems.

In the future, companies that can successfully integrate their operational and regulatory requirements into holistic, simple systems will have a sustainable competitive advantage over more traditional approaches to compliance. They will also enjoy the benefits of reduced product liability and regulatory risk.

Clay Anselmo is president and COO of Reglera Corporation, providing regulatory consulting and resources to biomedical companies: www.reglera.com.

Taking Flight

Sound Surgical president and founder William W. Cimino, Ph.D.

FROM AEROSPACE ENGINEER TO MEDICAL TECHNOLOGY ENTREPRENEUR, SOUND SURGICAL'S FOUNDER IS READY FOR TAKE-OFF.

It took leaving the aerospace industry to launch William W. Cimino, Ph.D. on a high-flying career path that engaged both his talent and his passion. "My first loves were always medicine and bio-engineering," he says. "So I made my move."

Fifteen years later, Cimino is chairman and president of Sound Surgical Technologies of Louisville, Colorado. Founded by Cimino in 1998, Sound Surgical is gaining altitude in the booming aesthetic surgery industry. The company's new LipoSelection℠ only by Vaser® procedure is an innovative alternative to liposuction which uses a proprietary ultrasound technology to remove unwanted fat tissue while improving treatment precision and patient comfort.

Prior to starting Sound Surgical, Cimino's flight path was a long apprenticeship spent designing and developing surgical products from cardiac catheters to ultrasonic neurosurgical devices. He earned a Ph.D. in bioengineering, and then took on increasingly responsible roles in engineering and business development for Heart Rhythm Technologies, Valleylab, and, most recently, Sound Surgical. Along the way, he earned 18 patents.

"I learned as much as I could about the entire business cycle," he says. "There's no better teaching experience than that gained by taking a medical product from initial design to market launch."

Entrepreneurship was not Cimino's goal. "But when the opportunity presented itself I took it." In the seven years since, he's become an expert in every aspect of a start-up biomedical enterprise. "It has been hard but then I expected it to be hard. I had a good foundation of experience to draw from and lots of help along the way."

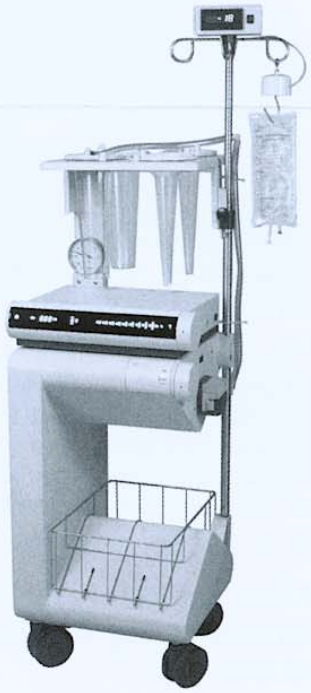
Cimino says taking an idea and building it into a new company is challenging. "There are a whole chain of elements that have to be proven. You have to prove and clearly show the clinical benefit. You have to demonstrate that you can actually build functional prototypes, manufacture the product, and market it successfully. You need to focus on creating something truly new and valuable, because anything else has probably already been done or can be done faster or cheaper by someone else."

To manage successfully, he says, "you don't have to be an expert in all areas of your business but you have to know enough to make good decisions. Also, stay lean and be realistic about the time it will take to complete important milestones such as the development of a credible business plan, raising the money, clinical proof of principle, intellectual property development, and managing the FDA process."

Cimino views Colorado as a great place to live and do business. "Most of the support industries and expertise that we need are right here. I can fly easily from Denver to either coast. And I find the quality of life for my family highly desirable."

Helping people is Cimino's passion. "I've always wanted to find solutions that benefit people. I look at medical equipment and procedures and ask myself how I can make them better for doctors and patients. Everyone wants a better result with maximum safety."

Now that he's gained cruising altitude, it looks like clear skies ahead for Cimino and Sound Surgical.



Sound Surgical's Vaser system.

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NEWS BRIEFS

SomaLogic to Collaborate with Quest Diagnostics

SomaLogic, Inc., a leading clinical proteomics company, announced a new technology development agreement with Quest Diagnostics. Quest Diagnostics will develop a new diagnostic test based on SomaLogic's aptamer array platform. As part of the collaborative effort, Quest Diagnostics made a $15 million equity investment in SomaLogic.

CBSA Members Finalists for Ernst & Young Entrepreneur of the Year

Three CBSA members are finalists for the 2005 Ernst & Young Entrepreneur of the Year Award. Judges selected 24 finalists from 100 nominations and the winners will be announced June 23 at the Denver Performing Arts Center. The three finalists are: Brian Baldwin, Chairman Emeritus, Baxa Corp., Mervyn Jacobson, CEO, President and Chairman, XY, Inc., and Timothy Rodell, CEO, GlobeImmune, Inc.

CSU Research Foundation Names Amato Tech Transfer Director

Interim director Gary Amato officially accepted the position of Director of Technology Transfer at the Colorado State University Research Foundation. The position recognizes Amato's outstanding work on behalf of CSURF tech transfer programs during the past year.

Inc. Magazine Honors Reglera

In its June issue, Inc. Magazine ranked Reglera Corporation number 43 on its Inner City 100 list, which honors companies growing rapidly despite being located in inner city neighborhoods. The winners were chosen from almost 8,000 nominees and were ranked according to their total revenue growth between 1999 and 2003. Reglera was singled out for helping medical device manufacturers and tissue banks navigate the regulatory maze to get their products to market.

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