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Myogen

THE CBSA COMPANY OF THE YEAR

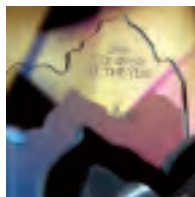


Dave Palmer of Greenberg Traurig (left) presented the Company of the Year Award to Bill Freytag of Myogen.

As Myogen celebrates its 10th anniversary, the Westminster biopharmaceutical company is on a serious roll. It submits its first new drug application (NDA) to the FDA later this year; it recently announced better than expected Phase 2 clinical results for another drug; it has strategic partnerships with Novartis and GlaxoSmith-Kline, and its stock shot up 337 percent in 2005, making it the second best performing biotech stock in the country.

It is no wonder that the Colorado BioScience Association recognized Myogen with the CBSA Company of the Year Award at the CBSA annual awards dinner on August 24.

"Myogen is a real Colorado success story," said CBSA executive director Denise Brown. "It is



developing exciting new treatments for millions of people with cardiovascular disease and opening the eyes of the world to the incredible work being

done by the bioscience community in Colorado."

Founded in 1996, Myogen is focused on treatments for cardiovascular disorders. It went public in 2003 (Nasdaq: MYOG), and now employs 153 people.

Myogen's pipeline includes ambrisentan, a drug that can slow clinical worsening, increase exercise capacity and make dosing easier for the 200,000 patients in the U.S. and Europe with pulmonary arterial hypertension (PAH), a highly debilitating lung disease. Earlier this year, Myogen announced positive results from two Phase 3 trials and a licensing

agreement with GlaxoSmith-Kline (GSK) to market ambrisentan outside the U.S. The company expects to submit ambrisentan for FDA approval by the end of the year. Myogen also acquired the U.S. rights to market GSK's drug Flolan, a life-saving treatment for patients with late stage PAH.

A second product, darusentan, completed Phase 2 clinical trials with better than anticipated results for patients with resistant hypertension. An estimated 65 million people in the United States and one billion worldwide have hypertension. About 5-15 percent of them cannot achieve recommended blood pressure ranges despite taking multiple medications on a daily basis.

"We are deeply honored and grateful to CBSA for this award," said J. William Freytag, Ph.D, president and chief executive officer of Myogen. "We have made significant progress since our founding 10 years ago, but our goal remains the same -- to find new ways to improve the lives of people who suffer from debilitating cardiovascular disease. C

BREAKING NEWS

At press time, Myogen was acquired by Gilead Sciences, one of the world's largest biotech companies, for \$2.5 billion. The deal is expected to close by the end of the year. According to analysts, it recognizes the future income potential of Myogen's drugs and provides the company with the resources to bring them to market. It is also an indication of the strength of Colorado research.

CBSA congratulates Myogen's founders and welcomes Gilead to Colorado's bioscience community.



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BioWest 2006

THE BEST YET



Ira Flatow, host of NPR's Science Friday, on the trials and tribulations of presenting science to the public.



Ralph Ives of AdvaMed looks at the future of the medical device industry.



Michael Orlando of the Federal Reserve Bank of Kansas City reveals where innovation happens.




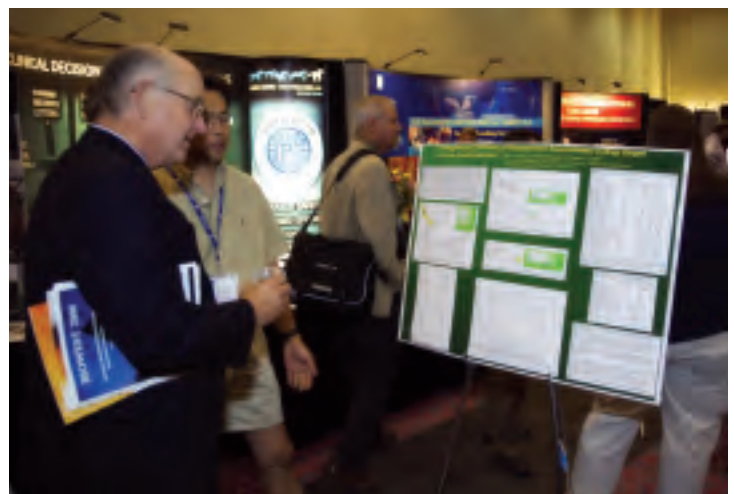
Cowboy Poet and Former Veterinarian, Baxter Black enthralled the crowd at the CBSA awards dinner.

The fifth annual Rocky Mountain region's medical device and biotechnology conference was a smash success. Nearly 900 people attended the event on August 23 and 24 at the Colorado Convention Center. There were 80 exhibitors and 50 speakers in nine sessions, including five keynote presentations.

BioWest is a joint venture of the Colorado Office of Economic Development and International Trade and the Colorado Bio-Science Association. Conference highlights included the venture showcase for early-stage bioscience companies; the investor forum; the technology transfer reception and the CBSA annual awards dinner.

Congratulations to the 2006 CBSA award winners and our sincere thanks to all the sponsors, exhibitors, speakers, volunteers and attendees for making BioWest 2006 such a huge success. Plans are already underway for next year so please check the CBSA Web site and our CBSA Focus newsletters for dates and details.

We welcome your feedback. Please take a few minutes to complete our survey: <http://www.biowestconference.com/2006biowestsurvey.htm>. 



Networking, networking, networking.

Congratulations to our 2006 CBSA Award Winners



Richard Duke was named the 2006 Volunteer of the Year.



Shelley Wilcox of Taligen Therapeutics received the Bioscience Company Rising Star Award from Rob Reuteman.



Brad Coors of C5 Medical Werks received the Bioscience Company Rising Star Award.



On behalf of Governor Bill Owens, Brian Vogt (right) accepted a Lifetime Achievement Award from presenter Brian Baldwin.



Kyle Lefkoff received the Colorado Office of Economic Development and International Trade 2006 Excellence Award.



Richard Nakashima of Faegre & Benson (left) congratulated Richard Duke of ApopLogic Pharmaceuticals, the Faegre & Benson Venture Showcase Award Winner.

THANKS TO
ROCKY MOUNTAIN NEWS
BUSINESS EDITOR
ROB REUTEMAN
FOR SERVING AS EMCEE
FOR THE ANNUAL
AWARDS DINNER.



Maggie Chamberlin Holben of Absolutely Public Relations accepted the Partner of the Year Award 2006 from Rob Reuteman.

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Paul Ray Honored

WITH CBSA LIFETIME ACHIEVEMENT AWARD

**LOOKING BACK AT
A LIFETIME OF
ACHIEVEMENTS,
PAUL RAY SINGLES
OUT HIS WORK WITH
IMAGE GUIDED
TECHNOLOGIES
AS PERHAPS HIS
GREATEST
ACCOMPLISHMENT.**

The phrase "lifetime achievement award" usually brings to mind the Oscars – not bioscience. But in the case of Paul Ray, it is particularly appropriate, because this former salesman and longtime biotech entrepreneur has played enough roles to fill several lifetimes.

In recognition of his outstanding achievements and dedication to furthering Colorado's bioscience industry, Ray was presented with the CBSA Lifetime Achievement Award at the CBSA annual awards dinner during the 2006 BioWest.

With a long history of successful start-ups, Ray has never been one to shy away from a challenge. In fact, he has been involved in over 15 new ventures in both the private and public sectors.

"I like the creativity it takes to put together a new entity," he said. "Not just on the private sector side, but also on the State side."

Ray has been an investor in numerous companies and has held board positions with early-stage companies like AccuNetx and Evolutionary Genomics. In the public sector, Ray is the former



Awards emcee Rob Reuteman (left), business editor for the Rocky Mountain News, presented Paul Ray with a Lifetime Achievement Award.

director of life sciences and biotechnology for Colorado, a founding board member of CBSA, and was also appointed to the Colorado Advanced Technology Institute.

He began his career path as a salesman for Dow Corning, where he eventually became a regional manager. In 1986, he moved to Colorado to start his first bioscience company. He has been here ever since. Ray believes it was this early work experience that prepared him for future ventures, and led to his personal formula for success.

Looking back at a lifetime of achievements, he singles out his work with Image Guided Technologies as perhaps his greatest accomplishment. In just seven years, Ray guided the Boulder company from a venture capital start-up, through an IPO, to its sale in 2000 to Stryker Corporation.

"It was the most challenging thing I ever did, but also the most rewarding," he said.

But Ray also understands that although he usually plays the lead, it takes the encouragement and trust of a supporting cast to create a successful company. "I have never asked anyone to invest more than they would be willing to lose," he said. "And I have never asked someone to invest in something I have not invested in myself."

Ray acknowledges that not every one of his ventures has been a success, but he is proud that he has always had the vision and the courage to move on to the next project when the time was right.

"If I do my job, I find myself out of work," said Ray. "Either the venture didn't work out or, in the best case, someone bought it. Hopefully the law of averages works out and I find more winners than losers."

After 22 years in the Colorado bioscience industry, Ray has no intention of slowing down. Recently, he became the president and CEO of Surginetics, a Boulder-based electrosurgical company. While the Lifetime Achievement Award represents a milestone for Ray, he believes he still has a few more great performances left.

"I am like a moth drawn to the light when it comes to new ventures," said Ray. "I love taking a project from zero to a point where it is building jobs and contributing to the well being of the community and the state." **C**

Mountainside Medical

DISCOVERS "BETTER WAY" TO MANUFACTURE SUCCESS



Mountainside Medical's Dave Fuller works on a machine used to manufacture components of laparoscopic devices.



Pete Neidecker
Founder
Mountainside Medical

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AND SET OUT
TO FIND IT.**

Neidecker saw that many contract manufacturers, in an effort to go public, lost sight of the quality of their service. He saw the focus of their companies shift from the quality of their work to the quality of their balance sheet.

"I wanted to enjoy manufacturing again," said Neidecker. "I wanted to work on a relationship basis, rather than showing a big profit or big return."

That is not to say that he is not interested in financial success. Neidecker believes he can accomplish both, and he has a plan. The foundation of that plan is to equip his company with advanced technology. As a well-funded private company, Mountainside Medical purchased top-of-the-line equipment that Neidecker claims rivals that of the major contract manufacturers. This technology enables the company to develop and manufacture high-end, specialty products efficiently.

The plan's strategy is niche oriented. While many of his competitors manufacture a variety of products, Mountainside Medical is focused completely on the medical device industry. It specializes in medical instruments, such as electrosurgical instruments, laparoscopic instruments and jaws, orthopedic implants and endoscopy devices.

To demonstrate its commitment to quality, Mountainside Medical received the ISO 13485:2003 certification, the international standard for quality of systems for medical device manufacturers.

"We are one of just a few job shops that have this certification," said Neidecker. "Most manufacturers would not focus on this certificate because of the requirements."

Thanks to its technology and focus on systems quality, Neidecker knows his company can match other manufacturers on quality, price and technology. But he believes it is its unique service model that gives Mountainside Medical an advantage. For Neidecker, the key difference is another element of his plan, cus-

tommer participation and process transparency.

"We want our customers to feel completely comfortable with the manufacturing process, so we let them look over our shoulder on a monthly, even daily, basis," he said.

Neidecker believes that relinquishing an element of control to the client helps to build a better partnership. "We want to become like an arm of their business, rather than a contractor that is located half way across the country," he said.

To accomplish this, Mountainside Medical plans to position its facilities near the regional hotbeds of the medical device industry. While the company's 10 employees will continue to be based in Colorado, it will open offices in Minneapolis, Boston, Memphis and Santa Clara, California. Rather than growing in one location, it will put down roots in target markets.

Neidecker, a Colorado native, said he chose Boulder for Mountainside Medical's first facility because it has more advantages than just being located near the mountains.

"A strong base of large companies anchors the industry in Colorado," he said. "There is also a high concentration of innovators in medical products and we have the expertise to help them bring their work to the market."

After the opening the Boulder office in March 2006, Neidecker is seeing his plan starting to blossom.

"We have been well received by large manufacturers," he said. "We have discovered a niche for this type of specialization." **C**

COMING EVENTS

October 25 - BioBreakfast

Conducting Your Clinical Trials Abroad. Meet 6 Canadian MRO companies and find out what your company should know about conducting clinical trials outside of the United States, including the advantages, challenges, and how to meet FDA expectations.

November 9 - Biofuels

Briefing (invitation only) - The importance of Biofuels for the world economy is increasing. CBSA will host a discussion about Biofuels and related issues such as University and Government Labs; Commercialization and Financing Issues; Public Policy and Economic Development; Colorado Companies.

November 16 - Longmont Life Science Thursday - Ramp-up Strategies.

Human resources managers will discuss how they've handled rapid personnel growth in dynamic bio-science companies.

November 29 - BioBreakfast

Dr. G.P. "Bud" Peterson, Chancellor of the University of Colorado at Boulder, and M. Roy Wilson, MD, MS, Chancellor of the University of Colorado at Denver and Health Sciences Center, will present a *University Leadership Briefing*.

A **Finance Seminar** will be held on **December 7** and at the **BioBreakfast** on **December 20**. More details TBA.

For more information about CBSA programs and events please visit our new Web site www.cobioscience.org.

New Rules for Dietary Supplements

BY CLAY ANSELMO

It is likely that when CBSA members think of good manufacturing practices (GMPs) and the FDA, we immediately think of drugs, biologics, medical devices and human tissues. That's the world most of us work in every day. There is another industry, however, that is also regulated by the FDA. And even though many of us use its products, few of us think about GMPs as they relate to foods and dietary supplements.

Since 1994 and the advent of the Dietary Supplement Health and Education Act (DSHEA), the FDA has had the authority to regulate dietary supplements in ways similar to other foods. In 2003, the FDA published a proposed rule for "Good Manufacturing Practices for Dietary Ingredients and Dietary Supplements". Of course, the FDA's rule making process is long and difficult, and it is not uncommon for it to take a decade for rules to be completely implemented.

In this case, sometime in the near future a final version of the GMPs for dietary ingredients and supplements will be published, creating a new regulated industry with a regulatory framework based on a combination of current Food and Drug Administration GMPs.

The situation is similar to what several sub-segments of the human tissue industry experienced in 2005. Most supplement manufacturers have little or no experience manufacturing products in a GMP environment, so the implementation of significant rules for supplement manufacturing is going to come as quite a shock to many companies.




Colorado's Lifeline Therapeutics takes these issues seriously. The company's CEO, Stephen K. Onody, says "Protandim is manufactured with the highest standards applicable under GMP guidelines." Regular quality assurance testing is run by Chemins.

For many years, consumers were generally unaware that the dietary supplements they were putting in their bodies were mostly unregulated by the FDA. With more than 30,000 supplement products on the U.S. market today, that perception is now changing. In fact, in one six-month period in late 2003 – early 2004, the FDA sent 119 warning letters to dietary supplement distributors and seized or supervised the destruction of nearly \$18 million of mislabeled or adulterated products.

Any increase in government regulation must be considered carefully, and this case should be no exception. While GMPs can make life difficult for those of us that work in FDA regulated industries, it is also difficult to argue that these regulations have not significantly improved the overall quality of medical devices, drugs and biologics. Dietary ingredients and supplements should be no exception.

CBSA represents the largest group of FDA regulated industry professionals in Colorado, so it is likely that many of us will have the opportunity to comment in one way or another to professionals from the supplement industry. It is our responsibility to help them understand that it is possible to operate a successful business in a compliant way. Just as CBSA helped the human tissue industry make the transition to a more significantly regulated environment, let's make sure we offer the same type of support to the supplement industry as it goes through a difficult period in its growth.

More information on the FDA's plans for the dietary supplement industry can be found at <http://www.cfsan.fda.gov/~dms/supplmnt.html>.

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

CBSA NewsMakers

Accera, Inc., a drug development company focused on Alzheimer's disease and related neurodegenerative diseases, initiated a multi-center, placebo-controlled Phase 2a study of Ketasyn (AC-1202) for the treatment of age associated memory impairment. The Phase 2 trial will evaluate the safety and effectiveness of Ketasyn in improving short term memory in patients aged 50-85. Accera recently closed a Series B financing round of \$7.5 million and appointed Dean Taylor, Ph.D. as vice president, business development.

Aktiv-Dry, LLC, received an \$850,000 SBIR grant from the National Institute on Drug Abuse at the National Institutes of Health to develop an inhalable nicotine vaccine to help smokers quit the habit for good. The company is a finalist for the 2006 Ernst & Young Entrepreneur of the Year Award in the Rocky Mountain Region.

Allos Therapeutics, Inc. announced an agreement with the FDA on the design of a pivotal Phase 2 trial of the company's novel, next generation antifolate PDX (pralatrexate) in patients with relapsed or refractory peripheral T-cell lymphoma (PROPEL). The company also enrolled the first patient in the trial. Allos completed patient enrollment in its pivotal Phase 3 ENRICH study of EFAPROXYNT (efaproxiral) in women with brain metastases originating from breast cancer. A total of 360 patients were enrolled at 126 participating centers in the United States, Canada, Europe and South America.

Amgen Colorado named Dave Bengston vice president and general manager of Colorado operations. He returns to Colorado after three years leading Amgen's Rhode Island site. Eric Bergeson, Amgen Colorado's head for the past three years, is now vice president of corporate quality.

Baxa Corporation took second place on the list of top large companies to work for in Colorado. For the first time,

Colorado Biz magazine, the Colorado State Council of the Society for Human Resource Management (SHRM) and the online employment service, JOBing.com teamed up to produce a list of the best companies to work for in the state. The Best Companies initiative honors Colorado companies that support employee growth and quality of life, promote best practice in employment, retention and benefit opportunities for their respective staff.

Six Colorado companies were selected by venture capitalists from the nation's leading firms to present at the 2006 BIO Mid-America Venture Forum (BMA) in Cleveland on September 25-27. **ApopLogic Pharmaceuticals, BioCare Systems, Globelmmune, Lead Horse Technologies, MBC Pharma and Sterling Bio-Technologies Corporation** presented their business plans to a national audience of venture capitalists and other potential investors.

Colorado State University announced the appointment of Bill Farland as the new vice president for research. As the highest ranking career scientist at the Environmental Protection Agency, he will bring his decades of interdisciplinary research leadership experience to CSU. He begins his new post on Oct. 16.

The **Colorado State University Research Foundation**, a private, non-profit foundation that aids the university in its research and educational efforts, named Mark S. Wdowik vice president of technology transfer.

Cedus, Inc., of Fort Collins was one of seven finalists in the fourth annual Purdue University Life Science Business Plan Competition. Cedus is developing a pharmaceutical single injection sterilization solution for the

veterinary market, utilizing their platform technology, GnRH conjugates.

CTEK has created the state's first funding network dedicated to fledgling bioscience companies. CBSA is assisting CTEK in organizing its new Bio-angel group.

Commerce Bank is one of three finalists for the 2006 Colorado Biz Top Company award in the financial service category. Award selection is based on strong financial performance, operational excellence and a record of community involvement. Commerce Bank is a CBSA member and corporate sponsor.

The **Office of Economic Development & International Trade** (OEDIT) has released the guidelines for implementation of the HB 1360. Contact the CBSA office to get a copy.

In July, **Replidyne, Inc.** completed its initial public offering of 4,500,000 shares of common stock at a price of \$10 per share. In July, the underwriters of the initial public offering exercised their over allotment option for an additional 506,000 shares of common stock that will be issued at \$10 per share. Earlier this year, Replidyne entered into a collaboration and commercialization agreement with Forest Laboratories to co-develop and co-market faropenem medoxomil in the US.

Rocky Mountain Biosystems received a Phase I SBIR grant for \$131,658 from the National Heart, Lung and Blood Institute of the National Institutes of Health. The grant will advance RMBI's Biofusinary Systems tissue sealing technology to effectively seal lung tissue and prevent air leaks, a serious complication in up to half of all lung resection surgeries.

Taligen Therapeutics, Inc. successfully reached the development milestone required to trigger the funding of the

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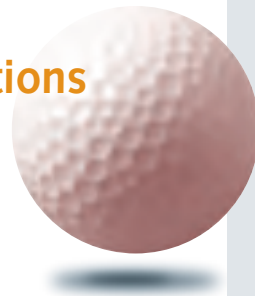
BIO NEWS, CONTINUED FROM PAGE 7

second round of its Series A Preferred Stock financing. The milestone was achieved by demonstrating in-vivo efficacy of a humanized version of Taligen's lead compound, TA106, a fragment of a monoclonal antibody which targets a critical regulator of complement activation. The company is now initiating manufacturing of the humanized TA106 and expects to file an IND for this product in 2007.

The **University of Colorado at Boulder** announced the appointment of G.P. "Bud" Peterson as Chancellor. Prior to assuming this role, he served six years as provost at Rensselaer Polytechnic Institute in Troy, New York.

The **University of Colorado at Denver and Health Sciences Center** announced the appointment of M. Roy Wilson, MD, MS as Chancellor. He was formerly president of Texas Tech University Health Sciences Center. **C**

Congratulations



... to the winners of the 2006 CBSA Golf Tournament!

1ST PLACE (SCORE 46):

Reglera Team

- Kevin Barfield
- Brian Eslinger
- Bob Kelley
- Jon Dahl

2ND PLACE (SCORE 47):

• **Noel Bertman**

Chubb Group of Insurance Companies

• **Ken Capone**

Schwander Insurance Services

• **Todd Michel**

Lockton Insurance &
Risk Management Specialists

• **Patrick Wheeler**

ARCA Discovery

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