THE CBSA FOCUS FALL 2005

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

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BioWest 2005

BRINGING HUNDREDS OF INDUSTRY LEADERS TO DENVER

On November 8 and 9, Colorado will highlight its status as the center of the Rocky Mountain region's bioscience industry as hundreds of professionals converge at the Denver Convention Center for the BioWest 2005 conference.

The only event of its kind in the region, it is expected to bring together 700 medical device and biotech players from Colorado, New Mexico, Utah, Montana, Idaho and Wyoming.

Two full days of exhibits, presentations and panels are designed to increase momentum for the growing industry in the region. Educational seminars will cover a range of topics for companies in all stages, including "Your Intellectual Property as an Asset" and "Regulatory Issues in Combination Products."

In addition to the conference, CBSA will hold its annual awards dinner November 8 to recognize achievement within the Colorado life sciences industry and announce the first $10,000 Faegre & Benson Venture Showcase Award.

The conference is presented by the Colorado Office of Economic Development and International Trade in partnership with CBSA. The $10,000 Faegre & Benson Award will be given to an outstanding medical device, biotechnology or pharmaceutical company presenting at the 2005 BioWest Venture Showcase. Ten early-stage companies were chosen to present.

Eligible companies include startup or early-stage companies with a Colorado presence and $2.5 million or less in total funding. Showcase presentations will be held on the morning of November 8 and will be judged by a panel of financiers from the venture capital and angel investing communities.

Thomas Cech

The highlight of the awards dinner will be a keynote address by Thomas Cech, president of the Howard Hughes Medical Institute. Cech won the Nobel prize in chemistry in 1989 and is a professor of chemistry and biochemistry at the University of Colorado at Boulder. Though he moved to Maryland in 2000 to become president of the institute, he continues his research at his lab in Boulder.

Other partnering organizations for the conference are Utah Life Science Association, Intermountain Biomedical Association, bioIdaho, University of Wyoming, the City of Denver, Colorado State University, Fitzsimons Redevelopment Authority, Metro Denver Economic Development Corporation, Montana BioScience Alliance, the University of Colorado and the University of Denver.

To register for the conference or to reserve an exhibit hall booth, visit www.BioWestConference.com.

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

October 6th
Longmont Life Science

December 1st
Longmont Life Science

December 1st
New Member Orientation

SAVE THE DATE

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.

GOLF

Congratulations to all the winners at the BioScience Bogie, especially to the foursome of Hunt Lambert, John Greff, Paul Hudnut and Eric Weber for lowest team score!

GETTING THE WORD OUT

Send us your press releases and other announcements for the *CBSA Focus*. Our Communications Committee is developing new ways to help you spread the news of your success by partnering with other business organizations and highlighting our members' achievements in our newsletter. E-mail your news to dbrown@cobioscience.com.

EXECUTIVE REPORT

John H. Wheeler
Vice Chair, CBSA
Founder, Chief Marketing Officer, MicroPhage, Inc.

I hope you enjoy the latest issue of the *CBSA Focus*. You will notice that we expanded by two pages this quarter to bring you more news and updates, including industry events and features about Colorado companies and executives. If you have news you want reported to our members, remember to send the CBSA staff your press releases and other announcements. As our communications strategy emerges under the leadership of the new CBSA communications committee, it will increase the opportunities for us to help you leverage your news.

THE LAST QUARTER OF 2005 WILL BE AN IMPORTANT ONE FOR CBSA MEMBERS.

The annual BioWest Conference has grown significantly this year and will include specialized programs for both the medical device and biotechnology sectors. And with 15 seminars, four keynote speakers, the venture forum and technology transfer poster sessions, there is sure to be something of interest to everyone in Colorado's bioscience industry. The CBSA annual awards dinner will be held on November 8th – the evening between the two days of the conference. You can register early online for the dinner and the conference at: www.biowestconference.com.

Our board and committees are busy planning for 2006. If you have good ideas for programs, communications, membership, trade shows, or legislative priorities, please contact any board or staff member. Now is the time to ensure that we meet the needs and priorities of our members in the coming year. Your advice and counsel is welcome as our plans develop.

Finally, I would like to make a personal observation about the benefits of being active in CBSA. MicroPhage presented at the venture forum in 2005 and found the exposure to investors very helpful. We received an award at the annual dinner that increased our visibility within the industry. As a company built on a technology from a Colorado research institution, the work of the technology transfer committee is very important to our future business with Colorado universities. Our senior staff and executives frequently attend CBSA events because the information is relevant to our business activities. In summary, our involvement with CBSA has been great for our company. I am confident you will find the same results if you take advantage of the opportunities we work hard to bring to you.

Communications Committee Starts Spreading the News

The newly formed CBSA Communications Committee, chaired by board member Maggie Chamberlin Holben, owner of Absolutely Public Relations, includes some of the area's top PR and marketing professionals. The committee's goal is to develop a strategic plan for communicating CBSA's story in Colorado and around the country.

Committee members include Brad Bawmann, the Bawmann Group; Denise Brown, CBSA executive director; John Downs, Downs Marketing; Holly El-Jammal, CBSA staff; Debbi Ford, Amgen; Bob Griff, Griff/SMC Marketing Communications; Melissa Katsimpalis, ISIS Public Relations & Marketing; Jennifer Neiman, Allos Therapeutics; and Jon Pushkin, Sage Public Relations Group.

"Our charge is to provide direction and ongoing evaluation for all CBSA communication initiatives," explained Holben. "We're dovetailing with the strategic planning process that other committees have already undertaken by developing objectives and tactics in line with the association's core values and mission."

The new committee will brainstorm ways to increase CBSA's visibility at major exhibits and conferences such as the BIO International Convention in Chicago next April. Committee members will guide the direction and content of CBSA's marketing communications tools for member acquisition and retention, and direct the ongoing public and media relations efforts for the association.

CBSA publications include the annual *Bioscience Colorado* magazine in collaboration with the Colorado Office of Economic Development and International Trade and the quarterly *CBSA Focus* newsletter.

Members are encouraged to contact the CBSA office with suggestions and feedback on this new committee.

iBalance Medical

ALIGNING ITSELF FOR SUCCESS

FOUNDED IN 2004 BY A MASSACHUSETTS TRANSPLANT, BOULDER START-UP iBALANCE MEDICAL RECENTLY CLOSED ON AN INITIAL $4.8 MILLION OF AN $8.24 MILLION COMMITMENT IN FIRST-ROUND VENTURE FINANCING.

The company is now ready to move into high gear on its new surgical product and procedure for knee reconstruction that focuses uniquely on treating malalignment of the joint, delaying or eliminating the need for total knee replacement surgery for many patients.

With millions of active people outliving their aging knees, the opportunity for iBalance Medical is significant. The most common threat to mobility for people aged 45 and over is knee osteoarthritis, a degenerative joint disease causing chronic pain and disability to more than 10 million Americans. The primary cause for progressing degeneration is a knee that is unstable and no longer transfers weight bearing forces normally. For many, the standard medical solution to years of wear and tear is total knee replacement surgery, which relieves pain and restores function but permanently restricts the patient's physical activity.

"Orthopedic surgeons know that degeneration worsens over time due to malalignment of the knee's weight bearing surfaces," says Vince Novak, founder, president and CEO of iBalance Medical. "But the only solution currently available to correct malalignment and delay or avoid total knee replacement is knee osteotomy, which is difficult to perform and has a high rate of complications. We want to supplant knee osteotomy with an improved product and procedure."

The company's proprietary Axial Knee Realignment (AKR) technology consists of a guidance device and an implantable support device. The AKR system will enable surgeons to perform a simple, predictable procedure to achieve precise realignment of the joint, and to maintain the weight-bearing surfaces in close contact in their proper alignment to promote regeneration of bone tissue. Patient benefits will include pain relief, restoration of knee function and a return to full physical activity. Improved tissue regeneration minimizes further joint damage.

iBalance Medical's first round of venture capital will fund the engineering and clinical groundwork to gain U.S. Food and Drug Administration (FDA) 510(k) market clearances in 2006. Then, according to Novak, "We plan to clinically validate the AKR procedure through a limited rollout to 12 or 15 surgical centers during 2007, followed by a full U.S. market launch in 2008."

Colorado's bioscience community compares favorably with Massachusetts, says Novak, "I haven't had any problem finding engineers and other folks with the right background. Prototyping costs half what it does in Boston, and office rent is about a third less."

Knowing how difficult it can be to get that first round of venture funding, Novak is grateful for the seed money he received from angel investors Steve Onody of Aurora and Tony Dimun of Short Hills, New Jersey. "It's the first $250,000 to $500,000 that's crucial to getting the patent protections, proof-of-concept and initial prototyping you need to attract venture capital," he says. "Lack of seed money is why so many good ideas don't get funded." First round venture capital for iBalance Medical came from Sutter Hill Ventures and Skyline Venture Partners of Palo Alto, California.

With its development capital secured and a huge potential market eager for an alternative to joint replacement surgery, it looks like the stars are perfectly aligned for a bright future for iBalance Medical.

Malalignment of the joint

AKR implant

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CBSA is proud to salute 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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Navigating the Pre-Market Submission Process

BY CLAY ANSELMO

For many young companies, navigating the regulatory landscape in the United States can be overwhelming. Deciding the best approach to clinical trials, not to mention the correct pre-market submission process is enough to send even the most determined entrepreneur into a bout of depression.

The various routes to market for medical devices, biologics and drugs can be extremely complex and lengthy if not approached correctly from the start. However, the FDA provides a wealth of resources to help companies successfully work through this process. There are two keys to getting to market successfully: do your homework, and get the FDA involved early.

"Doing your homework" simply means that you should educate yourself and your company on your options. Yes, you do have options in the pre-market submission process, and in many cases choosing the right approach can mean the difference between approval in 180 days and years of endless data gathering.

Over the past decade, the FDA has provided manufacturers with a variety of new ways to bring products to market in the U.S. The traditional pre-market submission processes (510(k), PMA, NDA, ANDA) now have numerous variations that permit manufacturers to take advantage of shortened review cycles. Spend the time necessary to understand the options available for your product and consider utilizing one of

the pre-submission applications (513(g), RFD, pre-IDE) to understand how the FDA views your product. There is no substitute for this most basic homework. You will find it a tremendous help and time saver, whether you are discussing your business plan with an investor, selecting a consultant to help you prepare your clinical trial program, or hiring your first QA/RA resource.

It is also extremely important to get to know anyone at the FDA who is likely to see your final submission. Most FDA personnel are happy to talk with you about this process and your specific application if you are respectful of their time and don't abuse the privilege. In fact, the FDA has set up several structured programs to allow you to discuss and educate them on your product and technology BEFORE you finalize your pre-market submission. Understand which programs are available to you and take advantage of them where it makes sense for your product.

Sending the FDA a cold submission on a new technology and expecting it to be approved on the first cycle is usually wishful thinking. Make it a point to understand the general concerns about related products and be sure to specifically address these in your submission. You will be surprised at how forthcoming and helpful the FDA can be if you take the time to use the communication channels they have set up.

Developing a well researched regulatory route-to-market and building a relationship with the appropriate groups at the FDA prior to your pre-market submission is a recipe for success in introducing medical technology in the U.S. marketplace. Your initial investment in time and resources will likely result in significant time savings during the process and will allow you to introduce your products on a best-case time schedule.

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

Raising Money and Eyebrows

REPLIDYNE MAKES BIG IMPRESSION

Dr. Urs Ochsner
Sr. Scientist II, Microbiology

Kenneth Collins
President and CEO,
Replidyne, Inc.

REPLIDYNE IS QUICKLY BECOMING A MAJOR PLAYER IN THE STATE'S BIOSCIENCE COMMUNITY.

After closing one of Colorado's largest 2005 private financing deals in September -- more than $62 million in newly secured funding -- Replidyne is quickly becoming a major player in the state's bioscience community. The Louisville biopharmaceutical company has raised over $121 million and lots of eyebrows since it was founded in 2002.

Replidyne develops and commercializes new antibiotics to treat infections caused by drug resistant bacteria. Resistance to antibiotics is a major challenge facing healthcare providers. Stories about mutating staph infections can cause fear among hospital patients and worry for even the most experienced doctors.

"It is a major issue," said Ken Collins, Replidyne's president and CEO. "Big pharma is focusing on blockbuster drugs and less on antibiotics. We determined there was a large unmet medical need and we made that our core technology."

Collins was with Pegasus Technology Ventures in Boulder in 2001 when he helped Replidyne secure seed money and its initial venture funding round. He became president and CEO in 2002 and put together an impressive management team that made later rounds of financing possible. He also helped the company develop a lucrative pipeline by in-licensing products from other companies, a business strategy that Collins knows is a key to Replidyne's success.

"To finance a biotech company today you need later stage programs and products," he said. In June 2003, Replidyne acquired the rights to an antibacterial program developed by GlaxoSmithKline that is nearly ready for clinical trials. The company plans to take REP 8839, a topical antibacterial used against staph infections and one of the compounds from the GSK program, into clinical trials in early 2006.

Replidyne's lead product is Faropenem, an oral antibiotic that has completed Phase III clinical trials as a treatment for community respiratory tract diseases such as sinusitis, bronchitis and pneumonia. Licensed from a Japanese company, Faropenem is the first oral penem available outside Japan.

"We believe that Faropenem could be a very important development for millions of people with bacterial respiratory infections. If approved by the FDA, Faropenem could be launched late next year," Collins said. In anticipation, Replidyne is developing a marketing partnership to reach physicians who treat these indications.

Collins says the most important things a young company can do to position itself for success are to have a good business plan, bring in an experienced management team, secure venture capital funding, and use late stage products to jumpstart financing.

"There is clearly money out there for good ideas, but it takes some effort," he said.

He credits Replidyne's success to the ability to bring in late-stage products that are close to market and to its experienced management team that includes respected industry veterans like chief medical officer Roger Echols, MD, and chief commercial officer Pete Letendre, PharmD. Both brought the company the kind of credibility sought by venture capitalists.

Although Collins says that Colorado's bioscience community is smaller than Boston or San Francisco, he believes that as more companies like Pharmion, Myogen, GlobeImmune and Replidyne gain the attention of big pharma, it should make it easier for new Colorado companies to find investors. It should get even easier in the near future as the products in Replidyne's pipeline enter the market.

Leaders Convene to Support Colorado Bioscience Industry

BIOSCIENCE IN COLORADO

AT A GLANCE:

Bioscience Companies:
347

Number of Bioscience Jobs:
11,885

Indirectly Supported Jobs:
20,204

Average Employee Salary:
$61,414

Total Taxes Generated:
$415.7 million

Nearly three hundred and fifty bioscience companies make their home in Colorado. These companies research cures to cancer, heart disease, and infectious diseases; improve agricultural yields; and develop cleaner, more efficient manufacturing methods.

Colorado's academic and research institutions work in partnership with the private sector to transfer innovation from the lab to the marketplace. In 2003-2004, the industry employed 11,885 workers with an average salary of $61,414. More than 20,204 additional service sector jobs were generated to support this growing industry.

The state's biosciences and service providers also contributed an estimated $415.7 million in local, state, and federal taxes.

James Greenwood and Andrew Romanoff

Jay Gershen and Ed Wood

On August 9, nearly 300 people attended an educational event hosted by the Colorado BioScience Association (CBSA) and the Biotechnology Industry Organization (BIO) to learn about the bioscience industry in Colorado. The forum, held at the Fitzsimons research complex, brought together federal and state lawmakers, leading life science executives, university officials, patient group representatives and news media.

U.S. Rep. Bob Beauprez described Colorado as the "shining city on the hill" as he spoke to a packed auditorium about the future of the bioscience industry in Colorado at the Fitzsimons Research Complex on August 9.

Beauprez joined representatives from government, industry and higher education as they gathered for a CBSA hosted forum to speak about the state of the bioscience industry in Colorado.

Many national industry observers see bioscience in Colorado as a fast-growing portion of Colorado's resurgent economic vitality and the presentations reflected this trend.

"The critical mass is already present to make this state a leader, and with a rapidly expanding number of bioscience companies we are already making a significant impact," said Ralph Christoffersen of Morgenthaler Ventures, the immediate past chairman of CBSA. He was joined on the industry panel by Richard Duke, director of GlobeImmune; Neal Masia, director of economic policy at Pfizer; Kevin Smith, Gambro president; Brian Vogt, director of the Colorado Office of Economic Development and International Trade; and Georg Wiebecke, president of Roche Colorado.

"I am impressed," said James Greenwood, former U.S. representative from Pennsylvania and president of the Biotechnology Industry Organization (BIO), in regard to the Fitzsimons campus. "It is amazing what you have done here."

While there was a buzz about the advancements being made, several speakers also used their platform to voice concerns.

Colorado Speaker of the House Andrew Romanoff talked about the importance of referendums C and D to Colorado's universities and to the health of the bioscience industry.

"If you want more companies like Amgen," said Romanoff. "We need to invest in education."

Referendums C and D would allow the state government to keep and spend all revenues collected from existing state taxes for the next five years and would set a new revenue cap. The money will be spent for education, health care, and transportation projects.

The higher education panel discussed the need for continued collaboration between industry and university research labs. Lynn Taussig, president of National Jewish Medical and Research Center, was joined by University of Denver chancellor Robert Coombe, Colorado State University president Larry Penley, and John Trefny, president of the Colorado School of Mines. Hank Brown, the new president of the University of Colorado, spoke about the work that has been done to make technology transfer a priority at CU.

Bioscience is a rapidly growing contributor to Colorado's economic vitality. The industry creates thousands of jobs, both within company ranks and with vendors that collectively benefit from the sale of research equipment, building construction and support services.

"The event was a great success," said CBSA chairman Ed Wood, who moderated the event. "It was wonderful to see so many individuals from different areas of the industry excited about what is happening in Colorado. I am especially pleased by the support for the event from BIO, Roche Colorado, Amgen, PhRMA and Pfizer."

CBSA BioNews

GlobeImmune Closes on Series B Financing

GlobeImmune successfully closed on $34.3 million in Series B financing. This round was led by Lilly Ventures and included corporate as well as traditional venture capital funds. GlobeImmune is developing immunotherapy products called Tarmogens™ for the treatment of cancer and chronic infectious diseases.

Baxa Corporation was recognized as a 2005 Colorado Top Company by *Colorado Biz* magazine. The annual awards highlight the best of Colorado business – those companies demonstrating financial and operational excellence as well as a commitment to giving back to their communities.

Scientists at **Sirna Therapeutics** published a research paper in July documenting how to effectively deliver RNA drugs in non-toxic doses.

AKTIV-DRY, LLC, of Boulder has received a $19.5 million grant from the Foundation for the National Institutes of Health to develop a needle-free, dry powder, inhalable measles vaccine delivered with a disposable plastic device.

Allos Therapeutics, Inc. published the results from its Phase 2 multicenter study of EFAPROXYN in patients with unresectable, non-small cell lung cancer receiving sequential chemoradiotherapy (S-CRT). Results from the study suggest that the addition of EFAPROXYN to S-CRT may improve survival over S-CRT alone without increasing radiation toxicity rates.

A new **Front Range Neuroscience Website** has been launched at www.FRNG.colostate.edu.

Accera Inc. has received approval to provide Alzheimer's patients in its ongoing Phase 2b clinical trial the opportunity to receive Ketayns™ treatment in a formal open label six-month extension study. Ketasyn™ is a first-in-class therapeutic that addresses the energy deficit observed in the brain of patients with Alzheimer's disease.

iBalance landed $8.24 million in venture capital funding. The Series A financing is from Sutter Hill Ventures and Skyline Venture Partners. iBalance is developing a new procedure for knee reconstruction.

OSI Pharmaceuticals Inc. will purchase Eyetech for about $935 million. OSI said the deal is part of a broader plan to diversify OSI's business into a variety of medical conditions. Eyetech focuses on ophthalmologic disease.

The **CBSA Government Relations and Public Affairs Committee** meets every first Tuesday of the month at CBSA offices.

Join in

Call the CBSA office to volunteer for any of the following committees: Membership, Programs and Events, Technology Transfer and Sponsored Research.

Colorado Tech Week – October 17 - 21

Technology's life-enhancing potential is infinite — and Colorado is on the cutting edge of the latest revolution. This statewide event showcases technological breakthroughs in business, academia, entertainment and sports with five days of demonstrations and events: www.coloradotechweek.com.

Exhibit at BioWest

Booths are still available. Reserve yours at www.biowestconference.com.

Colorado Companies Present at BIO Mid-America VentureForum

The Biotechnology Industry Organization (BIO) selected two private companies from Colorado to present at the BIO Mid-America VentureForum. MicroPhage (Longmont) and Thinc Pharmaceuticals (Aurora) joined other promising early-to late-stage companies from across the country in presenting business plans to a national audience of venture capitalists and other potential investors on September 21-23 in Minneapolis/St. Paul.

3rd Annual Awards Dinner – November 8th

Please join us for CBSA's 3rd Annual Awards Dinner on November 8th at the Colorado Convention Center. In addition to the 2006 award presentations, we are honored to announce the 2006 Cooley Godward Keynote Speech, featuring Dr. Thomas R. Cech, Nobel Laureate, President, Howard Hughes Medical Institute. The dinner follows the first day of BioWest.

New President/CEO Named at National Jewish Medical and Research Center

Michael Salem, M.D., an academic researcher, surgeon, and healthcare entrepreneur, has been named the incoming President and CEO of National Jewish. Dr. Salem succeeds Lynn Taussig, M.D., who is retiring after more than 12 years in the position. Dr. Taussig and Dr. Salem will work together through the rest of the calendar year.

CONTINUED ON PAGE 8

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NEWS BRIEFS, CONTINUED FROM PAGE 7

New Face at CBSA

CBSA would like to welcome Stephanie Kelly, our newest staff member. Stephanie joined the Association in mid-August to assist with database management and a variety of administrative functions. She recently graduated from Abraham Lincoln High School in Denver and plans to continue her education and training in law enforcement.

Referendums C & D

CBSA supports Referendums C & D. They are essential to maintain key elements of Colorado's public infrastructure, especially higher education. Please vote on November 1st. Visit the official campaign website for information to post for your employees: www.voteyesonc-d.com.

Myogen, Inc. announced the pricing of an underwritten public offering of 4,675,082 shares of newly issued common stock at $23.25 per share before underwriting discounts and commissions. The company intends to use the net proceeds of approximately $101 million from the financing to continue the development of its product candidates and research program.

The following companies were chosen to present to a panel of investors at the BioWest Conference Venture Forum on November 8th at the Colorado Convention Center: ApopLogic, AKTIV-DRY, Cytologic, Cerapedics, Thinc Pharmaceuticals, Lohocla, MBC Pharma, InViragen, Brotica and BioCare Systems. Congratulations and good luck!

The **Fitzsimons BioBusiness Incubator** is open and David Drake is the new executive director. The incubator is screening Colorado bioscience companies for potential clients. Contact David at DDrake@colobio.com. Look for more information in the December Focus.

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