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BioWest Takes Giant Step

Sometimes a little change is a good thing. Moving the 2005 BioWest conference to the Colorado Convention Center turned out to be a giant step in the right direction for the event as well as for the industry in Colorado.

"The move to the convention center was huge," said Christine Shapard who, as director of bioscience and emerging technologies for the Colorado Office of Economic Development and International Trade, helped direct the event. "It brought the entire conference a sense of importance."

The move was more than just symbolic. It also allowed event organizers to accommodate more attendees and exhibitors, and to expand the number and scope of the sessions.

"After two full days of dynamic presentations and record attendance, it is clear that the bioscience industry has a significant impact on the Rocky Mountain region's economy," said Denise Brown, CBSA executive director.

Over 670 people from all over the Rocky Mountain region attended the two-day event November 8 and 9, a significant increase from the previous year. Nearly 80 exhibitors participated in the trade show area, including mature companies, young companies, vendors and public sector organizations.

With five companies from Canada exhibiting, the conference took on an international flavor. BioWest



Steve Spangler inspires a new generation of scientists.

was such a hit that the Canadian Consulate is already planning a Canadian pavilion at the 2006 conference.

The impressive breadth of presentations and panelists covered a wide range of topics, including four keynote presentations and 15 different breakout sessions. Fort Collins-based InViragen took the \$10,000 prize in the Venture Showcase, which featured presentations from 10 different companies. CBSA board chairman Ed Wood said the combination products session with Mark Kramer, director of the FDA's Office of Combination Products, "was quite timely, as indicated by the audi-

ence participation during the Q&A section." Governor Bill Owens told industry leaders that the governor's office plans to introduce a net operating loss bill to attract and retain bioscience companies, and Steve Spangler made grown-ups act like kids with his "science experiments" during his keynote address.

Event organizers said the increase in media attendance was a good indication that there is a growing interest in bioscience. The *Denver Post*, *Rocky Mountain News*, *Denver Business Journal* and the *Boulder County Business Report* all sent reporters to cover BioWest.

With 87 percent of respondents to a post-event survey agreeing that BioWest was a valuable tool for their business, it is easy to see why the conference will continue to be an important step in the progress of CBSA and the state's bioscience industry.



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COMING EVENTS

CBSA has an exciting schedule of new programs and events planned for 2006. Check out our Web site for the latest details. Programs will cover a wide range of topics, such as regulatory issues, human resources, manufacturing, finance and accounting, sales and marketing, and technology transfer.

Our educational theme for 2006 is "Strengthening Bioscience Infrastructure in Colorado." At least 35 CBSA programs are planned.

SAVE THE DATE



BIOWEST

Start planning now to attend BioWest 2006 at the Colorado Convention Center August 23 and 24 and the CBSA annual awards dinner on August 24.

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

"IT IS HARD TO BELIEVE WE ARE PLANNING OUR THIRD YEAR OF ACTIVITIES AND OTHER SERVICES FOR CBSA MEMBERS."

Rick Jory
Treasurer, CBSA
President and CEO,
Sandhill Scientific

As CBSA treasurer, I have seen the growth and success of the association from a unique perspective. We have based our financial management goals on ensuring that your investments bring the highest possible return through outstanding programming, effective communications and advocacy, and leadership within the business landscape of

Colorado. By all accounts, the executive committee, board of directors, and staff of the association are doing a good job as stewards of your membership dollars.

As we prepare for 2006, I hope you will assist us by responding quickly when you receive your membership renewal package. Your early response helps us get down to business right after the New Year. CBSA's single largest source of revenue comes from membership dues. Thanks to the ongoing support of our 2003 founding members, and new members that have joined over the last two years, we have been able to sustain a growing association without an increase in the dues structure. Next year, our strategy is the same – increase benefits by increasing the community of committed members, not through the escalation of

costs to existing members.

Member benefits for 2006 will be guided by a new strategic plan. The chair of the CBSA board, Ed Wood, led the effort to create a comprehensive plan that includes specific actions and goals for each area of operation within the association. This ensures that we can focus our resources on the most important and productive areas and encourage the health and growth of the bioscience industry in Colorado. If you would like to see the plan, it is available on the CBSA web site at www.cobioscience.com.

I look forward to seeing you in 2006 and welcome your comments or inquiries about the financial performance of CBSA. Thank you in advance for your ongoing support!

BioWest Gallery



Looking into the Crystal Ball – The Future of the Bioscience Industry

L-r: Tom Bratschun, Swanson & Bratschun, David Urso, Forward Ventures, Kyle Lefkoff, Boulder Ventures, Peter Van Vlasselaer, Avidia.



L-r: Denise Brown and Holly El-Jammal celebrate after the Annual Dinner.



Ed Wood (right) welcomes Governor Owens (left).



Venture Showcase L-r: Dan Mitchell, Sequel Venture Partners, Joe Piper, Integra Ventures, Tim Mills, Sanderling Ventures, Teri Willey, Arch Development Partners.

BioStar on the Rise

ACQUISITION BY INVERNESS MEDICAL INNOVATIONS OPENS NEW ERA OF GROWTH



**BIOSTAR, INC.,
A COLORADO
PIONEER IN RAPID
DIAGNOSTIC
TESTING, IS
GROWING UP.**

BioStar, Inc. entered a new stage in its growth this fall when it was acquired by a leading developer of medical diagnostic products.

"We've made a significant transition," says Mark Jennings, vice president and general manager of the new Inverness Medical – BioStar, Inc., a division of Inverness Medical Innovations, Inc. of Waltham, Massachusetts. "We've grown from a startup, to a profitable business unit, to a key asset for a corporation focused on growing its presence in our target market."

Founded in Boulder in the 1980's, BioStar built a successful business in rapid diagnostic testing based on its Optical Immunoassay™, or OIA, technology. This innovative, proprietary technology translates biological reactions into signals that can be visually read. BioStar's products are among the most sen-

sitive tests available to physician offices and hospitals for the speedy diagnosis of respiratory infections, gastrointestinal infections and sexually transmitted diseases.

In 1998, BioStar was purchased by Thermo Electron Corporation. In 2002, it moved to its current home in Louisville. As Thermo BioStar, it grew quickly in sales and profitability. "Thermo was a terrific corporate parent," says Jennings. "It helped BioStar mature as a business, and gave us the infrastructure and capabilities we needed to grow profitably."

Inverness Medical Innovations purchased BioStar in late 2005, and is growing rapidly, Jennings points out, "and BioStar is a part of that progress. We add significant commercial capability in professional diagnostics, which is Inverness's largest strategic business unit. We will be an important part of the company's future."

Colorado is an important location for Inverness, according to Jennings. Product development, manufacturing, distribution and other activities will stay in Louisville, where 110 of BioStar's 180 employees work. "We will, however, merge commercial operations within Inverness," he says, "allowing us to extend our product line to more physicians and hospitals. BioStar will serve as the foundation for Inverness's direct sales capability, a critical role as Inverness brings new rapid-testing products to market."

Complementary products and a close match in missions bode well for BioStar's future with Inverness, says Jennings. "This is a corporation focused on rapid results for better treatment, which has always been our mission at BioStar. In fact, they are the largest company in the world dedicated to rapid-testing."

Jennings has always been driven. He graduated from West Point, served as an officer in the Army Rangers and earned his MBA at Harvard. After working as a strategy consultant with McKinsey and Company, he joined Thermo Electron in strategic planning before becoming vice president and general manager of Thermo BioStar in 2003.

As an experienced leader in a complex industry, Jennings can appreciate the constant challenge of finding top technical talent. "In this respect," he says, "we like being in Colorado. It's very talent-rich, and, compared to other biomedical hubs in the U.S., has distinct advantages in affordability and quality of life."

Jennings credits his entire management team with being eager to pursue the new opportunities ahead. "We are all very enthusiastic about being part of Inverness," he said. "We share a passion for helping clinicians practice better medicine, and this transition represents an opportunity for us to help Inverness be the world leader in rapid diagnostics products."

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REGULATORY UPDATE

Invest in Supplier Quality, Not in Costly Recalls

BY CLAY ANSELMO

As a regulatory and quality system professional, I constantly monitor FDA recalls and enforcements. Recently, a major recall in the human cellular products industry caught my attention. It related specifically to one topic that is consistently a subject of confusion for bioscience companies: supplier quality assurance.

Medical manufacturers today are outsourcing more and more activities to specialized contract manufacturers or service providers. As this becomes more prevalent, a company's risk from its supplier quality assurance program increases.

In this particular instance, a tissue recovery agency from New Jersey announced the recall of human tissue from 761 donors that was recovered and shipped to five tissue product manufacturers (processors) and subsequently processed and distributed for implant into patients. Information released by the FDA indicates that some or all of these donors were not adequately screened and tested by the recovery agency for potential to transmit communicable diseases. Each of the tissue product manufacturers that received tissue from this donor agency were forced to recall their affected products. Imagine the cost and product liability associated with this error.

Many companies treat supplier quality assurance programs as simply an FDA requirement, not as a key element in their overall quality system and certainly not as an important liability/risk reduction activity. They perform



few, if any, on-site audits, and the audit programs are mostly cursory. Keep in mind, however, that all companies rely heavily on the quality of their supplier base, often times to a greater degree than they would like to admit.

A good supplier quality assurance program is generally based on the adage "trust, but verify" – meaning that while it is important to trust your suppliers, it is also important to periodically verify the adequacy of their quality system. Efficient and effective supplier quality systems focus company resources on high risk suppliers, using product risk analysis, previous audit results and production quality data to categorize the risk associated with each supplier. Visiting high risk suppliers on an annual basis is costly, no question. But imagine

the potential cost of a recall in direct dollars and damage to a company's reputation. Incoming inspection of supplier materials is NOT a replacement for verifying the adequacy of a supplier's quality system and is often the source of false confidence in a supplier's products.

As you prepare for the upcoming year and decide how to invest your resources, don't forget to invest in your suppliers. Relatively small dollars spent on high risk suppliers of products and services can greatly reduce your product liability, regulatory risk and potential damage to your reputation.

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

InViragen Seizes an Opportunity

START-UP DEVELOPS VACCINES FOR AN EMERGING MARKET



InViragen wins the Venture Showcase award at BioWest. Left to right: Richard Nakashima (Faegre & Benson), Dan Stinchcomb (InViragen), Dan Mitchell (Sequel Ventures).

INVIRAGEN IS WORKING TO DEVELOP AND MANUFACTURE A VACCINE FOR THE DEADLY DENGUE VIRUS.

After a 16-year career in biotechnology management, Dr. Dan Stinchcomb was looking for a new opportunity.

"What I wanted most was to use my experience in biotech and vaccines," said Stinchcomb.

The market for new vaccines is changing dramatically. Vaccine shortages and worries about emerging infectious diseases have spurred increased government support for new research. Vaccine development also has been gaining support from several non-profit initiatives, most notably the Bill and Melinda Gates Foundation.

An opportunity came along for Stinchcomb to partner on a new venture with Dr. Jorge Osorio, an assistant professor at the University of Wisconsin with over 17 years of vaccine research and development experience. Together, they

founded InViragen, a two-year-old Fort Collins company focused primarily on developing vaccines to provide cost-effective solutions to infectious diseases worldwide.

"It was the perfect time to start a biotech company focused on developing vaccines," said Stinchcomb.

With Stinchcomb as the Chief Executive Officer and Osorio as Chief Scientific Officer, InViragen is collaborating with the Centers for Disease Control Division of Vector-Borne Infectious Disease to develop and manufacture a vaccine for the Dengue virus. This deadly disease threatens 2.5 billion people worldwide and is the leading cause of hospitalization and deaths of children in parts of Asia.

"Vaccines are still the best way to fight infectious disease," said Stinchcomb.

Currently, InViragen is seeking seed funding of \$2 million. This will help the company initiate clinical trials of a Dengue virus vaccine, complete pre-clinical development of a West Nile vaccine and support licensing and patent filings.

By partnering with companies worldwide and organizations like the CDC, InViragen plans to develop and manufacture vaccines that will not only be cost-effective, but also easily distributed to the areas of most need.

In the case of the Dengue vaccine, the company is partnering with Shantha Biotechnic, a pharmaceutical manufacturer in India, to produce the vaccine for clinical trials.

InViragen and its investors are not the only ones who feel that the company has a promising future.

The company was one of ten start-ups chosen to participate in the Venture Showcase at the 2005 BioWest conference in November, where it was selected for a \$10,000 prize by a panel of venture capitalists.

"It was an honor to be selected," said Stinchcomb. "It was a great opportunity for our company to get more exposure and a great opportunity to hear what my colleagues in Colorado are doing."

Not only has InViragen been recognized for its efforts to bring the Dengue vaccine to market, but it also has identified two other promising products with significant market opportunities: the West Nile vaccine and a plague vaccine for biodefense. Patents covering the technology used in the Dengue and West Nile vaccines have been filed worldwide by the Centers for Disease Control. InViragen is also anticipating over \$1 million in federal grants for 2006.

"Over the next ten years, our goal is to grow the company and launch a vaccine that can have an impact internationally," said Stinchcomb.

AT A GLANCE:

Over the last year and a half, the Denver metro area's northwest market (between Denver and Boulder) has seen an increase in leasing activity among biotech companies. This area is home to a critical mass of biotech companies. The following statistics were provided by Eric Brynestad of the Staubach Company, a CBSA member. These statistics do not include medical device companies.

- Total space leased or owned by biotech companies in the northwest metro area: 2.4 million square ft.
- The above amount is equal to: 55 acres
- Square-feet leased by biotech companies in northwest metro area: 1.1 million square ft.
- Renewed or newly leased space in the last 18 months: 447,000 square ft.
- Amount of the above newly leased space that is considered expansion: 200,000 square ft.

UNDER THE SCOPE FEATURE

Applause and Accolades

"BEST OF THE INDUSTRY"
HONORED AT THIRD ANNUAL CBSA AWARDS DINNER



Nobel Laureate Dr. Thomas Cech speaking at CBSA awards dinner.



Neil Westergaard presents the Company of the Year award to Baxa's chairman Greg Baldwin.

With laughter, applause and accolades, CBSA celebrated the industry's top companies and individuals at the third annual CBSA awards dinner November 8. The event was held at the Colorado Convention Center during BioWest.

"The companies and individuals recognized with these awards represent the best of Colorado's bioscience industry," said Denise Brown, CBSA executive director.

Highlights of the evening included the presentation of the *Lifetime Achievement Award* to Dr. Lynn Taussig, who was honored for his accomplishments as a physician, president of National Jewish Medical and Research Center, CBSA board member and leading advocate for the industry in Colorado.

Colorado-owned Baxa Corporation, one of the state's largest and most successful medical device companies, won *Company of the Year*. CellPoint was recognized as the

Rising Star Company of the Year for its work in developing new technologies that could revolutionize the way that cancer is diagnosed and treated. Dr. Timothy Estep was honored as *Volunteer of the Year* for his outstanding dedication, persistence, leadership, and commitment to CBSA. And a special *Chairman's Award* was presented to the law firm of Hogan & Hartson for the *pro bono* assistance the firm has donated to help grow the bioscience industry in Colorado.

"It's always nice to be recognized by your peers," said CBSA board chairman Ed Wood. "The awards dinner was a huge success."

Guest emcee Neil Westergaard, editor of the *Denver Business Journal*, hosted the festivities, which featured a stirring keynote address from Dr. Thomas Cech, University of Colorado Nobel Laureate and president of Howard Hughes Medical Institute.



Dr. Lynn Taussig accepting Lifetime Achievement award.

CBSA BioNews

More Good News for Myogen

The good news continues to roll in for Myogen. Positive clinical trial results recently sent shares of the Westminster-based biotech soaring up more than 40 percent, giving it a market value of more than \$1 billion.

The news involved ambrisentan, a drug in development for pulmonary arterial hypertension (PAH), a disease in which a lack of blood flow to the lungs makes patients so weak they cannot walk across the room. The disease can lead to deadly cases of heart failure. The drug is in the last stages of development before the company applies with the Food and Drug Administration for marketing approval.

In August, Myogen presented mid-stage results on darusentan. That medicine managed to further lower blood pressure in patients whose high blood pressure was not under control based on three other anti-hypertensive medications. That time, shares rose almost 90%.

Allos Therapeutics of Westminster announced positive results in two clinical trials for cancer agents. Investigators from Memorial Sloan Kettering Cancer Center studying the chemotherapeutic agent PDX showed a remarkably high remission rate in patients with non-Hodgkin's lymphoma. And a Phase 3 study of EFAPROXYN found it improved survival and quality of life in breast cancer patients with brain metastases.

Amgen expanded its operations in Colorado with a new facility for live-cell culture production. The \$150 million investment is a new launch site for new drugs awaiting approval from the FDA.

Stephen K. Onody, a member of the CBSA board of directors, accepted a position as CEO of **Lifeline Therapeutics** in Englewood. Lifeline Therapeutics, Inc., is a publicly traded company that markets Protandim.

Silverglide Surgical Technologies, Inc.

of Boulder won a legal dispute against Kirwan Surgical Products, Inc. involving Silverglide's proprietary non-stick technology used on bipolar electrosurgical forceps. In the suit, Silverglide claimed that Kirwan Surgical Products misappropriated technology that was developed and owned by Silverglide. Silverglide claimed that Kirwan used the technology in its AURA™ line of electrosurgical instruments. The ruling was in favor of Silverglide on all counts.

Silverglide also launched a new device to help neurosurgeons operate through tiny incisions by optimizing visibility, access and performance. The device is called the *Keyhole Maximum Access Forceps*. Silverglide's president and CEO is Jonathan Thorne, who is also a member of the CBSA board of directors.

Golden's **CeMines, Inc.** announced that the company has been soliciting offers to purchase its Research Tools business and related inventory of polyclonal antibodies, cDNA and mRNA. The business also includes associated trademarks and a multinational customer base that includes some of the world's most prestigious research institutions.

Denver's Medical Simulation Corporation

's *SimSuite* was featured on the TODAY Show on November 30th. The show was part of a series called *Saving Your Life: Modern Medical Miracles*. MSC provides training and education services for the health-care industry. William E. Younkes is president and CEO, and medical director Dr. John D. Carroll is director of interventional cardiology and the cardiac catheterization laboratories at University of Colorado Hospital in Denver.

Array BioPharma

of Boulder announced that it may receive an additional \$50 million for research from Genentech over the next three years. Array will receive milestone payments based on the progression of clinical drug candidates and royalties on net sales of any products that may arise from the collaboration. Robert Conway is CEO of the company.

Colorado State University

appointed Hunt Lambert associate vice president for economic development. Hunt was previously director of the Center for Entrepreneurship at CSU. In his new position, he will coordinate activities related to technology transfer, startup companies, workforce development, the growth of educational products for the private sector, and public policy aspects of economic development among university departments and the Colorado State University Research Foundation.



Dr. Mervyn Jacobson, executive chairman of Genetic Technologies Limited

participated in the "closing bell" ceremony at NASDAQ when the company was officially listed under the symbol GENE. Genetic Technologies Limited is an Australian company that is also listed on the Australian Stock Exchange.

The Aurora biotech company, Taligen,

closed a \$3.75 million Series A round of financing. The company commercializes technology developed at the University of Colorado. Taligen was founded in March 2004 by Woody Emlen, a former University of Colorado rheumatologist. Sources for the financing included High Country Ventures and Sanderling Ventures.

NEWS

BRIEFS, CONTINUED FROM PAGE 7

Visible Productions, a Fort Collins company, received two PEAK awards from the Colorado Chapter of the American Marketing Association for a CD and a brochure created for Novartis Animal Health.

Able Planet Inc. won a Best of Innovations award at the 2006 International Consumer Electronics Show. The company is based in Fort Collins and was recognized for its LINX technology, which is designed to assist people with hearing loss use telephones, computers, and other electronic devices.

Forest City Enterprises is the first developer to negotiate with Fitzsimons Redevelopment Authority (FRA) to become the agency's long-term development partner for the bioscience park in Aurora. About 3.5 million square feet of space projected to cost about \$2 billion is planned for the 160-acre park. Those numbers could increase, depending on the agreement that's reached with the developer. Negotiations are expected to be completed in the first quarter next year, according to Jill Famham, executive director of FRA.

Christine Shapard Joins CBSA

Christine Shapard, director of biosciences and emerging technologies for the Colorado Office of Economic Development and International Trade (OEDIT) for the past two years, will join CBSA in January as the association's director of marketing and communications.

Are you planning to attend the **Medical Design and Manufacturing Conference** in Anaheim on January 31 – February 2? CBSA is planning activities for anyone from Colorado attending the show, so let us know if your company will be represented.

CBSA is pleased to welcome Eva Llanas to our administrative staff. Her responsibilities include assisting in program and event coordination, database management, and customer service. Eva attends the Art Institute of Colorado and is pursuing a degree in arts and interior design.

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