

COMPANIES TO WATCH: COLORADO'S EMERGING LIFE SCIENCE COMPANIES

BY ADAM RUBENSTEIN

A significant temporal duration exists, at times exceeding a decade or more between idea-generation, clinical studies and commercialization. Gaps and valleys and troughs are often used to describe capital needs based upon where a company or technology sits on the development continuum. In Colorado, the cowboy spirit and can-do attitude permeates throughout the entrepreneurial ecosystem where biopioneers find themselves embarked upon sometimes unique paths to get their products to market, and in doing so, may often fly under the radar relative to others who have closed well publicized institutional financings.

Here we turn the spotlight on a few of those companies. Colorado is home to a diverse array of bioscience sectors featuring the development of not only biopharmaceuticals, devices and diagnostics but home to also emerging green-bio and medical-IT products and technologies. What follows are some of Colorado's most exciting emerging companies representing products and technologies from all sectors of the bioscience industry.

COMPANY: MICROPHAGE
SECTOR: BIO-DX
CEO: STEVE LUNDY
LOCATION: LONGMONT, CO
WEB: MICROPHAGE.COM



Based in Longmont, Colorado, privately held MicroPhage is focused on achieving a global leadership position in developing rapid, easy-to-use diagnostic products for bacterial identification and antibiotic susceptibility and resistance testing. Using their proprietary Bacteriophage Amplification platform, the Company has developed a patented process that is a product platform for rapid, easy-to-use, inexpensive diagnostic and screening tests. The platform does not require any instrumentation and is simple to operate, enabling microbiology testing outside of traditional laboratory settings.

The company has chosen to focus their initial efforts to help solve medical crises involving such problems as over use of antibiotics and antibiotic resistant bacteria. The first product expected in 2010 is anticipated to set a new standard for clinicians and hospital staff in methicillin-resistant *Staphylococcus aureus* (MRSA) identification and antibiotic testing. Additional bacterial pathogens that may be addressed with the company's technology include: Vancomycin-resistant *Enterococcus* (VRE), ESBL-producing *Escherichia coli*, drug resistant *Pseudomonas aeruginosa*, and penicillin-resistant *Streptococcus pneumoniae*.

2009 proved to be an exciting year for CEO Steve Lundy and company as a number of important milestones were achieved,

including: launching their multi-site clinical trial to support a FDA premarket notification [510(k)]; obtaining a CE Mark to market in Europe the first of their instrument-free tests designed to rapidly identify *Staphylococcus aureus* bacteria as well as determine methicillin resistance or susceptibility in suspected cases of bacteremia; and, announced a doubling of their office and laboratory space while increasing full time employees from 4 to 25. Look for MicroPhage to conclude their pivotal study to support their 510(k) premarket notification and initiate commercial operations in the first half of 2010.

COMPANY: SOURCE MDX
SECTOR: BIO-DX
CEO: KARL WASSMAN
LOCATION: BOULDER, CO
WEB: SOURCEMDX.COM



Based in Boulder, Colorado, Source MDx is developing and commercializing prognostic, predictive and early detection molecular diagnostic (Precision Profile™) assays and tests for cancer and other inflammatory diseases. The Company's lead development programs, in collaboration with the Dana-Farber Cancer Institute, include a family of Precision Profile™ assays for prostate cancer designed to: i. improve early diagnosis with a goal to reduce the need for biopsies, ii. predict the aggressiveness of the cancer, and iii. better define prognosis and more effectively stratify patients for drug response - all of which may serve to improve the management of patient care and lower healthcare costs.

The Company is also developing molecular diagnostics in collaboration with other leading



based on the discovery, characterization and management of naturally occurring consortia of ancient, anaerobic microorganisms that metabolize oil, organic-rich shale and coal within the earth into natural gas, thus generating clean renewable energy in a continuous, “real time” fashion. Luca employs genomics, molecular biology and other tools of biotechnology to detect, classify and study these organisms and the underground “Geobioreactors” in which they act.

2009 proved to be a very exciting year for the Luca team assembled by CEO Robert Pfeiffer, for in addition to having received a key notice of allowance by the US Patent and Trademark Office covering the Company’s technology for microbially enhanced methane production, Luca was also named to the Global Cleantech 100 list by the Guardian News and Cleantech Group. Supported by the Carbon Trust, the Global Cleantech 100 recognizes companies at the forefront of cleantech innovation offering solutions to some of the world’s most pressing environmental challenges. Luca was also selected by AlwaysOn as one of the GoingGreen Top 100 Winners, with the selection based upon a set of five criteria: innovation, market potential, commercialization, stakeholder value and media buzz.

COMPANY: OPX BIOTECHNOLOGIES	
SECTOR: BIO-GREEN	
CEO: CHARLES EGGERT	
LOCATION: BOULDER, CO	
WEB: OPXBIOLOGIES.COM	

Based in Boulder, Colorado, OPX Biotechnologies is a bio-products company using proprietary bioengineering technology to convert renewable feedstocks into biofuels and green chemistry products. The OPX EDGE (Efficiency Directed Genome Engineering) technology platform enables rapid, rational, and robust optimization of microbes and bioprocesses. The Company identifies the genes that control microbial metabolism and then implements a comprehensive, rational genetic change strategy to simultaneously optimize microbial production pathways and vitality as well as overall bioprocess productivity.

The OPX platform includes a first-of-its-kind, massively parallel, full genome search technology known as SCALES. The OPX EDGE technology is 1,000 to 5,000 times faster than conventional genetic engineering

academic medical centers in a range of cancers, including lung and melanoma, as well as certain inflammatory and autoimmune diseases such as multiple sclerosis. Source MDx’s patented assays and tests measure RNA-transcript-based gene expression in whole blood using quantitative PCR, optimized for clinical use in a commercial setting. The Company has a multi-year translational molecular medicine collaboration with Pfizer to develop and validate RNA-based pharmacodynamic and predictive biomarkers within Pfizer’s cancer and inflammation therapeutic development programs. Led by CEO Karl Wassman, Source MDx has worked with more than 30 major pharmaceutical firms on over 150 preclinical projects and clinical trials that have involved over 5,000 human subjects.

COMPANY: LUCA TECHNOLOGIES	
SECTOR: BIO-GREEN	
CEO: ROBERT PFEIFFER	
LOCATION: GOLDEN, CO	
WEB: LUCATECHNOLOGIES.COM	

Based in Golden, Colorado, Luca Technologies is developing a novel, long-term, biotechnology-driven solution to rising US dependence on foreign energy sources. Addressing the \$150 billion domestic natural gas market, the company is leveraging the ability of naturally occurring microorganisms to convert under-utilized domestic oil, organic-rich shale and coal resources to clean, renewable energy. The company’s business is characterized by: A technology platform

methods, meaning OPX creates optimized microbes and bioprocesses within months rather than years. Compared to petroleum-based alternatives, OPX EDGE bioprocesses deliver equivalent product performance with improved sustainability at lower cost. Using the EDGE platform, OPX has produced multiple biofuel and green chemistry products at laboratory scale from several different renewable feedstocks. OPX is proving its economical bioprocesses at larger scale in advance of a demonstration plant startup in 2011.

COMPANY: MIRAGEN THERAPEUTICS
SECTOR: BIO-PHARMA
CEO: BILL MARSHALL
LOCATION: BOULDER, CO
WEB: MIRAGENTHERAPEUTICS.COM



Based in Boulder, CO miRagen Therapeutics, a development-stage biopharmaceutical company is focused on developing innovative microRNA (miRNA) based therapeutics for cardiovascular and muscle disease. The Company is leveraging its core capabilities in miRNA profiling, oligonucleotide medicinal chemistry, cellular analysis, and in vivo testing in disease models to select highly potent modulators that target lead miRNAs in disease-specific pathways. miRagen has identified miRNA signature expression patterns associated with pathological cardiac hypertrophy, heart failure and myocardial infarction in humans and mouse models of heart disease, as well as discovering miRNAs that are important in vascular and skeletal muscle disease. The Company has validated numerous targets and moved potential clinical candidates through lead optimization into IND-enabling pre-clinical studies.

2009 has proven to be a very fruitful year for CEO William Marshall and the entire team at miRagen, a few highlights include: Chief Scientific Advisor and Co-Founder, Eric Olson, Ph.D., was awarded Grand Prize of the Institute de France's Foundation Lefoulon-Delalande, widely considered the most distinguished prize in the cardiovascular field, for his groundbreaking research into the mechanisms of gene regulation in heart development; a collaboration Archemix was announced to jointly pursue research and development efforts on aptamer-microRNA therapeutics; was awarded, by the Colorado BioScience Association, the 2009 Rising Star of the Year Award, recognizing a Colorado



life sciences company that has demonstrated itself as "one to watch."; and, published data in the journal *Science* demonstrating, in mice, that microRNA-206 plays a crucial role in the progression of amyotrophic lateral sclerosis (Lou Gehrig's disease) and in neuromuscular synaptic regeneration.

COMPANY: WESTERN STATES
BIOPHARMA
SECTOR: BIO-PHARMA
CEO: MICHAEL REILLY
LOCATION: AURORA, CO
WEB: WESTERNSTATESBIOPHARM.COM



Based in Aurora, Colorado, Western States Biopharmaceuticals is a privately-held company focused upon the development of novel, small molecule and biologic therapeutic approaches that selectively modulate adaptive immunity to treat inflammatory diseases. By focusing on activated macrophages, a key white blood cell in the adaptive immune system, Western States is designing drugs that target the pathogenesis of autoimmune disease while avoiding suppression of the innate immune system. The goal of Western State's drug discovery and development research programs are to identify human CD4+ T-cell and macrophage proteins that mediate adaptive immunity but leave the innate immune system intact. The Company refers to these novel human T-cell proteins as "T-cell Cytokine-Inducing Surface Molecules", or TCISM. Western States has recently shown that two important human TCISM are upregulated upon CD4+ T-cell activation and physiologically associate at the T-cell membrane surface. T-cell driven macrophage cytokine levels

were decreased by 90-100% when expression was simultaneously inhibited by dual siRNA knockdown for both T-cell proteins.

2009 proved to be an important year not only for the demonstration of certain TCISM candidates but Scientific Advisory Board member Charles Dinarello was awarded three significant prizes, including: the Crafoord Prize in Polyarthritis by the Royal Swedish Academy of Sciences, for pioneering work to isolate interleukins, determine their properties and explore their role in the onset of inflammatory diseases; the Albany Medical Center Prize in Medicine and Biomedical Research, for groundbreaking work on anti-cytokine therapies that block the immune system's inflammatory reaction; and, the Paul Ehrlich and Ludwig Darmstaedter Prize, for his outstanding contributions to research in the field of cytokines.

COMPANY: VALVEXCHANGE
SECTOR: MED-DEVICE
CEO: LARRY BLANKENSHIP
LOCATION: AURORA, CO
WEB: VALVEXCHANGE.COM



Based in Aurora, Colorado ValveXchange is developing a revolutionary two-part bioprosthetic tissue heart valve system that resolves the long standing compromises between conventional mechanical and tissue-based prosthetic valves. Unlike today's transcatheter valves, the ValveXchange system is being designed to offer leaflet exchange, as well as the original implant, without open-heart surgery and without the safety and longevity compromises of transcatheter approaches. The ValveXchange procedure can be done without open chest surgery or cardiopulmonary bypass, the procedure can be done transapically, through a small incision between the ribs and a small hole in the apex of the heart, both of which heal readily.


In 2009 CEO Larry Blankenship and his team were incredibly efficient with resources having designed and fabricated an exchangeable valve prototype; tested its performance in the sheep model; developed an open-surgery exchange tool set; and, demonstrated that heavy pannus overgrowth can be managed with the ValveXchange system. This rapid progress has not gone unnoticed by the broader medical device community, for the Company was awarded the 2009 North American Frost & Sullivan Technology Innovation of the Year Award at their annual "Excellence in Medical

Technologies & Life Sciences Awards” banquet where other category company winners included Covidien, GE Medical, Philips Healthcare, Siemens Healthcare and Intel.

COMPANY: PHARMJET	
SECTOR: MED-DEVICE	
CEO: HEATHER POTTERS	
LOCATION: GOLDEN, CO	
WEB: PHARMJET.COM	

Based in Golden, Colorado, the PharmJet needle free technology delivers pharmaceuticals – vaccines and drugs — through the skin via a proprietary jet injection technology, no needles – big or small, or patches of any kind are used. The Company’s delivery device is FDA cleared for marketing and can deliver 0.5ml of a liquid medication through the skin of the arm, the abdomen, the thigh, into the muscle or into the subcutaneous layer between the skin and muscle. The PharmaJet needle free device can be used to inject nearly any licensed injectable liquid drug or vaccine. The technology development does not end with the 0.5ml device, the pipeline is currently filled by a 0.1 ml device for intradermal delivery into the 2mm upper layer of the skin where the immune system is very active as well as a variable volume device.

In 2009 CEO Rajen Dalal and his team executed a collaboration with PATH (an international non-profit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health) to evaluate needle-free injections for developing-country immunization programs; regulatory product clearance was received in Brazil by the National Agency of Health Surveillance; and, a variety of New Jersey counties and townships incorporate the PharmJet device at their seasonal flu vaccination clinics.

COMPANY: HEALTHAGEN	
SECTOR: MED-IT	
CEO: PETER HUDSON	
LOCATION: GOLDEN, CO	
WEB: HEALTHAGEN.COM	

Based in Golden, Colorado, Healthagen is a developer of healthcare information software that empowers patients to make better decisions and gives healthcare treatment facilities improved access to additional patients. iTriage, the first application available

from Healthagen, is designed to aid the public to evaluate their symptoms, list potential diagnoses and provide access to appropriate locations for treatment. The proprietary healthcare search engine is designed to provide for personalized point-of-care healthcare decision-making.

The Company, led by CEO Peter Hudson saw 2009 yield a number of important technological and commercial milestones including: the iTriage application becoming available for the iPhone for free download on the iTunes store, as well as becoming available for all smart phones with a mobile internet browser and connectivity including BlackBerry, Android, Samsung, LG, Nokia, Palm, T-Mobile, Sony and Motorola; a new partnership with Centura Health, Colorado’s largest healthcare provider, offering a premier listing service for its healthcare facilities in Colorado available on all of its smart phone iTriage applications; in addition to partnerships with Health Grades, Teladoc, Coalition America and the National Organization of Urgent Cares.

COMPANY: MD-IT	
SECTOR: MED-IT	
CEO: THOMAS CARSON	
LOCATION: BOULDER, CO	
WEB: MD-IT.COM	

Based in Boulder, Colorado, MD-IT was originally founded as a technology company

with the goal of replacing traditional medical transcription protocols. The MD-IT product included front-end speech recognition coupled with basic electronic medical records before transcription and document management services were integrated into their platform. Today the Company’s platform is a turn-key secure, web-based transcription management system that handles transport, workflow, delivery and archival of medical transcriptions. MD-IT is focused upon the flow of patient information among physician offices, transcriptionists, insurance companies, and computer systems, all in an environment that ensures security and privacy of patient health information and achieving all HIPAA compliance requirements.

CEO Thomas Carson and his talented team at MD-IT concluded a very exciting year of growth, some highlights included; opening a new office in Seattle; three acquisitions of existing transcription-oriented entities in Texas, Michigan and Colorado; and, announced that their charter membership in a new industry consortium, the Medical Transcription Service Consortium (MTSC), formed to make it easier for physicians and other authorized persons to exchange electronic health information required for patient care. The MTSC was established by ICSA Labs, an independent division of Verizon Business, and the Medical Transcription Industry Association.

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