Discussion Session - Partnerships for Innovation: Creative Approaches

Colorado companies are finding sources of investment and support from strategic partnerships. Our expert panel will cover critical partnerships for life sciences companies at all stages of commercialization. We'll focus on IP protections, working effectively with regulators, regulators, partnering on clinical trials, successful relationships with federal agencies, and outsourced manufacturing.

Panelists include:

(Moderator) David Walker, Esq. – Shareholder, Sheridan Ross

David Walker is a shareholder and head of the Life Sciences Practice Group at Sheridan Ross PC. He partners with life science and pharmaceutical companies to protect their innovations. A registered patent attorney with a master's degree in molecular biology, Dave brings expertise in biotechnology and pharmaceuticals. Dave works with clients through all stages of the portfolio development projects, and he helps clients develop worldwide protection strategies in highly competitive markets. From patent drafting and prosecution to technology licensing and noninfringement opinions, Dave's counsel focuses on offering clients strategic advice that is rooted in the day-to-day realities of their business.

He also assists clients with M&A due diligence, global prosecution strategy, portfolio monetization projects, and post-grant proceedings. Dave's background includes work on small molecule pharmaceuticals and biologicals, nucleic acids, genetically modified organisms, antibodies, proteomics, cell and gene-based therapeutics, tissue engineering and clean technology, among others. Dave received bachelor's and master's degrees in molecular biology from the University of Denver, with a master's emphasis on neuroendocrinology, and a law degree from the University of Denver Sturm College of Law.

Kanchana Iyer, M.S. - Senior Consultant, Regulatory Affairs, Halloran Consulting Group

Kanchana has more than 10 years of experience in developing science-based regulatory strategy, negotiating with FDA and global regulatory authorities, and driving efficiency throughout the premarket process. As a Senior Consultant, Regulatory Affairs at Halloran, Kanchana provides expertise with driving regulatory decisions for innovative technologies including medical devices, digital health, and personalized medicine.

Her expertise includes Medical Devices, In Vitro Diagnostic (IVD) Devices, Software as a Medical Device (SaMD).

Prior to joining Halloran, she worked extensively in medical device regulatory affairs, starting her career as a premarket reviewer at FDA with the most recent at a Software as a Medical Device (SaMD) startup as Director Regulatory Affairs.

Kanchana earned a Master of Science, Biomedical Engineering from the University of Iowa and is a proud member of RAPS and ASQ.

David Trollinger - Director, National Jewish Health; Business Development, Advanced Diagnostic Laboratories

David B. Trollinger, MBA, Director of Business Development, National Jewish Health Advanced Diagnostic Laboratories, representing specialized laboratory testing to improve diagnostics and patient care. Our institution and laboratories work with innovators with our specialized infectious disease testing and functional immunology biomarkers as well as validate new assays in a CAP/CLIA laboratory under CAP/ISO 15189 accreditation to support novel clinical programs.

Prior to joining National Jewish, David spent 20 years in biotechnology from discovery research, building a genome sequencing lab to applying molecular technologies for lead optimization and translational medicine. David was at Amgen for 8 years, a co-founder of a personalized medicine company, Source Precision Medicine and managed translational research studies at Array BioPharma, later becoming a part of Pfizer. David also led business development in the US for a UK based clinical diagnostics innovator, Randox Biosciences.

Vikhyat Bebarta, M.D. - Director, CU Center for COMBAT Research

Dr. Vikhyat Bebarta is an emergency medicine physician in Aurora, CO, and is affiliated with multiple hospitals in the area, including University of Colorado Hospital and Children's Hospital Colorado. He received his medical degree from George Washington University School of Medicine and has been in practice 19 years. He specializes in medical toxicology and is experienced in general emergency medicine, trauma, toxicology, military medicine, and biomedical research. He has more than 230 publications and over 1100 citings.

Gary Pestano, Ph.D. - Chief Development Officer, Biodesix, Inc.

Dr. Pestano heads the Development organization at Biodesix, a leading data-driven diagnostic solutions company. He is the NYS CLEP Laboratory Director of the company’s corporate clinical testing laboratory in Boulder, CO. His greater than 20 years of experience in laboratory and assay development for high complexity molecular diagnostics for oncology includes molecular and proteomic approaches in support of Biodesix Nodify and IQ Lung blood-based tests. Most recently his work has focused on the detection and standardization of testing for cell free nucleic acids as a part of a consortia led by the Friends of Cancer Research. As a critical part of product development Dr. Pestano has fostered innovative key collaborations with leading academic and industry partners across the globe. Prior to Biodesix, Dr. Pestano was at Ventana, a member of the Roche Group, where he led project teams in Pharma Services and in Assay Development. Dr. Pestano received his Ph.D. training at The Graduate Center, City University of New York and conducted his post-doctoral training in cancer immunology at the Dana Farber Cancer Institute, Harvard Medical School.

Sally M. Dyer - SVP, General Manager, Colorado Operations, Umoja Biopharma

Sally Dyer joined Umoja Biopharma in February of 2022 as the Senior Vice President and General Manager for Colorado Operations. Umoja is preparing to establish operations at the Colorado Laboratory and Innovative Manufacturing Building (The CLIMB) located in Louisville, CO with the aim of creating In-Vivo CAR-T oncological therapeutics. Over the course

of her career, she has leaned upon the leadership principles of building an empowered team that acts with purpose for patients as well as with a sense of community.

Sally built her expertise over a 21-year tenure at Amgen, Inc. in a variety of site-based and global operations roles including manufacturing facility start-up assignments in Puerto Rico and Singapore. She left Amgen to return to Colorado and joined AstraZeneca as the head of manufacturing eventually achieving her dream job of being a Site Head. After AZ shuttered operations in Colorado Sally had the privilege to lead a highly skilled team at Novartis Gene Therapies (AveXis, Inc.). Sally's career has been inspired by the people she works with and the patients she works for in pursuit of delivering high quality therapeutic products.

Sally holds a Bachelor of Science degree in Biological Sciences from the University of California at Davis.