

## FOR IMMEDIATE RELEASE

#### **Contact:**

James McCullough Chief Executive Officer Exosome Diagnostics (212) 781-1213 james@exosomedx.com

#### **Media Contacts:**

Robert Flamm, Ph.D., or David Schull Russo Partners (212) 845-4226 robert.flamm@russopartnersllc.com david.schull@russopartnersllc.com

# Exosome Diagnostics Announces Additions to Management and Scientific Advisory Board as Company Expands Clinical Validation Studies in Oncology

NEW YORK Oct. 4, 2011 – Exosome Diagnostics, a leading developer of biofluid-based molecular diagnostic tests for use in personalized medicine, today announced the appointment of David Okrongly, Ph.D., as chief operating officer, Michael Donovan, M.D., Ph.D., as chief medical officer, and Sally Bowden as director of regulatory affairs. Raphael Bueno, M.D., associate chief of cardiothoracic surgery Harvard University and Michael Manyak, M.D., FACS, executive director global medical affairs at GlaxoSmithkline were named to the Scientific Advisory Board.

The hiring of Drs. Okrongly, Donovan and Ms. Bowden reflect the Company's expanded research and clinical validation program for its proprietary exosome RNA biofluid technology in oncology diagnostics. Exosome Diagnostics is applying the stable RNA content of blood and urine exosomes to develop *in-vitro* diagnostics for transcriptional disease profiling, patient stratification and disease monitoring in prostate cancer, melanoma and other cancers.

"The collective professional experiences of Drs. Okrongly, Donovan and Ms. Bowden are invaluable management additions as we expand clinical studies for our lead exosome biofluid

RNA diagnostics," said chief executive officer James McCullough. "The addition of Dr. Bueno and Dr. Manyak to our Scientific Advisory Board builds on our strategy of working closely with top clinical investigators to more accurately assess how exosome technology can be best applied to address unmet medical needs."

Dr. Okrongly has significant experience developing and commercializing advanced diagnostic platforms. Dr. Okrongly was president and chief executive officer of Quanterix from August 2009 to May 2011, leading the company in development of the first fully automated, single-molecule diagnostic platform with 1,000 times better sensitivity than ELISA. From May 1997 to December 2006, Dr. Okrongly was with Bayer Diagnostics (ETR:BAYN), where he was the leader of the global R&D organization, launching industry-leading platforms in immunoassay, hematology, clinical chemistry and molecular diagnostics. After the Siemens (NYSE:SI) acquisition of Bayer Diagnostics in 2006, he was appointed senior vice president in charge of the Molecular Diagnostics Business Unit from January 2007 to August 2009. Prior experience includes vice president of R&D Xytronyx, a San Diego-based POC company from 1994–1997 and Applied Immune Sciences, a Santa Clara, CA stem cell therapy company, where he led product development from 1987 to 1994. During Dr. Okrongly's tenure, the company completed an IPO and was eventually acquired by Rhone Poulenc-Rorer (now Sanofi). He received his Bachelors degree from the University of Wisconsin-Madison and his PhD from Columbia University, both in Chemistry.

Dr. Donovan is board certified in anatomic and clinical pathology and pediatric pathology with extensive experience designing and conducting clinical trials in melanoma and prostate cancer. Prior to joining Exosome Diagnostics, he held positions as chief scientific officer for Aureon Biosciences, assistant professor at Harvard Medical School, senior director of Molecular Pathology at Millennium Pharmaceuticals, and senior vice president at Incyte Genomics. At Millennium, he was involved with the clinical development of Velcade<sup>®</sup>, the first proteasome inhibitor approved for clinical use. He also contributed to the expanded of use of Tarceva in glioblastoma multiforme, and the development of Iressa in non-small cell lung cancer. Dr. Donovan received his M.D. from the University of Medicine and Dentistry of New Jersey, and his Ph.D. in cell and developmental biology from Rutgers University. Dr. Donovan has recently joined the faculty at Mt. Sinai School of Medicine as a Professor in the Department of Pathology and Genetics and will also serve as director of Experimental Pathology.

Ms. Bowden has over 20 years of experience in the quality and regulatory field in medical devices, companion diagnostics, education and health care systems. She has served in executive positions as vice president of Quality Systems and Process Improvement at Ventana Medical Systems and as vice president of Quality and Regulatory Compliance at Roche Diagnostics Corporation. She was an associate professor for Purdue University School of Engineering and Technology where she developed the Quality Management Curriculum within the Mechanical Engineering Technology department. Ms. Bowden founded Samco & Associates, Inc in 2009 to

provide consulting for companies interested in developing quality systems that meet FDA and global requirements and re-engineer them for efficient, effective compliance in the medical device field for all classes. In addition, she is helping to pioneer the Companion Diagnostic process in collaboration with pharmaceutical and diagnostic firms while building strong relationships with the applicable regulatory agencies. Ms. Bowden is a graduate of Purdue University School of Engineering.

Dr. Raphael Bueno is a professor of surgery at Harvard Medical School and associate chief of thoracic surgery, Director of the Thoracic Intermediate Care Unit, director of the Thoracic Surgery Training Program, and director of the Photodynamic Therapy Program at Brigham and Women's Hospital. Dr. Bueno joined the Division of Surgery at Brigham and Women's Hospital in 1996. Having graduated from Harvard University and Harvard Medical School, he completed his surgery residency at BWH and Massachusetts General Hospital. His clinical interests include tracheal surgery, lung cancer, mesothelioma, esophageal cancer, benign esophageal disorders, thymomas and minimally invasive surgery. His research interest is in the area of genomic research in thoracic cancers, primarily to better characterize the behavior of lung cancers and mesothelioma at the molecular level and to utilize this information in order to design novel diagnostic and therapeutic modalities. Dr. Bueno is a member of the American Association for Thoracic Surgery (AATS), the Cardiothoracic Surgery Network (CSN), the European Society of Thoracic Surgeons (ESTS), the General Thoracic Surgical Club (GTSC), and the International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) and The Society of Thoracic Surgeons (STS). Dr. Bueno also serves on the Editorial Board of the Journal of Thoracic and Cardiovascular Surgery (JTCVS).

Dr. Michael J. Manyak is executive director of Global Medical Affairs for the urology franchise at GlaxoSmithkline (LON:GSK) and professor of Urology, Engineering, Microbiology, and Tropical Medicine at The George Washington University. He has served as board member, consultant, or director to more than 25 biotechnology and pharmaceutical firms. He is a founder of Metastatin Pharmaceuticals, purchased by Samaritan Pharmaceuticals. Dr. Manyak has been granted 11 patents and has several pending. He served on the Imaging Subcommittee of the Medicare Coverage Advisory Committee for the Center for Medicare and Medicaid Services. He received a presidential appointment to the National Kidney and Urological Disease Advisory Board. He has served twice as a voting member of the FDA Regulatory Panel for Genitourinary and Gastrointestinal Devices. Dr. Manyak served as Chairman of the American Urological Association (AUA) Technology Assessment Council and on five other AUA committees related to technology. He has published nearly 200 professional abstracts, book chapters, and refereed journal articles.

### **About Exosome Diagnostics**

Exosome Diagnostics is a leading developer of biofluid based molecular diagnostic tests for use in personalized medicine. Exosomes are shed into all biofluids, including blood, urine, and CSF,

forming a stable source of intact, disease-specific nucleic acids. The Company's proprietary exosome technology makes use of this natural stability to achieve high sensitivity for rare gene transcripts and the expression of genes responsible for cancers and other diseases. The Company is commercializing *in vitro* diagnostic tests for use in companion diagnostic applications and real-time monitoring of disease. The Company maintains facilities in New York, St. Paul, MN and Munich, Germany.. For more information, please visit <a href="https://www.exosomedx.com">www.exosomedx.com</a>