

2010 Wolfe Biopharma Conference

*Emerging Markets and Technologies*  
*2020 Vision<sup>SM</sup>*



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*Drug Development Done Right. On Time.*

# Conference *Agenda*

- 7:30am **Registration and Breakfast**
- 8:30am **Opening Remarks**  
Janet Wolfe, Ph.D., President & Founder, Wolfe Laboratories, Inc.  
Robert Coughlin, President & CEO, MassBio
- 9:00am **Speaker Presentations - Emerging Technologies**  
Steven Burrill, CEO, Burrill & Company
- 9:30am Robert Armstrong, Ph.D., VP, Global External Research & Development, Eli Lilly and Company
- 10:00am **Networking and Refreshment Break - sponsored by Hitachi Data Systems and Datalink**
- 10:30am Theodore Torphy, Ph.D., VP & Lead, External Innovation, Johnson & Johnson Pharmaceuticals
- 11:00am William Chin, MD, Executive Dean for Research, Harvard Medical School
- 11:30am Daniel Junius, President & CEO, ImmunoGen, Inc.
- 12:00pm **Lunch**
- 1:00pm **Fireside Chat**  
Doug Flutie, NFL legend and Founder, Doug Flutie, Jr. Foundation for Autism  
*Discussion with: Michael Rinaldo, Managing Director, Global Healthcare, Fleishman-Hillard, Inc.*
- 2:00pm **Speaker Presentations - Emerging Markets**  
Mervyn Turner, Ph.D., Chief Strategy Officer, Merck & Co., Inc., and SVP, Emerging Markets, Merck Research Laboratories
- 2:30pm **Personalized Medicine Panel**  
Mara Aspinall, CEO, On-Q-ity  
William Pignato, Global Head of Regulatory Affairs, Novartis Molecular Diagnostics  
Steven Averbuch, MD, VP, Oncology Transition Strategy & Development and Head, Pharmacodiagnosics, Global Clinical Research, Bristol-Myers Squibb  
*Moderator: Steven Dickman, CEO, CBT Advisors*
- 3:30pm **Networking and Refreshment Break**
- 4:00pm Sam Azoulay, MD, SVP, Medical & Development, Emerging Markets Business Unit, Pfizer, Inc.
- 4:30pm Melinda Moree, Ph.D., CEO, BIO Ventures for Global Health
- 5:00pm **Fireside Chat**  
Wycliffe Grousbeck, Managing Partner, Governor & CEO, Boston Celtics  
*Discussion with: Janet Wolfe, Ph.D., President & Founder, Wolfe Laboratories and Michael Rinaldo, Managing Director, Global Healthcare, Fleishman-Hillard, Inc.*
- 6:00pm **Cocktail Reception and Jazz Trio**
- 9:00pm **Reception Concludes**

# The Plenary

## *Address*



### **Wycliffe Grousbeck, Managing Partner, Governor & CEO, Boston Celtics**

Wycliffe Grousbeck assumed the role of Managing Partner, Governor and Chief Executive Officer of the Boston Celtics in December 2002, after organizing and leading a local investment group that purchased the team. Wyc is the NBA Governor of the Celtics, the Chair of the NBA Planning Committee, and is a member of the NBA Labor Relations, Audit, Compensation and Finance Committees.

Wyc named the investment group "Banner 17 LLC" to signify his primary goal, returning the Celtics to contention for their 17th World Championship. He was honored to accept the Larry O'Brien Trophy signifying that championship on June 17, 2008, as the Celtics defeated the Lakers by 39 points and became World Champions for the first time in 22 years. On behalf of his partners and Celtics fans everywhere, Wyc dedicated the victory to the franchise patriarch, Red Auerbach.

Wyc's family has been touched by blindness, and he and his family have been devoted to research and educational initiatives relating to blindness and other conditions for many years. Wyc founded and co-directs a genetic therapy research project targeting CEP-290 related blindness, involving eight leading medical institutions and 12 prominent medical researchers (four of whom are Howard Hughes Investigators). His family was honored to endow the Grousbeck Professorship in Pediatric Hematology/Oncology at the Harvard Medical School, currently held by Leonard Zon, MD, a leader in stem cell research and cancer biologics. His wife, Corinne, is Founder and Chair of the Trust Board at Perkins School for the Blind (Watertown, MA), an institution devoted to educating blind and deaf/blind students worldwide. Corinne has also served for many years on the Trust Board of Children's Hospital Boston. Wyc and Corinne are also involved in the Boston Celtics Shamrock Foundation; National Braille Press; Horizons for Homeless Children; Cradles to Crayons; and the Lovelane Special Needs Riding Program.

Prior to purchasing the Celtics with his partners, Wyc served as a General Partner of Highland Capital Partners, co-managing \$1.8 billion in venture capital funds. He led successful investments in medical technology, software and health care services. His earlier career included four years as a venture capital lawyer in Silicon Valley and two years as a manager in a public biotech company.

Wyc holds a bachelor's degree in history from Princeton University (1983), a law degree from the University of Michigan (1986) and an MBA from Stanford Business School where he was a Miller Scholar (1992). At Princeton he rowed on the undefeated varsity eight that claimed the Ivy League and national rowing championships in 1983.



## **Doug Flutie, NFL legend & Founder, Doug Flutie, Jr. Foundation for Autism**

Doug Flutie's name has been synonymous with excellence in both college and professional football, as he has received many honors including: All American at Boston College, 1984 College Football Player of the Year, the 1984 Heisman Trophy Winner, 1991-1994/1996/1997 Grey Cup Most Valuable Player. He played in the Canadian Football League for 8 years, where he was a marquee attraction, being named the league's Most Outstanding Player an unprecedented six times.

Doug went on to sign with the National Football League's Buffalo Bills in 1998, and then at the age of 38, signed a contract with the San Diego Chargers to become their starting quarterback. After 4 seasons with the Chargers, Doug was offered the opportunity to finish his career with his hometown team, the New England Patriots. Doug played one season with the Patriots before he retired, but in true Flutie fashion, he went out with a bang. On New Year's Day 2006, Doug completed the NFL's first "drop kick" for an extra point in 64 years! A fitting end to a long, storied career.

Throughout Doug's career he has been able to endorse fine companies, such as State Farm, Capital One, Eastern Bank, and Reebok. Post football, Doug has been a color analyst and in-studio broadcast analyst for ABC and ESPN College Football and on Versus with the newly formed United Football League.

Doug has a charismatic personality whose approachable and personable style has translated his success on the football field into success off the field. He graduated from Boston College with degrees in Communications and Computer Science. Doug is the drummer of the Flutie Brothers Band. He has also written an autobiography, entitled "Flutie", recounting his life both on and off the field. Married to his high-school sweetheart, Laurie Flutie, and the father of two children, Doug and his wife established, the "Doug Flutie, Jr. Foundation for Autism" in 1998 in the name of their son Dougie, Jr. to help less-fortunate families who have children with autism. He also created a cereal, Flutie Flakes, with the benefits going towards this organization. The Flutie Foundation has raised over \$12 million dollars for autism causes.

## Michael Rinaldo, Managing Director, Global Healthcare, Fleishman-Hillard, Inc.



As Managing Director of Fleishman-Hillard's Global Healthcare Practice, Michael Rinaldo brings more than 25 years of experience in the healthcare public relations field to a broad range of client assignments from product launches to mature-brand repositioning and from disease education to issues management, from corporate reputation to strategic planning. He has worked on assignments executed in markets around the globe from Europe to the US, and from Asia to Latin America.

Mr. Rinaldo's background includes extensive work with prescription medications, over-the-counter drugs and non-profit organizations. He has spearheaded award-winning programs that have helped improve the treatment of asthma among inner city school children, gain recognition for osteoporosis as a major threat to women's health, expanded the number of diagnosed thyroid disease patients and reclaim market share for a fifty year-old over-the-counter drug. He has leveraged his experience to help major pharmaceutical and biotechnology companies navigate the waters of regulatory and

science-based issues involving widely prescribed medications.

During his career, Mr. Rinaldo has handled programs for some of the industry's best-selling prescription drugs including AstraZeneca's Prilosec and Nexium, Abbott Laboratories' Synthroid, Smith Kline & French's Tagamet and Ayerst Laboratories' Inderal. He has also supported clients on global brand launches and has counseled clients on complex issues management assignments ranging from scientific study failures to intellectual property disputes involving multiple markets around the globe.

Mr. Rinaldo's work has been honored with awards including several Silver Anvils from the PRSA and multiple Big Apple Awards from the New York chapter of PRSA. He led a team that captured the Best in Silver Anvil Award and the PR Week Award for PR Campaign of the Year for Project E.R.A.S.E., a program designed to address the challenges of asthma among children in the inner city environment. He has also been honored with PRSA-NY President's Award for contributions to the PR industry and service to the chapter, where he once served as president.

Mr. Rinaldo is currently chairman of the Board of Directors of the Family Resource Network of New Jersey, an organization dedicated to serving the needs of individuals with developmental disabilities. He continues to serve on the PRSA NY Chapter Board and is a member of the PRSA Foundation Board of Directors.

# Opening *Remarks*



## **Janet Wolfe, Ph.D., President & Founder, Wolfe Laboratories, Inc.**

Dr. Janet Wolfe is President and Founder of Wolfe Laboratories, a biopharmaceutical development services company located in Watertown, Massachusetts. With a scientific and business career focused on the intersection of the critical path activities in CMC, DMPK, preclinical and clinical development, Dr. Wolfe has designed and directed early stage development programs for small molecules and biologics across therapeutic areas such as CNS, cardiovascular, metabolic diseases, immunology, and oncology.

Prior to starting Wolfe Laboratories in 1999, Dr. Wolfe was on the faculty of the Department of Pharmaceutical Sciences at the University of Tennessee, Memphis, which followed her postdoctoral fellowship in the Warren G. Magnuson Clinical Center Pharmacy at the National Institutes of Health. Dr. Wolfe has almost twenty years' experience in pharmaceutical research and development and is the author of numerous articles and presentations. She has mentored undergraduate and graduate students and postdoctoral fellows over the course of her career. Dr. Wolfe received her bachelor of science from the University of Sciences in Philadelphia and doctorate in pharmaceutical chemistry from the University of Kansas.

Dr. Wolfe serves on the boards of the Interpolymer Corporation and the Institute for Pediatric Innovation. She is also co-chair of United Way's Math, Science and Technology Initiative. Dr. Wolfe was named Boston's 2008 Entrepreneur of the Year by the Greater Boston Chamber of Commerce, awarded the 2009 Leadership Prize from Women Entrepreneurs in Science and Technology, and was named Ernst & Young's 2009 Entrepreneur of the Year award finalist in New England. This year, Wolfe Laboratories was the Eastern Regional Finalist for the U.S. Chamber of Commerce's DREAM BIG Small Business of the Year Award and was ranked in PharmaVoice's Top 100 Most Inspiring Entrepreneurs in the Life Sciences.



## **Robert Coughlin, President & CEO, MassBio**

Bob, the President & CEO of MassBio since September 2007, is a former state representative and businessman. In his leadership role within Governor Deval Patrick's administration, he worked to retain and recruit life science organizations and other key businesses for the state. He is very familiar with all areas of the Massachusetts life sciences super cluster and is a passionate advocate for the research and biotechnology community.

Prior to his role in economic development, Bob was a Principal at MC Solutions, a corporate consulting and capital management firm, and Susquehanna Capital Management, where he managed five portfolio companies. He also brings years of experience in business development, sales, and marketing. From 1991 – 1999, Coughlin worked for Clean Harbors Environmental Services, Inc., where he served as an Account Manager and eventually became Director of Sales and Marketing. Coughlin was President and co-founder of SportsAttire Incorporated, a technology company supporting the sports apparel industry.

A graduate of the Massachusetts Maritime Academy and lieutenant in the United States Naval Reserve, Coughlin has also been active in the community, serving on the boards of the Academy and Beth Israel Deaconess Hospital, as honorary chairman of the Great Strides Cystic Fibrosis Walk, and as a member of the National Volunteer Leadership Board, among other organizations.

# Emerging Technologies

## *Speakers*

### **G. Steven Burrill, CEO, Burrill & Company**



G. Steven Burrill has been involved in the growth and prosperity of the biotechnology industry for over 40 years. Mr. Burrill is one of the original architects of the industry and one of its most avid and sustained developers. He serves as Chairman of the Boards of Pharmasset, BioImagene and Abunda Corporation, and is a member of the Boards of Directors of Catalyst Biosciences, DepoMed, Ikano Therapeutics, NewBridge, ProteoGenix, Proventys, Targacept and XDX. Before founding Burrill & Company in 1994, he spent 28 years with Ernst & Young, directing services to clients in the biotechnology/life sciences/high technology/manufacturing industries worldwide. In 2002, Mr. Burrill was recognized as the biotech investment visionary by the Scientific American magazine (The Scientific American 50).

Mr. Burrill is a founder and Chairman of the Board of the Foundation for the National Medals of Science and Technology. He serves as Chairman of the San Francisco Mayor's Biotech Advisory Committee (MayBAC). He serves on the Boards of the Bay Area Science Infrastructure Consortium, BayBio (Emeritus), California Healthcare Institute (Emeritus), The Exploratorium (Emeritus), The Kellogg Center for Biotechnology, the MIT Center for Biomedical Innovation, and the National Health Museum (Vice Chairman). He also serves on the Purdue Discovery Park External Advisory Committee and on the editorial board of the Journal of Commercial Biotechnology and is on the advisory board of the Center for Policy on Emerging Technologies (C-PET). He is an advisor to the University of Illinois Institute for Genomic Biology, University of Wisconsin - College of Agriculture and Life Sciences, University of Minnesota College of Biological Sciences, Duke University, and is an adjunct professor at University of California, San Francisco.



### **Robert Armstrong, Ph.D., Vice President, Global External Research & Development, Eli Lilly and Company**

Robert W. Armstrong, Ph.D., became vice president of global external research and development for Eli Lilly and Company in November 2006. He previously was vice president of discovery chemistry research. Armstrong's new position will serve to accelerate LRL's ability to access external innovation, including scientific and medical capabilities and capacity, as well as new drug candidates. He is also a member of the senior management council.

Prior to joining Lilly in November 1999, Armstrong had been director and head of small molecule drug discovery at Amgen, Inc.

He received bachelor of science degrees in chemistry and biochemistry from the University of California at San Diego in 1979 and a doctorate degree in chemistry from Colorado State University in 1984. Upon completion of an NIH postdoctoral fellowship at Harvard University in 1986, was a faculty member in the Department of Chemistry and Biochemistry at the University of California at Los Angeles, where he remains an adjunct faculty member.



## Theodore Torphy, Ph.D., Vice President & Head, External Research, Johnson & Johnson Pharmaceuticals

Ted is Vice President and Head of External Research for the Research Capabilities Organization in Johnson & Johnson's Pharmaceuticals Group. In this role he is responsible for building and managing a portfolio of external pharmaceutical R&D collaborations on product and technology opportunities. Before assuming his role in 2010, Ted led the External Research and Early Development organization, which focused on building new collaborative business models between large pharmaceutical companies, venture capitalists and academia. From 2003 to 2007 Ted headed the Corporate Office of Science & Technology, a corporate function that identifies transformational healthcare technologies for all of Johnson & Johnson's business sectors. Previously, he spent three years at Centocor, the biopharmaceutical arm of J&J, where he was Senior Vice President for Discovery and Preclinical Development. Prior to joining Centocor he spent 17 years with SmithKline Beecham, most recently as Vice President of Research for the Cardiovascular, Pulmonary and Metabolic Diseases.

He is the author of more than 120 journal articles, review articles, book chapters, and patents. He serves on the editorial advisory boards of eight journals, chairs the Board of Directors of the Cystic Fibrosis Foundation Therapeutics, Inc., and is a board member of several other non-profit organizations.

Ted holds a B.S. degree in Pharmacy from the University of Wisconsin and a Ph.D. in Pharmacology and Toxicology from West Virginia University. He completed his postdoctoral training at the University of California, San Diego.



## William Chin, MD, Executive Dean for Research, Harvard Medical School

Born in New York, Chin received his A.B. in chemistry *summa cum laude* from Columbia College and his medical degree from Harvard Medical School. He then completed a residency in internal medicine at the Beth Israel Hospital and a fellowship in endocrinology and metabolism at the Massachusetts General Hospital, Boston, Massachusetts.

Chin served on the faculty of Harvard Medical School for 25 years and was professor of medicine, and professor of obstetrics, gynecology and reproductive biology at Harvard Medical School; investigator of the Howard Hughes Medical Institute; and chief of the division of genetics and senior physician at the Brigham and Women's Hospital, Boston. Chin then joined Eli Lilly and Company in 1999, and served most recently as senior vice president of discovery research and clinical investigation, with overall responsibilities for the therapeutic areas, chemistry, toxicology, ADME and early clinical development. He serves as a member of the company's senior management council. He previously was vice president of discovery biology research and clinical investigation. In 2010, he returned to academia as the Executive Dean for Research and Professor of Medicine at Harvard Medical School.

He has received many accolades, including the Robert H. Williams Distinguished Leadership Award from the Endocrine Society, the Sidney H. Ingbar and Van Meter Awards from the American Thyroid Association, the Bowditch Award from the American Physiological Society, and the AFRC Young Investigator Award, and election to the American Society for Clinical Investigation and the American Association of Physicians. Chin has been a member of the board of scientific counselors of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health (NIH), and chair of the NIH endocrinology study section. He has also provided leadership on the council of several key professional societies, including service as president of the American Thyroid Association and the Interurban Clinical Club.

Chin is a member of the Board of Directors at the Indianapolis Museum of Art and the Indianapolis Prize [the largest monetary prize for wildlife conservation in the world] Jury. He has also been an overseer of the New England Conservatory of Music and a co-chair of Project Success, a science program for underprivileged secondary students in Boston.



**Daniel Junius, President & CEO, ImmunoGen, Inc.**

Daniel Junius was promoted to President and Chief Operating Officer of ImmunoGen in July 2008 and became President and Chief Executive Officer of the Company effective January 1, 2009. He joined ImmunoGen as Chief Financial Officer (CFO) and Senior Vice President, Finance in May 2005 and was promoted to Executive Vice President, Finance and CFO in July 2006.

Mr. Junius was Executive Vice President and CFO of New England Business Service, Inc. (NEBS) from 1998 until its acquisition by Deluxe Corporation in 2004. Prior to NEBS, he was Vice President and CFO of Nashua Corporation. He joined Nashua Corporation in 1984 and held financial management positions

of increasing responsibility before becoming CFO in 1996. Mr. Junius holds a Masters in Management from Northwestern University's Kellogg School of Management.

# Emerging Markets *Speakers*



**Mervyn Turner, Ph.D., Chief Strategy Officer, Merck & Co., Inc., and Senior Vice President, Emerging Markets, Merck Research Laboratories**

Dr. Mervyn Turner joined Merck Research Laboratories in 1985. Over the last 25 years he has held many positions of increasing responsibility at Merck. In August 1999, Dr. Turner was appointed Senior Vice President, Merck Frosst Centre for Therapeutic Research in Montreal, Canada. Dr. Turner returned from his assignment in Montreal in October 2002 to take up the position of Senior Vice President, Worldwide Licensing and External Research. In this role, he was responsible for the oversight of all of Merck's licensing activities, and for the management of academic relations. Through his multiple and diverse experiences in the Merck Research Laboratories, Dr. Turner has acquired a broad perspective on the issues surrounding drug discovery and development.

2004 through 2008 saw a sizeable increase in deal activity for Merck, with over 190 transactions completed. Merck has also been active in M&A, with Aton, Abmaxis, GlycoFi, Sirna and NovaCardia, all acquired to build areas of key strategic importance. Dr. Turner saw all this activity as a logical product of a cultural shift within Merck towards a more outward-facing organization.

In September 2008, Dr. Turner was also appointed to the newly created role of Chief Strategy Officer for Merck & Co. Inc. where he leads the formulation and execution of Merck's long term strategic plan and the linkage of that strategy to the business plans of Merck's Franchises, Divisions, and Functions. In November 2009, Dr. Turner turned over the licensing reins when, in addition to his CSO role, he was appointed Senior Vice President, Emerging Markets, Merck Research Laboratories where he is responsible for developing MRL strategy to both support our commercial aspirations in the regions, and also to leverage emergent capabilities in India and China to the global benefit of the MRL pipeline.

Dr. Turner is the author of over 80 articles in peer reviewed journals. He has served on the Editorial Board of a number of journals, and from 1998 to 2008 he was a member of Health Care Ventures Scientific Advisory Board. In September 2009, Dr. Turner was appointed to the Advisory Board of the USA-India Chamber of Commerce.



## **Sam Azoulay, MD, Senior Vice President, Medical & Development, Emerging Markets Business Unit, Pfizer, Inc.**

Dr. Sam Azoulay is Senior Vice President, Medical & Development, of Pfizer's Emerging Markets Business Unit, a role he has held since his appointment in November 2008.

Dr. Azoulay joined Pfizer as a result of the company's acquisition of Parke Davis, Warner Lambert in 2000, where he had served as Development Site Head in Eastleigh, UK and Head of Cardiovascular for International. Following the merger with Pfizer, Dr. Azoulay moved to the US Pfizer Global Research & Development (PGRD) headquarters in New London, CT, as Vice President, Global Project Management in charge of the cardiovascular and infectious disease portfolio. In 2003, he led the varenicline (Champix) smoking cessation program up to its filing in the US and EU. In early 2006, Dr. Azoulay

moved to Tokyo, PGRD to lead the Development organization where he supervised 400 colleagues and was accountable for a number of approvals and submissions of major products. In April 2008, Dr. Azoulay was appointed Development Lead for the CardioVascular Metabolic and Endocrine Disease (CVMED) Research Unit.

Before joining Parke Davis, Sam served as Cardiovascular Head, and previously as Medical Manager, for Houde Labs, Hoechst Roussel, in Paris, France. Later, he served as head of the cardiovascular division and head of the Development Operations group of Pierre Fabre Labs in Paris, where he played an integral role in the development of the European organization. He also briefly worked as Senior Medical Director in Basel, Switzerland, for Roche.

Upon completion of his internship, Sam received his medical degree with a specialization in cardiology from Paris University. He also holds a DESS (M.B.A.) from La Sorbonne, Paris.



## **Melinda Moree, Ph.D., CEO, BIO Ventures for Global Health**

Melinda Moree was named Chief Executive Officer of BIO Ventures for Global Health (BVGH) on December 30, 2009. She served as Interim CEO of BVGH from July - December 2009 and has been a member of the board of directors since the company's inception in 2004. In her tenure as CEO, Dr. Moree has grown the organization and introduced two significant new programs -- the Pool for Open Innovation against Neglected Tropical Diseases and Global Health Connect -- both of which find the common ground between the goals of global health and the pragmatic needs of companies to bring more biopharmaceutical companies into neglected disease product development. In addition, she has overseen the design of a new "Pay for Success" incentive aimed at increasing the number of companies working on products for neglected diseases. She has also significantly increased funding for the organization and overseen the opening of a San Francisco office.

Before joining BVGH, Dr. Moree was the Principal Investigator on the Malaria Policy Project conducted with the Center for Global Development, a member of the team evaluating the International AIDS Vaccine Initiative, and consulted with the Global Alliance for Vaccines and Immunizations. Until early 2007, Dr. Moree was the Director of the Malaria Vaccine Initiative (MVI), a public-private-partnership with a mission to accelerate the development of malaria vaccines and to ensure that they are available and accessible to people in developing countries. While at MVI, she was instrumental in setting the overall vision for the program and in ensuring an organizational design and a sense of urgency that enabled rapid execution and solid relations with industry. Dr. Moree oversaw the growth of the program from \$50 million to \$300 million and a tripling in staff. Most importantly a key milestone event - proof of concept (efficacy) in children in Africa - was achieved under her leadership.

Prior to joining MVI, Dr. Moree was Manager of Advanced Research at EKOS Corporation and worked in technology transfer at the University of Washington School of Medicine. This work was preceded by an American Association for the Advancement of Science (AAAS) Science and Diplomacy fellowship at the United States Agency for International Development. During the fellowship Dr. Moree began her first work on public private partnerships for the development of technologies and diagnostics for the developing world. She received her PhD in Medical Microbiology from the University of Maryland at Baltimore.

# Personalized Medicine

## Panel



### **Mara Aspinall, President & CEO, On-Q-ity, Inc.**

Mara Aspinall is President and CEO of On-Q-ity, an innovative diagnostics company focused on informing and transforming cancer life cycle management through diagnostics. The company is developing diagnostics to identify the unique characteristics of an individual's cancer, predicting the response to therapy and monitoring the efficacy of treatment in multiple cancer types. On-Q-ity leverages two core technologies: microfluidic chip technology to capture, enumerate, and molecularly characterize circulating tumor cells (CTC) from a single sample of blood as well as DNA repair pathway biomarkers to predict treatment response in tissue and blood.

Mara was previously President of Genzyme Genetics, leading provider of testing in the oncology and reproductive markets. Under Mara's leadership, Genzyme Genetics set the standard for quality in the industry, while profitably growing at an unprecedented pace. She transformed the business – expanding its scope and reach to become one of the nation's largest diagnostic laboratories. Previously, Mara served as President of Genzyme Pharmaceuticals where she restructured the business from generic drug manufacturing to value-added custom production.

Mara served as Board Member of Predictive Biosciences for three years and Chairman for 2008 and 2009. Mara has an appointment as Lecturer in Health Care Policy at Harvard Medical School and teaches a seminar on business and medicine.

She is an active member of the Federal Secretary of Health and Human Services' Advisory Commission on Genetics, Health and Society; a Board member of the Personalized Medicine Coalition as well as a Founding Board member of the European Personalized Medicine and Diagnostics Association (EPEMED). In 2007, she co-authored, "Realizing the Promise of Personalized Medicine" in the *Harvard Business Review*.

Bain & Company, an international strategic consulting firm, was where Mara started her business career. She earned her MBA from Harvard and her BA from Tufts University.



### **William Pignato, Global Head of Regulatory Affairs, Novartis Molecular Diagnostics**

William Pignato is Global Head of Regulatory Affairs at Novartis Molecular Diagnostics. He currently leads the diagnostic regulatory program at Novartis' molecular diagnostic business unit, which is focused on employing a variety of innovative molecular technologies to help personalize diagnosis and treatment for patients. Previously, he worked at Genentech, Inc leading the regulatory effort specific to the company's companion diagnostic initiative. Bill was also the founder of W.J. Pignato & Associates a Boston consulting firm specializing in regulatory affairs that focused on in vitro diagnostics, medical devices and the biotech industry. Bill brings over 25 years of strategic regulatory diagnostic experience in bringing products to market. Prior positions include Vice President of Regulatory Affairs for EXACT Sciences Corp., an applied genomics company focused on the early detection of colorectal cancer and Vice President of Regulatory Affairs for Valeo Medical. He has also held senior regulatory positions at Bayer Diagnostics, Chiron and Ciba-Corning Diagnostics. Bill has been active in numerous FDA/Industry cooperative activities regarding regulatory policy impacting diagnostic devices and spoken widely on the regulatory issues and challenges

associated with personalized medicine and companion diagnostics. He is a Northeastern University undergraduate in environmental engineering and graduate studies from Tufts University.



## **Steven Averbuch, MD, Vice President, Oncology Transition Strategy & Development and Head, Pharmacodiagnosics, Global Clinical Research, Bristol-Myers Squibb**

Dr. Averbuch is a medical oncologist with US and international clinical development experience at three leading pharmaceutical companies. He is currently Vice President, Oncology Transition Strategy & Development and Head, Pharmacodiagnosics, Global Clinical Research, Bristol-Myers Squibb Company based in Lawrenceville, NJ., USA. In his current role, Dr. Averbuch co-leads the team that provides early strategic direction across the exploratory oncology pipeline, he is responsible for all oncology transition Phase 3 enabling programs and he leads a multidisciplinary team that guides companion diagnostic development across all therapeutic areas.

Dr. Averbuch graduated with a B.S. in Pharmacy from the University of Kansas and received his M.D. from the University of Illinois, Chicago in 1979. Following training in Internal Medicine at Northwestern University and the University of Illinois, Dr. Averbuch was a Medical Oncology Fellow at the National Cancer Institute from 1982-1985. From 1985-1987 he held a joint appointment at the NCI and as a Research Assistant Professor in the Division of Clinical Pharmacology at the Uniform Services University of the Health Sciences. In 1987, Dr. Averbuch was appointed Assistant Professor and Assistant Attending in the Department of Neoplastic Diseases, Mount Sinai School of Medicine and Hospital in New York City.

In 1990, Dr. Averbuch joined Merck Research Laboratories, Rahway, NJ and then he was with AstraZeneca, Wilmington, DE from 1995-2003 where he led the global development of several early stage oncology products, including IRESSA. From September, 2003 to June, 2005, Dr. Averbuch was Executive Director and Therapeutic Area Head for oncology at Merck Research Laboratories where he played a primary role in building a new oncology clinical research group. He is a member of the American Society of Clinical Oncology and the American Association for Cancer Research.



## **Steven Dickman, CEO, CBT Advisors**

Steven Dickman is CEO of CBT Advisors, a life sciences consulting firm in Cambridge, Massachusetts. CBT Advisors works on product positioning and corporate strategy; communications and fund-raising materials; and market analysis based on research and expert interviews. Clients include public and private pharma and biotech companies as well as life science venture funds.

Mr. Dickman publishes an industry blog, Boston Biotech Watch [www.bostonbiotechwatch.com](http://www.bostonbiotechwatch.com), that tracks industry, VC and technical trends.

Before founding CBT Advisors in 2003, Mr. Dickman spent four years in venture capital with TVM Capital. There, Mr. Dickman's deals included Sirna Therapeutics, sold to Merck in 2006 for \$1.1 billion. Earlier, he was a Knight Science Journalism Fellow at MIT, a freelance contributor to *The Economist*, *Discover*, *Science*, *GEO* and *Die Zeit* and the founding bureau chief for Nature in Munich, Germany. Fluent in German, Mr. Dickman received his biochemistry degree *cum laude* from Princeton University.

# Diamond *Sponsor*



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Hitachi Data Systems provides best-in-class information technologies, services and solutions that deliver compelling customer ROI, unmatched return on assets (ROA) and demonstrable business impact. With a vision that IT must be virtualized, automated, cloud-ready and sustainable, Hitachi Data Systems offers solutions that improve IT costs and agility. With more than 4,200 employees worldwide, Hitachi Data Systems does business in more than 100 countries and regions. Hitachi Data Systems products, services and solutions are trusted by the world's leading enterprises, including more than 70 percent of the Fortune 100 and

more than 80 percent of the Fortune Global 100. Hitachi Data Systems believes that data drives our world – and information is the new currency. To learn more, visit [www.hds.com](http://www.hds.com).

# Bronze *Sponsor*

## MINTZ LEVIN Mintz Levin Cohn Ferris Glovsky and Popeo PC

Mintz Levin is an AmLaw 100 firm comprised of 450 attorneys across 15 distinct practice areas with eight offices (Boston, New York, Washington, Stamford, Los Angeles, Palo Alto, San Diego, and London) strategically located to meet the evolving needs of our clients. Our Life Sciences service teams include attorneys,

senior professionals, and PhDs with scientific or industry-specific experience and knowledge of finance, management and systems, clinical strategy, regulatory affairs, licensing, patents, corporate transactions, immigration, tax, manufacturing, product economics, and real estate. We represent more than 400 life sciences clients including biotechnology, medical device, medical technology, healthcare IT, and pharmaceutical companies; venture capital firms and investment banks; and research institutes and institutions of higher education located throughout the U.S., Europe, Asia, and the Middle East in a broad range of transactional, regulatory, counseling, and intellectual property matters.

# Media *Sponsor*

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BioPharm Insight is the leading provider of intelligence to the biotechnology & pharmaceutical industry. We provide: detailed company profiles for over 4,100 biotech & pharmaceutical companies; listings on 36,000+

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*Drug Development Done Right. On Time.*

# About *Wolfe Laboratories*



Founded in 1999, Wolfe Laboratories, Inc. is a recognized leader in providing early development services to the biopharmaceutical industry, offering integrated IND-enabling programs and customized translational research services across all therapeutic areas for both small molecules and biologics. Integration of these interdependent critical path services in CMC, ADME, Phase 0 and Phase 1 streamline the drug development process for its pharmaceutical and biotechnology client companies. Biopharmaceutical companies access experienced, technically proficient experts at Wolfe Laboratories, and are assured that early development work of the highest caliber is completed on time, adding significant value to their pipeline. Wolfe Laboratories has contributed to the advancement of molecules through all stages of development and commercialization, allowing hundreds of pharmaceutical and biotechnology companies to facilitate the translation of their compounds from late-stage discovery into the clinic. Over the years, Wolfe Laboratories' strong reputation has enabled the company to expand its services and develop a growing client base that includes repeat regional, national, and global clients.

## **Pre-formulation and Formulation Development**

We have extensive experience in pre-formulation and can develop liquid, lyophilized, dispersed systems, solids, and semi-solid dosage formulations. Using the pre-formulation data, we work with our clients to develop a formulation that meets the pharmacology, toxicology and clinical requirements. We develop injectables, both liquid and lyophilized, oral solids, liquids and dispersed systems, and topical formulations, depending upon the program requirements. We provide a range of stability testing services, including stability under ICH conditions and can identify degradation products using our HPLC-MS/MS instrumentation. We work with manufacturing sites to seamlessly transfer process technology and can support finished product testing and product complaints.

## **Analytical Characterization Studies**

We develop and qualify a range of analytical methods for clients or install and qualify existing methods to be used for subsequent formulation development or stability testing activities. In addition to developing stability indicating analytical methods, we identify impurities and degradation products from solid API material, as well as formulated product using HPLC-MS/MS. We develop appropriate methods to characterize small molecule using a variety of solid phase techniques, as well as for proteins, including molecular weight determination and peptide mapping.

## ***In Vitro* ADME and Pharmacokinetic Support**

We have a number of *in vitro* ADME assays available to help identify the compound with the right balance of properties to move into pre-clinical development. Typical assays include plasma and metabolic stability, protein binding, permeability, as well as individual CYP450 profiling. Our modern HPLC-MS/MS capabilities allow us to develop highly sensitive and specific quantification methods for test compounds in a variety of biological matrices to support sample analysis from PK studies. In addition, we can conduct metabolite identification using both *in vitro* and *in vivo* samples.

## **Cytotoxic and High Potency Facility**

We have a high potency facility and experienced staff capable to handle cytotoxic compounds. With 700 square feet of dedicated laboratory space, two four-foot hoods vented outside, 100% fresh air intake, and limited access, Wolfe Laboratories operates under the safest conditions when dealing with highly potent, cytotoxic compounds.

## **GLP and GMP Services**

We recently expanded our service coverage into GLP- and GMP- compliant activities within the CMC and bioanalytical areas of operation, and are in the process of establishing GMP aseptic processing. We are now better positioned to serve clients' needs as they progress into IND-enabling pre-clinical work and early clinical development studies.

Blessing of the Tuna Fleet at Groix, P. Signac, 1903



## **Wolfe Laboratories, Inc.**

A fleet of IND-enabling services at your disposal

*Drug Development Done Right. On Time.*

*We look forward to seeing you next October at the  
2011 Wolfe Biopharma Conference!*



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