SCHEDULE OF EVENTS

WEDNESDAY, SEPTEMBER 26, 2012

4:30pm – 7:00pm Grand Ballroom Foyer	**Registration Open**
6:00pm – 7:30pm Salon C	**Pre-Conference Networking and Welcome Reception**
8:00pm – 12:00am Exhibit Hall (Salons D-E)	**Exhibitor set-up**

THURSDAY, SEPTEMBER 27, 2012

8:00am – 7:00pm Grand Ballroom Foyer	**Registration Open**
8:00am – 9:00am Exhibit Hall (Salons D-E)	**Continental Breakfast / BioMatch Partnering**
8:00am – 8:00pm Exhibit Hall (Salons D-E)	**Exhibit Hall Open**
9:00am – 10:00am	**CONCURRENT SESSIONS 1**

Session 1A
Salon C

Presenting Companies: *First-Look*
Get a sneak preview at nascent technologies representing exciting innovations. First Look is designed to shine the light on early stage firms who are reinventing the world we live in, but who are still building their tools and technologies. See page 56 for full listing of presenting companies and their profiles.

Session 1B
Salon B

Innovative Partnering Models for Moving Bioscience Discoveries to the Marketplace
The gap between discoveries at our research institutions and their commercial development to therapies and products available to patients has received increased attention in recent years from many sides. A great variety of approaches to accelerating the translation of promising research to the marketplace and clinic are under development and use, involving innovative collaboration structures, novel financing, redirection of resources, and realignment of incentives. Join members of the university, corporate, investor and NIH communities to look at several innovative models in translational research and commercialization, to assess what is working and what opportunities are available.

Moderator: Mark Crowell, Executive Director, UVa Innovation and Associate Vice President for Research, University of Virginia

Panelists:
Christopher P. Austin, M.D., Director, NCATS Division of Pre-Clinical Innovation, National Center to Accelerate Translational Science
Todd Chappell, BioHealth Innovation, Entrepreneur in Residence, NIH
Anthony Coyle, Ph.D., VP/CSO, Centers for Therapeutic Innovation, Pfizer Inc.

SCHEDULE OF EVENTS (continued)

	Session 1C Salon A	**Succeeding in Rare Diseases: A Collaborative Approach** The enormous revenue pressures on the life science industry matches well with tremendous opportunities to develop and commercialize novel treatments for orphan diseases. Orphan products can often deliver life-saving therapies where no other option previously existed. Due to the limited number of patients and substantial costs, success will require astute clinical validation, product positioning and commercialization skills. Recent regulatory changes, combined with the ever increasing environment in which reimbursement will be limited to the most innovative products, create both traps and opportunities. Success with orphan products will require expertise, new relationships and novel strategies allowing the potential to generate significant financial returns. **Moderator: Sara Nayeem, MD**, Principal, New Enterprise Associates (NEA) **Panelists:** **Ros Cheetham, M.D.**, Vice President, Medicine Development Leader, Rare Diseases, GlaxoSmithKline **Tim Cote**, CMO, National Organization for Rare Disorders (NORD), and former Director Office of Orphan Product Development, FDA **Anne Pariser, M.D.**, Associate Director for Rare Diseases, Rare Diseases Program, Office of New Drugs, Center for Drug Evaluation and Research, FDA
10:00am – 10:20am Exhibit Hall (Salons D-E)	**Networking / BioMatch Partnering Break**	
10:20am – 11:30am Salons F-H	**Welcoming Remarks: Michael D. Grisham**, Managing Member, GPB Scientific, LLC, Chairman, Virginia Bio **PLENARY:** **Patrick Mahaffy**, Co-founder, President, & CEO of Clovis Oncology	
11:40am – 12:40pm	**CONCURRENT SESSIONS 2**	
	Session 2A Salon C	**Presenting Companies: *Showcase*** Established growth enterprises from a broad array of life science sectors will present to capital sources and potential industry partners in 15 minute increments. See page 56 for full listing of presenting companies and their profiles.
	Session 2B Salon B	**Novel Funding Sources for Bioscience Companies** With venture funding dollars decreasing overall, companies must continue to look for novel ways to fund their research. Emerging biotechnology companies are bridging the valley of death with more creative funding partnerships. Many of those partnerships are with venture philanthropy groups, and federal/state organizations. Crowd funding may open a new financing window. This discussion of a mix of funding programs will ensure you have the right information to fund your programs.

SCHEDULE OF EVENTS (continued)

		Moderator: Peter Ginsberg, Vice President for Business and Technology Development, North Carolina Biotechnology Center **Panelists:** **Margaret Anderson**, Executive Director, FasterCures **John Hollway**, President, Pragmatos Consulting **David Sandak**, Vice President for Research and Business Development, Accelerate Brain Cancer Cure (ABC2) **Freeman White**, CEO Launcht and Participating Member, Crowd funding Intermediary Regulatory Advocates
	Session 2C Salon A	**Regenerative Medicine: Breakthroughs in Business Models and Technology** Building on years of scientific advances, the business of bringing the promise of regenerative medical science to the clinic and marketplace is making strides and reaching milestones. Leaders in the business and science of stem cells and regenerative medicine identify breakthrough companies, technologies and products, discuss what is working and what is up ahead. **Moderator: Brian A. Pollok, Ph.D.**, Principal, Rapidan BioAdvisors **Panelists:** **Curt I. Civin, M.D.**, Associate Dean for Research, University of Maryland School of Medicine, Director, Center for Stem Cell Biology & Regenerative Medicine **Thomas Fellner, Ph.D., MBA**, Director, Innovation, Pluripotent Stem Cell Technologies, Lonza **Mahendra S. Rao, M.D., Ph.D.**, Director, NIH Intramural Center for Regenerative Medicine **Michael Werner**, Executive Director, Alliance for Regenerative Medicine
12:40pm – 1:40pm Exhibit Hall (Salons D-E)	**Networking Lunch**	
1:40pm – 3:00pm Salons F-H	**PLENARY PANEL: Seeing a Bright Future Through the Dense Fog – What's Ahead for an Ever Changing Life Sciences Industry** Thought leaders from industry, investment and public policy share observations and insights on developments, trends and opportunities. **Moderator: Steve Usdin**, Senior Editor, BioCentury Publications **Panelists:** **M. James Barrett, Ph.D.**, General Partner, New Enterprise Associates (NEA) **Ron Cohen, M.D.**, President and CEO, Acorda Therapeutics, Inc. **Vicki Seyfert-Margolis, Ph.D.**, Senior Advisor to Chief Scientist, FDA	

SCHEDULE OF EVENTS (continued)

3:00pm – 3:20pm Exhibit Hall (Salons D-E)	**Networking / BioMatch Partnering Break**	
3:20pm – 4:20pm	**CONCURRENT SESSIONS 3**	
	Session 3A Salon C	**Presenting Companies: Emerging Growth - *Block I*** Companies in their early stages of development, with promising technologies or products, will present to a broader audience of industry, scientists, investors, and advisors in 10-minute increments. See page 56 for full listing of presenting companies and their profiles.
	Session 3B Salon B	**Personalized Medicine in Oncology and Beyond: Advances in Defining and Treating Patient Subpopulations** Developing targeted therapeutics is a key goal in oncology today, as genomic advances have accelerated our ability to pinpoint the driving mutations in individual tumors. In some cases, biomarkers have also allowed us to monitor responses of cancer patients to therapy. Beyond cancer, researchers have made progress in defining and treating patient sub-populations in respiratory indications (with approval of a targeted therapeutic for cystic fibrosis), in genetic diseases such as Duchenne muscular dystrophy, and in other therapeutic areas such as autoimmune disease. The recently passed PDUFA V legislation reflected the emerging "targeted therapies" paradigm by clarifying the ability of the FDA to use biomarkers as surrogate endpoints and increasing resources to study and approve use of biomarkers in trials. A number of challenges remain in oncology and in other areas, including determining how to define patients most likely to respond (which markers are most important?), how to test and seek approval for targeted therapies (what is the applicability to diagnostic negative patients and can they be excluded from trials to contain costs?), and how to develop companion diagnostics. Experts from pharma, diagnostics/biomarkers, and academia will explore these challenges and opportunities. **Moderator: Judy Britz, Ph.D.**, Executive Director, Maryland Biotechnology Center **Panelists:** **Isaac Bright, M.D.**, Vice President, Corporate Development, bioTheranostics **Eric Hedrick, M.D.**, Chief Medical Officer, Epizyme **Antony Newton**, Chief Commercial Officer, Personal Genome Diagnostics **Sonia Pearson-White, Ph.D.**, Scientific Program Manager for Oncology, Inflammation and Immunity, The Biomarkers Consortium, Foundation for the National Institutes of Health

SCHEDULE OF EVENTS (continued)

4:30pm – 5:45pm Salons F-H	**CAPSTONE PLENARY PANEL:** ***The Business of Health Delivery from Leaders of Today's Hospital Systems*** In today's economy, the biotech industry needs to be much more in tune with what hospitals and health systems will be willing to purchase related to new health care technologies and are looking for a conversation with health care leaders. This keynote panel focuses on the challenges faced by health care providers as they transition from the current fee-for-service sick-care system to be successful in the out-comes focused budgeted system of the future. In particular, panelists will discuss how this transition will impact healthcare technology providers. **Moderator: Bruce C. Robertson, Ph.D.**, Managing Director, H.I.G. BioVentures **Panelists:** **William G. "Bill" Robertson**, President and CEO, Adventist Healthcare **J. Knox Singleton**, CEO, Inova Health System **Closing Remarks:** **Dominick Murray**, Deputy Secretary, Maryland Department of Business and Economic Development **Thomas Dann**, Managing Director, Maryland Venture Fund
6:00pm – 8:00pm Exhibit Hall (Salons D-E)	**CEO Celebration:** Cocktails and Strolling Dinner Buffet (open to all attendees)

FRIDAY, SEPTEMBER 28, 2012

7:00am – 2:00pm Grand Ballroom Foyer	**Registration Open**
7:00am – 12:00pm Exhibit Hall (Salons D-E)	**Exhibit Hall Open**
7:30am – 8:45am White Oak	**Board of Directors Leadership Breakfast** (by invitation only)
7:30am – 8:45am Exhibit Hall (Salons D-E)	**General Breakfast – Roundtables of Interest** Join your fellow colleagues for an informal discussion on a variety of topics that are important to our industry. Discussions will be at designated tables in the exhibit hall.
8:00am – 2:00pm Grand Ballroom Foyer	**Innovation Corridor – Poster Presentations Open**
9:00am – 10:00am	**CONCURRENT SESSIONS 4**
Session 4A Salon C	**Presenting Companies: Emerging Growth -** ***Block II*** Companies in their early stages of development, with promising technologies or products, will present to a broader audience of industry, scientists, investors, and advisors in 10-minute increments. See page 56 for full listing of presenting companies and their profiles.

SCHEDULE OF EVENTS (continued)

Session 4B
Salon B

Reassessing Intellectual Property Strategies in Response to the America Invents Act

The America Invents Act is putting into effect what may be the most comprehensive revision of US patent law in 50 years. Over the coming year several significant changes will be phased into law: a modified first-to-file system for awarding patents; pre-issuance submissions; a post grant review procedure on petition by a third party; an expanded definition of prior art; an expanded prior use defense against infringement; and a new administrative derivative proceeding, among others. While administrative rules are still being drafted, certain modifications to strategy and practice are becoming clear. The best response may differ for university based researchers, independent inventors, startups and large companies. Intellectual property experts from corporate, university, and private practice who are daily studying and responding to these changes in the law will offer insights.

Panelists:
Bruce Artim, Director, Federal Affairs, Eli Lilly and Company
Wes Blakeslee, Executive Director, Johns Hopkins Technology Transfer
Louis D. Lieto, Esq., Ph.D., Wilson Sonsoni Goodrich & Rosati
Erik B. Milch, Esq., Cooley LLP

10:00am – 10:20am
Exhibit Hall (Salons D-E)

Networking / BioMatch Partnering Break

10:20am – 11:20am

CONCURRENT SESSIONS 5

Session 5A
Salon A

New Developments in Traditional and Corporate Venture Capital

Investors from traditional and corporate venture capital firms will discuss current opportunities and challenges in building biopharma and medical device companies. Topics will include shifts at the FDA, implications of the PDUFA V legislation, and trends in overall development costs ("virtual models" to reduce burn, companion diagnostics, and development in / partnerships for ex-U.S. markets). Panelists will also discuss exits: appetite for mid-stage to late-stage healthcare companies among public investors, big pharma / big device company interest in mid-stage products, and implications of recent liquidity trends for the venture capital industry.

Moderator: Nina Kjellson, General Partner, InterWest Partners

Panelists:
David Berry, M.D., Ph.D., Partner, Flagship Ventures
Art Pappas, Managing Partner, Pappas Ventures
Brian Gallagher, Ph.D., Partner, SR One
Robert Weisskoff, Ph.D., Partner, Fidelity Biosciences

SCHEDULE OF EVENTS (continued)

Session 5B
Salon B

Transformative Technologies to Ensure Food Safety and Security

The United Nations estimates that by 2050, the world will need 100 percent more food while lack of food safety and insecurity threaten one billion people around the globe. In the United States the 2011 Food Safety Modernization Act put in place comprehensive controls to prevent outbreaks of food-borne disease. One provision mandated that the USDA and DHHS create the National Agriculture and Food Defense Strategy while the President has also declared that agriculture is "critical infrastructure." The life sciences have a range of techniques that can mitigate risks to our nation's food supply. Whether through testing seeds, environmental monitors or other early detection systems, biotechnology can be an important tool in implementing this food safety and security priority. Join a panel of experts to hear the latest science and related issues on this topic: current issues in food safety and how these issues might be addressed; current topics in Food Safety policy and regulation, in particular any barriers that exist and potential solutions or work arounds; type of research that is occurring and the role that research plays in enhancing food safety; and local vs. global perspective.

Moderator: Kara Cooper, Ph.D., Senior Scientist, Global Health and Security, MRI Global

Panelists:
Janie Dubois, Ph.D., Manager, International Food Safety Training Laboratory at University of Maryland
Thomas S. Hammack, Acting Director, Division of Microbiology, FDA
Ted Olsen, President and CEO, PathSensors, Inc.
Douglas White, CEO, Opgen, Inc.

Session 5C
Salon C

Best Practices for Working with the FDA - *Part I*

The panel will provide insight on how companies can successfully interact with the FDA throughout the submission process. Speakers will address the best practices for working with the FDA, including best timing for initiating discussions; preparing for communications; how to present your product and questions; responding to feedback; and what regulatory capabilities companies need and when.

Moderator: Peter A. Patriarca, M.D., Senior Clinical Consultant, Biologics Consulting Group

Panelists:
Joelle P. Blakaitis, MS, RAC, Director, Global Regulatory Affairs, MedImmune
Lynn Whipkey Mehler, Partner, Hogan Lovells
Shannon Williams, Ph.D., Chief Science Officer, ADial Pharmaceuticals
Robert A. Yetter, Ph.D., Associate Director for Review Management, Center for Biologics Evaluation and Research, FDA

SCHEDULE OF EVENTS (continued)

11:30am – 12:30pm **CONCURRENT SESSIONS 6**

Session 6A
Salon B

CEO Roundtable: Building Value and Planning Exits - Lessons Learned
There are many paths to building enterprise value and many roads to an eventual exit event. Seasoned CEOs from different sectors of the life sciences and companies at different stages along the way tell their stories – dead ends, hairpin turns, boulevards and super highways, and share their insights.

Moderator: Brad L. Stewart, Chairman, CEO and President, Cylex, Inc.

Panelists:
Ken Carter, Ph.D., President and CEO, Neximmune, Inc. and Chairman, Nobel Life Sciences, Inc.
Cynthia Collins, President and CEO, GenVec, Inc.

Session 6B
Salon C

Best Practices for Working with the FDA - *Part II*
The second hour will focus on impact of recent changes under PDUFA V, and the use of electronic submissions with the FDA. (i) The recent reauthorization of PDUFA V strives to improve the drug development and review process through increased transparency and scientific dialogue. The presentation will highlight specific changes in procedures and their practical implications, including enhanced communications and the new molecular entity (NME) review program. (ii) Increasingly companies are making regulatory submissions to the FDA electronically. While electronic filing is not required by the Agency, it is strongly preferred. Companies that have switched to electronic submissions are finding internal efficiencies and benefits in interacting with the Agency. This session will introduce key aspects of the preparation and transmission of electronic regulatory submissions using the FDA's Electronic Submissions Gateway and top level considerations focusing on IND submissions and the electronic Common Technical Document ("eCTD") format, and identify helpful resources and FDA Guidelines.

Andrew J. Emmett, Managing Director, Science and Regulatory Affairs, Biotechnology Industry Organization (BIO)
Daniel P. Offringa, Head of Electronic Publishing, Biologics Consulting Group, Inc.

12:30pm – 2:00pm
Salons F-H

PLENARY LUNCHEON:
Peter Greenleaf, President of MedImmune

SCHEDULE OF EVENTS (continued)

2:00pm – 4:00pm
Salon A

SBIR/STTR: Strategies, Program Changes, and Current Opportunities
The SBIR (Small Business Innovation Research) grants and STTR (Small Business Technology Transfer Research) grants provide one of the largest sources of early stage bioscience funding. In December 2011, the SBIR/STTR programs were reauthorized with a number of changes, including expanding eligibility for VC-backed small companies and providing funds for additional commercialization assistance. The implementation of the revised program across the 11 Federal agencies that participate and specific initiatives in many agencies are underway.

In the first of this special two-hour session, experts will describe the changes in rules proposed to implement recent reauthorization, and discuss the role of SBIR/STTR and non-dilutive funding in the financial strategy of a developing bioscience company.

Matt Portnoy, Ph.D., NIH SBIR/STTR Program Coordinator, Director, Division of Special Programs, OEP, OER, NIH, DHHS
Christy Shaffer, Ph.D., Venture Partner and Managing Director Hatteras Venture Partners

In the second hour, program representatives from leading NIH institutes will describe current open funding opportunities, and will be available for one-on-one breakout discussions with attendees.

Kurt Marek, Program Director SBIR coordinator, National Heart Lung Blood Institute (NHLBI)
Stephanie Fertig, Research Project Manager SBIR Program, National Institute of Neurological Disorders and Stroke (NINDS)
Jennifer Shieh, AAAS Science & Technology Policy Fellow, SBIR Development Center, National Cancer Institute (NCI)

Conference attendees may prearrange for one-on-one sessions with these and select additional NIH Institute SBIR program managers through BioMatch (listed under SBIR/STTR - found under “view profiles/meetings”).