BioHealth Innovation in Maryland

Richard A. Bendis
President & CEO
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UMD Conference Center

www.BioHealthInnovation.org
“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise
State of Maryland: Federal Resources

- 59 Federal Laboratories, Centers, & Institutes in Maryland

- Maryland Federal R&D investment exceeding $12 billion annually
A Region Rich with Research Institutions
Alignment of National, State, and Regional Policies

- Link Both State, County & City Strategies to Obama Administration Objectives
- Develop an integrated Regional BioHealth Economic Development and Transit Strategy
- Present the “Regional Job Generating BioHealth and Transit Plan” to the White House & partner with federal agencies and other stakeholder organizations as a “Showcase Model.”
- Develop structure & governance for the regional BioHealth innovation intermediary
- Obtain Priority Federal Funding for Region’s BioHealth Industry-Federal Labs-University Innovation Intermediary Pilot Plan
- Obtain Priority Federal Funding for the region’s Innovative “State of the Art” Comprehensive Rapid Transit Vehicle Plan (CCT et al)
- Develop a pilot BioHealth-Regional Innovation Cluster (H-RIC) program
Challenges to Innovation Economy

- Lack of connection of innovation resources
- Lack of an entrepreneurial culture and C-level executives
- Lack of early-stage funding for commercializing technologies
- Lack of a STEM Workforce

BHI Value Proposition

- Connects regional innovation assets
- Develops an entrepreneurial talent and support pipeline
- Attracts funding for technology commercialization
- Develops a continuum of innovation workforce

BioHealth Innovation
Maryland’s Commercialization Collaborative
BioHealth Regional Innovation Cluster Assets
What is A Regional Innovation Intermediary?

- An organization at the Center of the region’s, state’s and country’s efforts
  - Align local technologies, assets and resources
  - Advance Innovation

- Regionally-oriented
- Private-public partnership, 501(c)(3) nonprofit
- Market-driven, private sector-led
- Neither a government initiative, nor a membership organization
BHI: An Innovation Intermediary that Connects Sectors, Industries, Communities, & Markets

Connects Private, Public and Academic Sectors

Connects Bio-Health Cluster Industries

Connects Regional, National and Global Markets

Connects Central Maryland Communities
BHI Board of Directors

Michael J. Baader, Esq.
Managing Director, Venable LLP

Richard Bendis
President & CEO, BioHealth Innovation, Inc.

Scott Carmer (Chair)
Executive Vice President of Commercial Operations, MedImmune

Kenneth Carter
Chair, Noble Life Sciences

Scott Dagenais
Senior Vice President, M&T Bank

Ronald J. Daniels
President, Johns Hopkins University

David M. Gillece (Secretary)
Regional Managing Principal, Cassidy Turley

William E. Kirwan
Chancellor, University System of Maryland

Douglas Liu
Senior Vice President of Global Operations, Qiagen

David Mott
General Partner, New Enterprise Associates

Jerry Parrott
Vice President, Corporate Communications and Public Policy, Human Genome Sciences

Jay Ridder
Office Managing Partner, Ernst & Young

William G. Robertson (Treasurer)
President & CEO, Adventist Healthcare

J. Thomas Sadowski
President & CEO, Economic Alliance of Greater Baltimore

Thomas Street
Assistant Chief Administrative Officer, Montgomery County Government
**BHI/EIR Technology Focus**

- Therapeutics
- Diagnostics
- Medical Devices
- Healthcare Services
- E-Health
- Mobile Health
- Electronic Medical Records
- Health Informatics
- BioHealth Cyber Security
Innovation Paradigm Shift

PROOF OF CONCEPT
(Technological Feasibility)
Laboratory Push
“It Works!”

PROOF OF COMMERCIAL RELEVANCE
(Market Pull)
“It Works To Solve A Problem”
“I’ll Buy It”
# BioHealth Innovation Capital

## “VALLEY OF DEATH”

<table>
<thead>
<tr>
<th>Stage</th>
<th>POR / Pre-Seed</th>
<th>Seed/Start-Up</th>
<th>Early</th>
<th>Later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source</td>
<td>Founders, FFF</td>
<td>Angels, IBED, SBIR</td>
<td>Venture Funds</td>
<td></td>
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<tr>
<td></td>
<td>Bootstrapping</td>
<td>Accelerator Seed Funds</td>
<td>M&amp;A, IPO</td>
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<td></td>
<td>Crowdfunding</td>
<td></td>
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<tr>
<td>Demand</td>
<td>$0K</td>
<td>$500K</td>
<td>$2.5M</td>
<td>$5.0M</td>
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</tbody>
</table>

Funding Gap

"VALLEY OF DEATH"
# Central Maryland Innovation Capital Map

## Capital Sources by Investment Stage

<table>
<thead>
<tr>
<th>Pre-Proof of Concept</th>
<th>Translational Research / Proof of Concept</th>
<th>Proof of Commercial Relevance / Pre-Seed</th>
<th>Seed / Start-Up</th>
<th>Early Stage</th>
<th>Later Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>$25K - $1.5M (over 5 years)</td>
<td>$15K - $2M</td>
<td>$50K - $500K</td>
<td>$50K - $1M</td>
<td>$250K - $2M</td>
<td>$2M+</td>
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<tr>
<td>NIH R01</td>
<td>NIH Center for Accelerated Innovations (CAI)</td>
<td>Maryland Industrial Partnerships (MIPS @ UMD)</td>
<td>Dingman Center Angels (UMD)</td>
<td>Maryland Health Care Product Development Corporation (MHCPDC)</td>
<td>Maryland Venture Fund Authority</td>
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<tr>
<td>NIH R03</td>
<td>NCATS Cures Acceleration Network (CAN)</td>
<td>Maryland Biotechnology Center's Biotechnology Commercialization Awards</td>
<td>TEDCO Johnson &amp; Johnson Joint Investment Program</td>
<td>ABS Capital Partners</td>
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<tr>
<td>NIH R21</td>
<td>Small Business Innovation Research Grant (SBIR) Phase I</td>
<td>TEDCO Maryland Technology Transfer and Commercialization Fund (MTTCF)</td>
<td>Propel Baltimore Fund</td>
<td>Greenspring Associates</td>
<td></td>
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<tr>
<td>Small Business Technology Transfer Research Grant (STTR) Phase I</td>
<td>Maryland Stem Cell Research Fund (MSCRF)</td>
<td>SBIR / STTR Phase II</td>
<td>SBIR / STTR Phase II</td>
<td>Novak Biddle Venture Partners</td>
<td></td>
</tr>
<tr>
<td>Innovate Maryland</td>
<td>TEDCO University Technology Development Fund (UTDF)</td>
<td>BHI Central Maryland Angel Fund</td>
<td>BHI Central Maryland Angel Fund</td>
<td>Sterling Venture Partners</td>
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<tr>
<td></td>
<td>TEDCO TechStart</td>
<td></td>
<td></td>
<td>Harbert Venture Partners</td>
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<tr>
<td></td>
<td>Maryland Biotechnology Center’s Translational Research Award</td>
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<td>JMI Equity</td>
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<td></td>
<td>National Venture Capital Association (NVCA)</td>
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<td>National Venture Capital Association (NVCA)</td>
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### Funding Type Key

- **Academic**
- **Accelerator**
- **Associations**
- **BioHealth Innovation, Inc.**
  - Innovation-based Economic Development (IBED)
- **Federal**
- **Venture Capital**

### Tax Credits

- Maryland Biotechnology Investor Tax Credit
- Montgomery County Biotechnology Investor Tax Credit

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**Funding Type Key:**

- Association of University Resource Parks (AURP)
- Association of University Technology Managers (AUTM)
- Licensing Executive Society (LES)

**BioHealth Innovation, Inc.:**

- Innovation-based Economic Development (IBED)
- State of Maryland
- Venture Capital

**Tax Credits:**

- Maryland Biotechnology Investor Tax Credit
- Montgomery County Biotechnology Investor Tax Credit
How does **BHI** work?

Commercialization Pipeline

- **Sources** and evaluates biohealth intellectual properties (IP)
- **Funds** market-relevant IP
- **Grows** and markets businesses and products
Partnership Intermediary Agreements (PIA)

• PIA between BHI and NIH’s Office of Technology Transfer (OTT) that supports the 27 NIH institutes’ $3 billion intramural research and the Food and Drug Administration to **promote and foster cooperative research and accelerate technology commercialization** among NIH/FDA, businesses, and universities.

• PIA between BHI and the Telemedicine & Advanced Technology Research Center (TATRC) to capture USAMRMC and TATRC research outcomes and promote further research, product development, commercialization, and economic development opportunities.
  
  – TATRC has funded 241 MD based projects over the last 12 years.
Entrepreneur-in-Residence (EIR)

- A team leader who combines scientific, financial/VC and entrepreneurial management experience to:
  - Perform due diligence
  - Develop biohealth project-focused companies

Proactively identifies and commercializes market-relevant intellectual properties from:

- Federal Labs
- Universities
- Private Sector

Progress (4½ months into Program)

- 55 Innovations identified and initially screened
- 7 Progressed to Secondary Analysis in BHI Pipeline (Safety & Efficacy Profiling, IP Diligence, Regulatory & Development Pathways)
- 26 No BHI Interest, 22 still Under Review
- Goal to fund the operation of more EIRs
Entrepreneur-in-Residence (EIR)

- Identify market viable biohealth assets
- Act as liaison among federal labs, academic, industry, venture capital, and non-profit
- Detailed commercial evaluation of most valuable technologies
- Provide early-stage developmental strategies
- Nurture relationships with scientists, mentor to ensure research becomes commercially valuable, and track progress
- Identify creative funding to advance exciting, novel technologies
- Create new BioHealth companies
EIR Criteria

• Senior management in an early stage life sciences startup
  – Entrepreneurial life science start up or spin out activity

• Management in an organization that specializes in startup companies

• Experience in a seed stage venture capital firm

• Served in a business development role in a high performing university or business development organization that successfully formed new ventures

• Served in a business development role, product development role, or other capacities for biotech products or services that enable substantial knowledge of the earliest stages of development for a new technology startup company
EIR Expectations

• Assist OTT in the evaluation of existing technologies
• Provide an entrepreneurial perspective to OTT in its evaluation of new licensing proposals
• Advise OTT on opportunities for new ventures based on NIH/FDA technologies
• Assist with developmental strategies
• Mentor scientists to help ensure their research becomes commercially valuable

• Identify market viable innovations from NIH and other regional institutions
• Act as liaison among regional biohealth stakeholders and NIH
• Primary and secondary commercial analysis of lead technologies
• Develop novel technologies that are at conceptual stage
• Act as catalyst to license most interesting technologies and fund start-up companies
Maryland Universities/EIR Interaction

• $5.8M budget

• 5 University partners

• 5 University site miners

• 40 University pre proof-of-concept technologies funded

• $25-$150K funded per technology

• Regular meetings between BHI/EIR and site miners

• BHI identifies most commercially relevant technologies

• BHI and INNOVATE MD partnership opportunities
EIR Integration into NIH System

• **Office at the central Office of Technology Transfer (OTT)**
  – Volunteer status
  – Report to Director and Deputy Director of centralized OTT
  – Full access to NIH campus and staff

• **Active participant in Technology Review Groups at top three institutions**
  – Review of patent prosecution decisions for new and existing inventions

• **Active participant in Technology Development Coordinator meetings**
  – Key decisions on selected technologies

• **Access to database (SYNAPSE) detailing invention filings**
NIH Overview

• Intramural budget is approximately $3B per year
  – 6,000 scientists
  – 27 institutes and centers (ICs)

• Three largest centers: NCI, NIAID, and NHLBI
  – In aggregate represents more than half of invention filings

• Centralized Office of Technology Transfer
  – Responsible for patenting
  – Technology transfer specialist at each institution
  – ~150 licensing staff members at NIH
Early-Stage Analysis of Commercial Relevance

Selected Criteria for Value Proposition

- Differentiation
- Efficacy Data
- Market Size
- Reimbursement
- Safety Data
- Unmet Medical Need
- Stage of Development
- Industry Interest
- Intellectual Property
- Competitive Landscape
- Advantages for Clinical Development
- Novelty

1. Identify Key Issues
2. Primary and secondary analysis
3. Can key issues be overcome by capital efficient investment?
Key Considerations for Technology Focus

• Clear unmet need that benefits public health
• First-in-class, best-in-class therapies
• Target therapeutic areas that reflect strategic objectives
• Clinical development advantage
• Relevance to strategic needs
What is the Overall Process for Licensing / Creating Company?

Industry Needs
- BHI Board
- Venture Capital
- Regional Pharma / Biotech
- Literature
- Personal Network

Identification
- Scientists
- Tech transfer
- NIH review meetings
- NIH Licensing Managers
- NIH database

Market Analysis
- Primary: Literature
- Secondary: KOLs
- Development strategy
- Scientific/commercial validation with internal and external experts

Funding
- IC (e.g. NCATS)
- SBIR-TT
- CRADA
- TEDCO
- Innovate MD
- Invest MD
- BioHealth Innovation
- Angel funding
- Venture capital
BHI Commercialization Pipeline

**STEP I: Innovation Exposures / Sourcing**
- Federal Labs
- Academia
- Investor Groups
- Industry
- Personal Networks

**STEP II: Screening**
- Stage of Development
- IP Status
- Level of unmet medical need
- Industry interest
- Market size
- Competitive Advantage
- Scientific Reputation

**STEP III: Secondary Analysis**
- Disease Overview
- Safety Profile
- Efficacy Profile
- Market Differentiation
- IP Diligence
- Competitive Landscape
- Regulatory Path
- Development Plan

**Step IV: Primary Analysis**
- Commercial Expertise
- Industry Input
- Investor Input
- Regulatory Input
- Payer Interviews
- Third-party scientific expertise

**Commercial Relevance**
- Investment
- Partnerships
- Funding
- SBIR/STTR
- NIH Collaboration
- Joint Ventures
- Licenses
BHI Innovation Capital

• **SBIR/STTR Assistance Program** - The BHI SBIR/STTR Assistance Program (in development) will provide assistance to biohealth-driven companies in the Central Maryland region in preparing for high-quality SBIR/STTR grant proposals for submission to federal funding agencies.

• **BHI Angel Fund** - The BHI Angel Fund (in development) will be a member-managed private equity investment fund that bridges the gap between pre-seed investments and institutional venture capital serving the Central Maryland region entrepreneurial needs.

• **BHI Commercial Relevance Investment Fund** - The BHI Commercial Relevance Investment Fund (in development) will be a pre-seed and early-stage, equity-based innovation capital fund to help grow, attract, retain and connect Central Maryland biohealth innovation-based companies that need financing to grow their enterprises.
BHI News & Website

BHI Web site
The BHI Web site has news, an events calendar, research publications, regional organization feature stories and resources for the biohealth industry.
http://www.biohealthinnovation.org

BHI News
BHI’s weekly e-newsletter highlights the Central Maryland Region’s news articles, national biohealth trends and feature stories.
http://www.biohealthinnovation.org/news
Innovation Resource Guide

“Financing and Entrepreneurial Resource for Montgomery County and the Greater Baltimore Region”

- Entrepreneur and Innovation Resource Network
- Innovator Financing Guide
- The Startup’s Guide to Intellectual Property
### How is Success Measured?

#### BHI Metrics – First 5 Years

<table>
<thead>
<tr>
<th>Metric</th>
<th>Now</th>
<th>In 5 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC Funding for Biotech</td>
<td>$79 Million</td>
<td>$150</td>
</tr>
<tr>
<td>Government Funding for Biotech</td>
<td>Increased SBIR proposals &amp; success</td>
<td>Improve Maryland’s ranking</td>
</tr>
<tr>
<td>Source Prospective Deals Annually</td>
<td>30</td>
<td>150</td>
</tr>
</tbody>
</table>

- Improve return on R&D investment by leveraging equity investment
- Create and retain 1,300 jobs
- Recruit entrepreneurs, experienced managers and businesses
- Commercialize biohealth technologies and create biohealth companies
BHI and JG Business Link International, Inc.
MOU

• BHI will act as JGBLI’s primary local partner in Maryland while JGBLI will act as BHI’s primary connection in South Korea

• Will serve as a bridge to enable companies associated with both parties to navigate through regulatory approval problems and aid in the commercialization of research in both countries.
BHI: The Triple Bottom Line

Grows high-paying jobs and businesses

Expands tax base; improves economic vitality

...and Benefits human health!
BHI Staff

Richard Bendis  
President & CEO  
(215) 593-3333  
rbendis@bendisig.com

Todd Chappell  
Entrepreneur-In-Residence  
(978) 933-1622  
tchappell@biohealthinnovation.org

Ethan Byler  
Director, Innovation Programs  
(301) 637-7952  
ebyler@biohealthinnovation.org

Renée Enright  
Executive Administrator  
(301) 637-5372  
renright@biohealthinnovation.org

Amanda Wilson  
Operations Manager  
(301) 637-0699  
awilson@biohealthinnovation.org

Adam Hafez  
Student Intern  
(301) 637-7270  
ahafez@biohealthinnovation.org

BioHealth Innovation, Inc.  
22 Baltimore Road | Rockville, MD 20850  
bhi@biohealthinnovation.org

BioHealth Innovation  
Maryland’s Commercialization Collaborative