BioHealth Innovation, Inc.

Introduction
Richard Bendis, President & CEO
BioHealth Innovation, Inc.
7/11/2012
Rockville, MD

www.biohealthinnovation.org
The Problem--A National Challenge

America is falling behind the world it invented because we are:

– Out-educated
– Out-built in infrastructure
– Out-invested in R&D
by countries in both Europe and Asia.

--“That Used to Be Us” by Thomas Friedman, 2011

The Reverse Brain Drain

• “Opportunities in China Lure Scientists Home” --The Washington Post, February 20, 2008

• American returnees to India cited as reasons for going “back” to where they came from:
  • Better Economic Opportunities
  • Family Ties
  • Better Access to Markets
National Leadership

President Obama:
• Bioeconomy Initiatives
• America Invents Act (2011)

• America Invents Act
• Center for Advancing Translational Sciences in NIH to advance commercialization (NCATS)
• Develop a National Bioeconomy Blueprint
  – Support R&D investments
  – Facilitate the transition from research lab to market
  – Reduce barriers, increase speed and predictability of regulatory process, and reduce cost.
  – Update training programs and align academic institutions incentives
  – Identify and support the development of PPPs and pre-competitive collaborations
State Leadership

Maryland Governor O’Malley:
• BioMaryland 2020
• Invest Maryland
• Innovate Maryland

• Maryland Biotechnology Investment Tax Credit ($6 m/yr)
• BioMaryland 2020 blueprint
• Invest Maryland ($70 million)
• Maryland Life Sciences Advisory Board
• The Maryland Venture Fund
• Maryland Innovation Initiative
“The Region”--Central Maryland

Unrivaled Research Assets
Unfulfilled Commercial Promise

[Logos of National Institutes of Health, FDA, NIST, Johns Hopkins University, University System of Maryland, Center for Medicare & Medicaid Innovation, United States Army Fort Detrick]
A Region Rich with Research Institutions
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
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
Regional BioHealth Ecosystem Partners

**ACADEMIA**
- Research/T2
- Lifelong Learning
- Economic Development

**INDUSTRY**
- Profit
- Process
- Product

**GOVERNMENT**
- Sustainability
- Infrastructure Support
- Economic Policy

**FOUNDATIONS**
- Economic Growth
- Community Investment
- Regional Collaboration

**INSEPARABLE MISSIONS**
BHI Partners and Sponsors

BHI Funding Sources:
• private sector
• universities and foundations
• public sector
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

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

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”
# Innovation Capital

"VALLEY OF DEATH"

## Stage

<table>
<thead>
<tr>
<th>POR / Pre-Seed</th>
<th>Seed/Start-Up</th>
<th>Early</th>
<th>Later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Founders, FFF, Bootstrapping, Crowdfunding</td>
<td>Angels, IBED, SBIR, Accelerator Seed Funds</td>
<td>Venture Funds</td>
<td></td>
</tr>
</tbody>
</table>

## Source

- Founders, FFF, Bootstrapping, Crowdfunding
- Angels, IBED, SBIR, Accelerator Seed Funds
- Venture Funds (M&A, IPO)

## Demand

<table>
<thead>
<tr>
<th>$0K</th>
<th>$500K</th>
<th>$2.5M</th>
<th>$5.0M</th>
</tr>
</thead>
</table>

## Supply

- "VALLEY OF DEATH"
- Funding Gap

---

*BioHealth Innovation*

Maryland’s Commercialization Collaborative
Connect Funding Sources at Every Stage to Fill Gaps

<table>
<thead>
<tr>
<th>DREAM</th>
<th>CONCEPT</th>
<th>APPLIED</th>
<th>COMMERCIAL RELEVANCE</th>
<th>STARTUP</th>
<th>ROLL OUT</th>
<th>GROWTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>FoundersFFF Bootstrapping Crowdfunding</td>
<td>Seed</td>
<td>Accelerator</td>
<td>IBED</td>
<td>Federal</td>
<td>ANGEL</td>
<td>VC</td>
</tr>
<tr>
<td>VISA</td>
<td>NEA</td>
<td>Maryland Technology Development Corporation</td>
<td>TEDCO</td>
<td>SBIR &amp; STTR</td>
<td>a</td>
<td>H.I.G. BioVentures</td>
</tr>
<tr>
<td>Mastercard</td>
<td>Invest Maryland</td>
<td>Maryland Department of Business &amp; Economic Development</td>
<td>MHPDC</td>
<td>TIP</td>
<td>SBA</td>
<td>mava</td>
</tr>
<tr>
<td>Friends Family Series</td>
<td>Fools</td>
<td>Maryland Rural Development</td>
<td>DED</td>
<td>USDA Rural Development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crowdfund</td>
<td>Kickstarter</td>
<td>RocketHub</td>
<td>Tech Council of MD</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BioHealth Innovation
Maryland’s Commercialization Collaborative
How does BHI work?

Commercialization Pipeline

Sources and evaluates biohealth intellectual properties (IP)

Funds market-relevant IP

Grows and markets businesses and products
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.
Partnership Intermediary Agreement (PIA)

• PIA between BHI and NIH’s Office of Technology Transfer 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.
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
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 liasion 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
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**
Example of 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
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

Identify Key Issues

Primary and secondary analysis

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
Industry Feedback

EIR identifies asset (e.g. NIH, University)

- Does not meet BHI strategic objectives
- Meets BHI strategic objectives

Scientific / Commercial Validation

- VC/BHI/Angel Funding
- License

License

- Regional companies
- Established with development expertise takes on asset

Additional experimentation

- Creative funding
- NIH programs
- Institution investment

Traditional Biotech

- Platform technology / portfolio of products
- Build internal team
- Lab space

Project-focused Company

- Single asset
- One FTE
- Consultants
- Virtual operation

Novel technology, but not ready for investment
Funding Mechanisms

• Institution or Center participates in direct funding of innovation
• Cooperative Research and Development Agreement (CRADA)
  – Written agreement between a private company and a government agency to work together on a project
  – Allows the Federal government and non-Federal partners to optimize their resources, share technical expertise, share intellectual property emerging from the effort, and speed the commercialization
BHI H-RIC Model

Health Regional Innovation Cluster (H-RIC)

- Regional, cluster-based economic development model
- Modeled after the Department of Energy’s Regional Innovation Cluster
- Connects innovation assets to related industries
- Advances human health and economic prosperity
BHI Road Map & H-RIC Implementation Strategy

Regional Innovation Planning
- Regional Cluster Study
- Asset Mapping
- Innovation Index
- Entrepreneur’s Resource Guide

Innovation Capital
- BHI Direct Investment Program
- Regional Angel Fund ($5M) Start up/Mgt
- SBIR/STTR Assistance Program Mgt.
- Early-stage Venture Fund ($100M) Start up/Mgt

Commercialization & Jobs
- University & Federal Lab Commercialization Program
- BioHealth Innovation Acceleration Program
- E-Health and M-Health Competition & Accelerator
- Executive in Residence Programs

Innovation Workforce
- Entrepreneurial Support Programs
- INNoVATE program
- Community College Bio Workforce

Location & Infrastructure
- Incubators & Accelerators Facility Enhancement
BHI Resources

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

BHI & EAGB Innovation Resource Guide
## 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: The Triple Bottom Line

Grows high-paying jobs and businesses

Expands tax base; improves economic vitality

...and Benefits human health!