A new private public partnership model on accelerating the commercialization of BioHealth technologies and science

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“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
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
<table>
<thead>
<tr>
<th>Challenges to Innovation Economy</th>
<th>BHI Value Proposition</th>
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<tbody>
<tr>
<td>Lack of connection of innovation resources</td>
<td>Connects regional innovation assets</td>
</tr>
<tr>
<td>Lack of an entrepreneurial culture and C-level executives</td>
<td>Develops an entrepreneurial talent and support pipeline</td>
</tr>
<tr>
<td>Lack of early-stage funding for commercializing technologies</td>
<td>Attracts funding for technology commercialization</td>
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<tr>
<td>Lack of a STEM Workforce</td>
<td>Develops a continuum of innovation workforce</td>
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</table>
Regional BioHealth Ecosystem Partners

ACADEMIA
- Research/T2
- Lifelong Learning
- Economic Development

INDUSTRY
- Profit
- Process
- Product

GOVERNMENT
- Sustainability
- Federal Laboratories
- Infrastructure Support
- Economic Policy

FOUNDATIONS
- Economic Growth
- Community Investment
- Regional Collaboration

INSEPARABLE MISSIONS
BHI Board of Directors

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Managing Director, Venable LLP

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President & CEO, BioHealth Innovation, Inc.

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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>
</tr>
<tr>
<td></td>
<td>Bootstrapping</td>
<td>Accelerator Seed Funds</td>
<td>M&amp;A, IPO</td>
<td></td>
</tr>
<tr>
<td>Source Demand</td>
<td>$0K</td>
<td>$500K</td>
<td>$2.5M</td>
<td>$5.0M</td>
</tr>
</tbody>
</table>

**“VALLEY OF DEATH”**

- **Funding Gap**
- **Secondary Funding Gap**
## 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>
</tr>
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</table>

- **Pre-Proof of Concept**
  - NIH R01
  - NIH R03
  - NIH R21
  - Small Business Innovation Research Grant (SBIR) Phase I
  - Innovate Maryland

- **Translational Research / Proof of Concept**
  - NIH Center for Accelerated Innovations (CAI)
  - NCATS Cures Acceleration Network (CAN)
  - Small Business Innovation Research Grant (SBIR) Phase I
  - Maryland Stem Cell Research Fund (MSCRF)
  - TEDCO University Technology Development Fund (UTDF)
  - TEDCO TechStart
  - Maryland Biotechnology Center’s Translational Research Award

- **Proof of Commercial Relevance / Pre-Seed**
  - Maryland Industrial Partnerships (MIPS @ UMD)
  - Maryland Biotechnology Center’s Biotechnology Commercialization Awards
  - TEDCO Maryland Technology Transfer and Commercialization Fund (MTTCF)
  - BHI SBIR/STTR Commercial Relevance
  - BHI Commercial Relevance Fund (CRF)

- **Seed / Start-Up**
  - Dingman Center Angels (UMD)
  - TEDCO Johnson & Johnson Joint Investment Program
  - Propel Baltimore Fund
  - SBIR / STTR Phase II
  - BHI Central Maryland Angel Fund
  - National Association of Seed & Venture Funds (NASVF)
  - Angel Capital Association (ACA)

### Funding Type Key
- Academic
- Accelerator
- Federal
- BioHealth Innovation, Inc.
- Innovation-based Economic Development (IBED)

### Tax Credits
- State of Maryland
- Venture Capital
- Maryland Biotechnology Investor Tax Credit
- Montgomery County Biotechnology Investor Tax Credit

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**BioHealth Innovation**
Maryland’s Commercialization Collaborative

**TECH TRANSFER SUMMIT**
North America

17
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 (6 months into Program)
- 73 Innovations identified and initially screened
- 7 Progressed to Secondary Analysis (Safety & Efficacy Profiling, IP Diligence, Regulatory & Development Pathways) and 12 to Primary Analysis
- 32 No De-prioritized, 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 Approach to Progressing NIH Assets

EIR…
1) Identifies NIH Asset
2) Conducts Scientific & Commercial Due Diligence
3) Interacts with Inventor & NIH OTT

BHI Commercial Relevance Board…
1) Provides Industry Input & Commercial Expertise
2) Makes recommends on commercial next steps i.e. NewCo formation, capital raising, etc.

BHI Staff & appropriate Board & other parties…
1) Assist in building NewCo Management Team, Board of Directors, & Scientific Advisors
2) Provides ongoing commercial strategy and support to the NewCo
3) With BHI support, NewCo files application to license technology with the NIH OTT

BHI Entrepreneur In Residence (EIR)

BHI Commercial Relevance Advisory Board Review

NewCo Formation

License Negotiated between NewCo & NIH OTT

Capital Raise

BHI Entrepreneur

BHI Commercial Relevance Advisory Board…
1) Provides Industry Input & Commercial Expertise
2) Makes recommends on commercial next steps i.e. NewCo formation, capital raising, etc.

Licensing Interest

Novel Technology but not ready for development

BHI…
Continues to track / monitor progress. Additional experimentation likely required
• Creative funding
• NIH programs
• Institution investment

NewCo…
Formed

License Negotiated between NewCo & NIH OTT

Capital Raise

BHI…
Works with Regional Companies to scout technologies for their own pipelines. When an asset is identified, companies will perform their own due diligence and investigate a licensing deal

BHI…
Is a silent partner to licensing process with NIH OTT. Any exclusive licenses are required to be posted on the Federal Register

BHI…
Supports NewCo with capital raise including Angel, Venture Capital, SBIR/STTR and Federal Funding, Foundation Resources, State Funding Programs, TEDCO, Accelerator, etc.

BHI…
Assists with finding appropriate laboratory space locally and other local partners appropriate for development

BHI…
Assists with referring appropriate development partners, consultants, and virtual services

Traditional Biotech Company

Project Focused Company
BHI SBIR Assistance Program

• SBIR/STTR Pre-Application Form submitted by small businesses in Central Maryland

• Scoring and feedback provided on Pre-Application by 3 qualified reviewers from a national pool using an online evaluation system

• BHI Committee reviews and determines whom to work with from a perspective of nurturing commercially relevant startups

• Financial grant considerations offered to assist in preparing full SBIR/STTR submission
BHI SBIR/STTR: Proof of Commercial Relevance (PCR)

Central Maryland SBIR Candidates

1. Phase I Awardees
2. Pre-Phase I (Phase Zero) – Early Commercial Relevance Indication

Companies Invited by BHI to submit SBIR concept

BHI Online Review System

Scientific Experts

SBIR Consultants

BHI

Reviews, Feedback, Troubleshooting, Strategy

Full Proposal Preparation Assistance

Mentoring $$$

BioHealth Innovation
Maryland’s Commercialization Collaborative

TECH TRANSFER SUMMIT
NORTH AMERICA
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
“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
**BHI International Partnerships**

- **Korea** – MOU signed with JGBLI
- **China** – MOU signed with TASLY
- **Israel** (pending)
- **Latin America** (pending)
- **Europe** - Technopolicy Network (advisory board member)
- **Italy** - INSME - International Network for Small and Medium Enterprises
## 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>
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**Improvements:**

- 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!
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