



BioMADE

**Bioindustrial Manufacturing
and Design Ecosystem**

Bioindustrial Manufacturing: Opportunities & Challenges

Douglas Friedman | PCAST Meeting | 29 November 2021

www.biomade.org

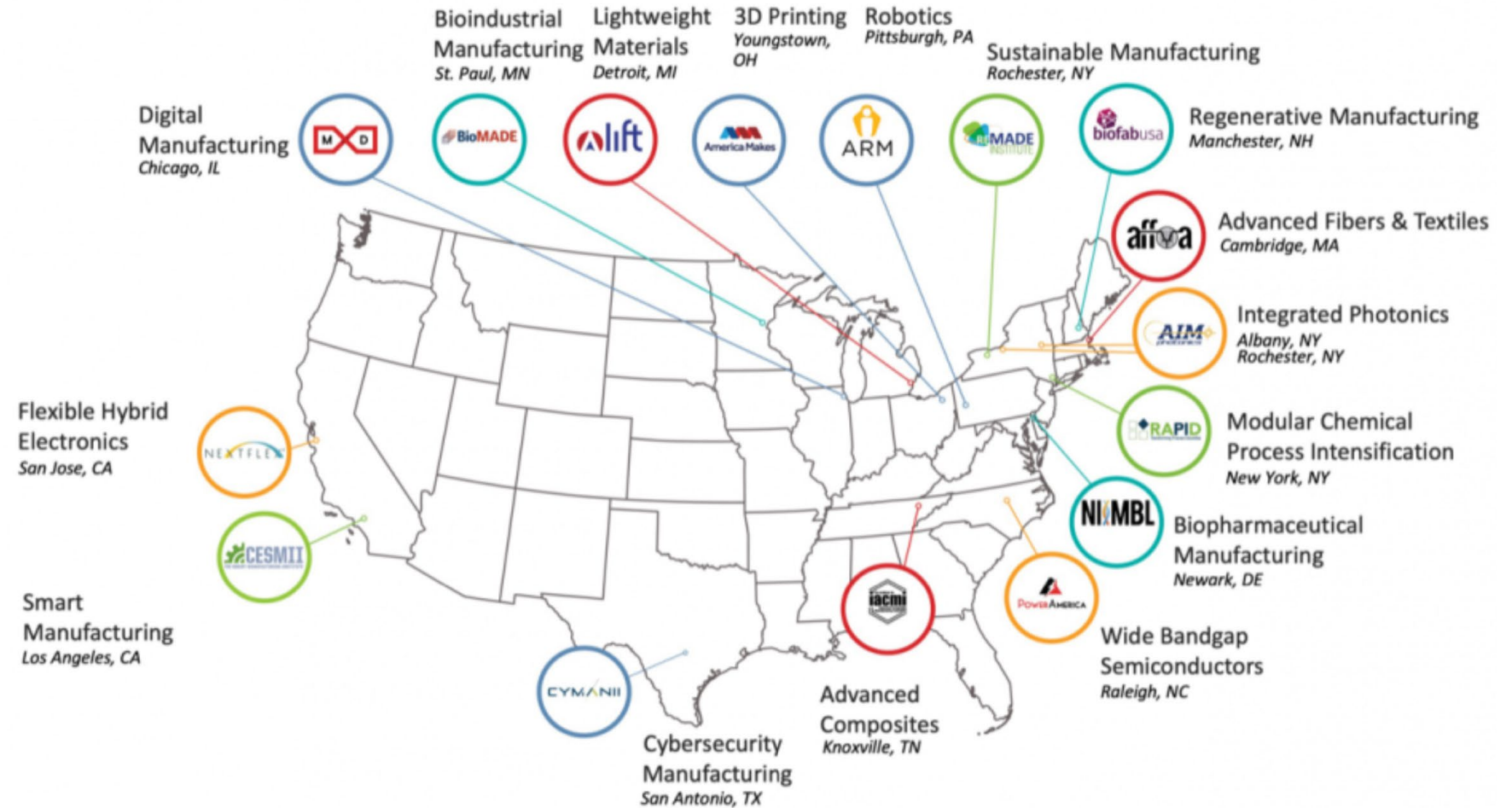
About BioMADE

BioMADE launched in 2021 and is an independent non-profit, public-private partnership sponsored by the U.S. Department of Defense. In partnership with our members, we are securing America's future through biomanufacturing innovation, education, and collaboration by:

- › Propelling new biotechnology products from the laboratory to the commercial market
- › Creating a more robust and resilient supply chain and helping the U.S. become more self-sufficient
- › Ensuring that the workforce of the future is prepared and ready to fill new jobs
- › Bringing together a range of member organizations to bridge the gap between lab-scale research and at-scale manufacturing



Manufacturing Innovation Institutes



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Georgia Tech

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TEXAS
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College of Natural Sciences

RICE

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NC STATE UNIVERSITY

NCERC at SIUE



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CENTER FOR ADVANCED BIOENERGY AND BIOPRODUCTS INNOVATION

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AMERICAN RIVER COLLEGE

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BioMADE
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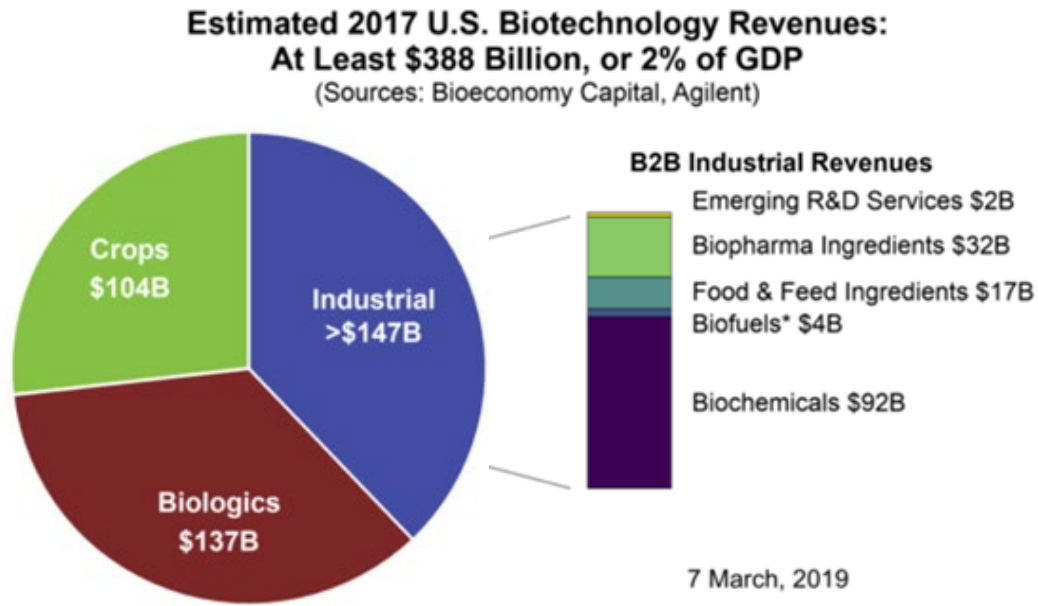
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We have an opportunity to accelerate a strong domestic bioeconomy.



U.S. Strategic Bioeconomy Assets:

- **United States attracts talented international students** who study and work for our university labs.
- **Powerful basic research programs** that support the early research that generates start ups.
- **50% of patents filed by U.S. life science researchers are judged to have commercial potential.**
- Incredible potential for **massive cultivable biomass feedstocks.**

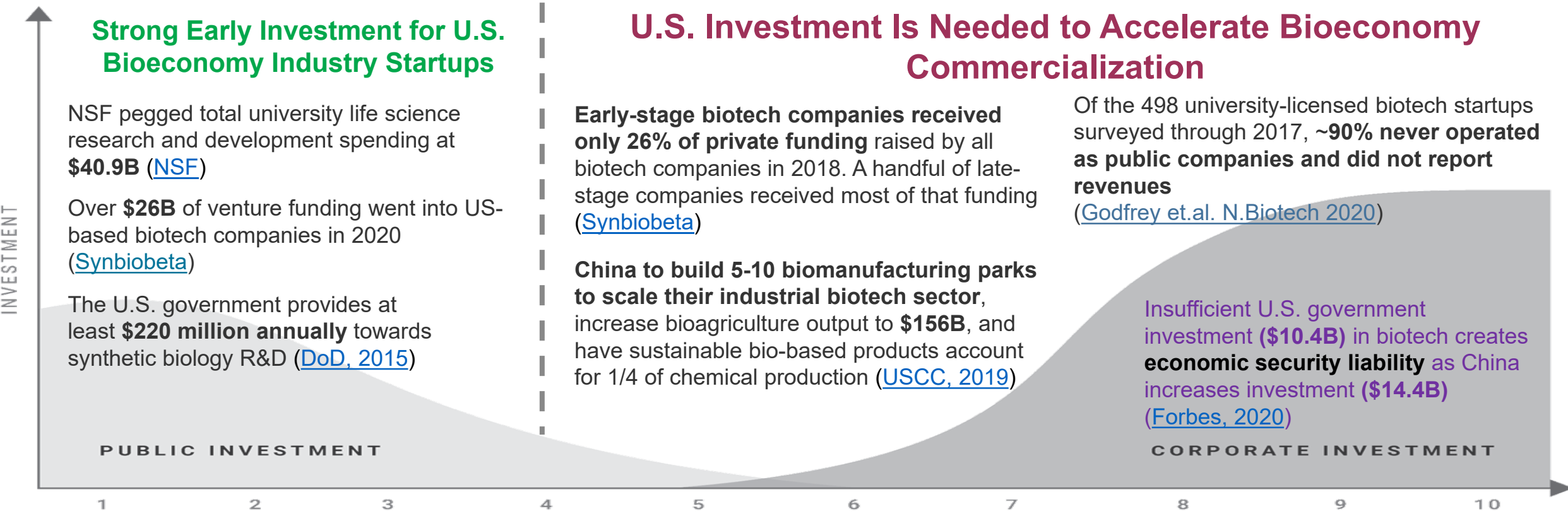
U.S. Bioeconomy

is **sustainably diversified** between crops, biologics, and industrial biotechnology

U.S. Bioeconomy is robust and growing:

- **1.7 Million Jobs** provided by USDA BioPreferred Products in 2016.
- **\$388B (>2% GDP) of US-biotech revenue** in 2017.
 - for reference, 2017 *worldwide* revenues for semiconductors was ~\$400B.
- \$14B across 74 deals for total biotech IPOs in 2020.
- \$26B of Venture Capital Funding for US-biotech Companies in 2020.
- 2,562 Biotechnology Firms across the United States in 2016.

Investment is needed to accelerate bioeconomy commercialization.



U.S. Investments that Enabled Bioeconomy Startups MRL

- 3 Bioenergy Research Centers (DoE)
 - Increased Venture Capital
 - SynBERC (NSF)
 - Living Foundries (DARPA)
 - Agile Biofoundry (DoE)
 - Somatic Cell Genome Editing (NIH)
 - URoL - Syn Cell (NSF)
 - Cell Manufacturing (NSF)
 - Center for Biorenewable Chemicals (NSF)
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U.S. and Foreign Biotech Commercialization Efforts

- BioMADE (USA)
- National Biologics Manufacturing Centre (UK)
- Pilots4U (EU)
- Industrial Biotechnology Innovation Centre (UK)
- Shared Pilot Facilities (EU)
- BioFabUSA (USA)
- NIIMBL (NIST)
- Biotechnology Innovation Platforms (CN)
- Institute of Synthetic Biology (CN)





Three Focus Areas



› BioMADE's 4S program is facilitating responsible bioindustrial engineering and manufacturing, addressing ethical and security concerns in intellectual property management, and increasing public understanding and support for bioindustrial engineering and manufacturing

› BioMADE is committed to incorporating 4S into the fabric of all technical, educational, workforce, and community projects

Education & Workforce Development

➤ The bioindustrial manufacturing sector is poised for significant growth in the coming decade and will need a trained and prepared workforce.

➤ BioMADE is building the workforce of the future by partnering with K-12 schools, community colleges, universities, and professional development organizations.

Priority Areas

Building awareness
of bioindustrial
manufacturing careers

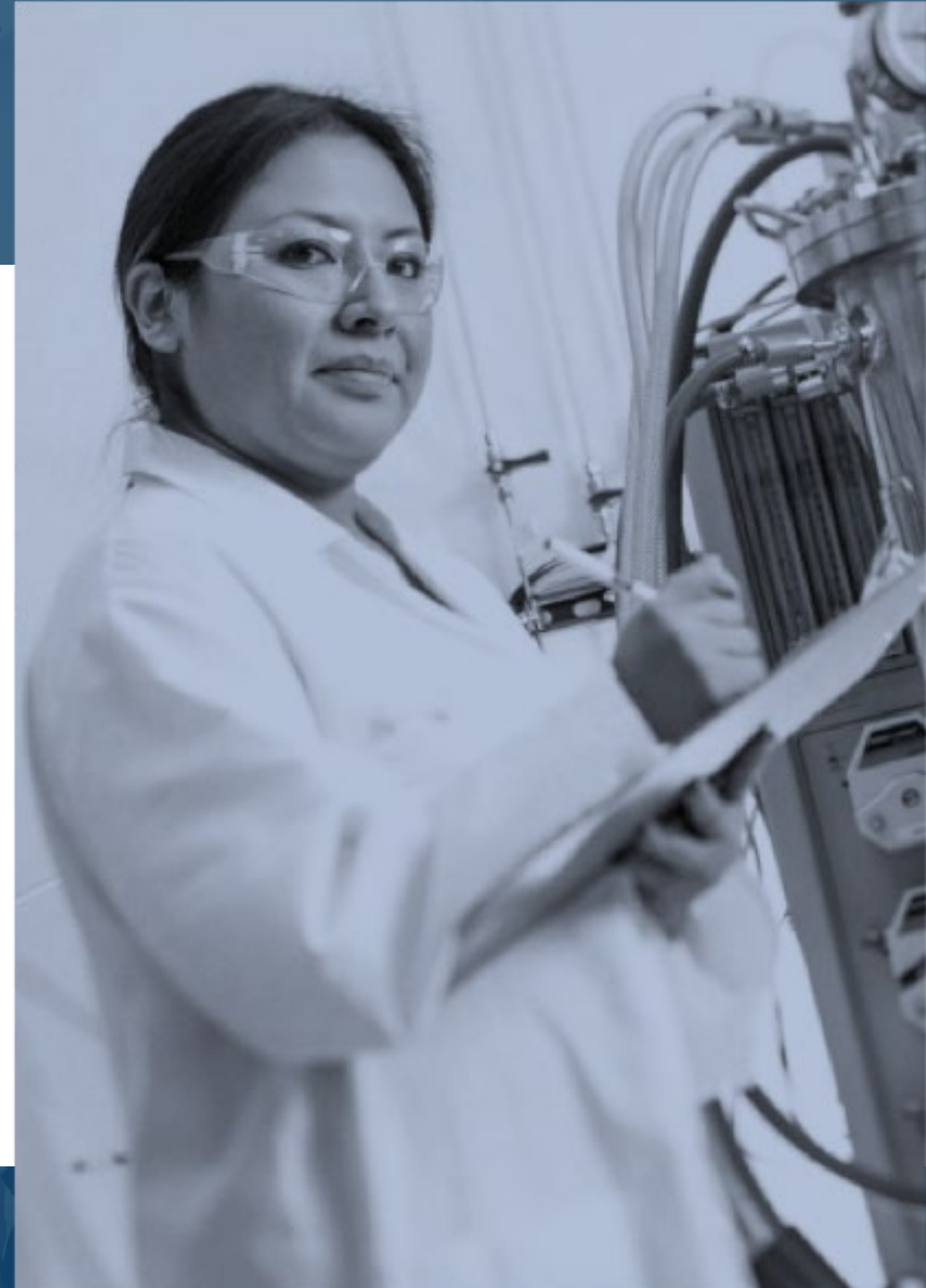
Preparing the future workforce
with innovative education

Supporting the growth of the
current workforce with world-
class professional development

Education & Workforce Development

Meeting the Emerging Needs for the Bioeconomy requires a novel approach:

1. Industry-directed career pathways in Bioindustrial Manufacturing must engage a multi-disciplinary strategy that combines traditional biotechnology with principles in engineering, materials science, advanced data analytics, process automation, supply chain logistics, and emergent technologies.
2. Accelerating workplace readiness by:
 - a. *Increasing societal awareness and accessibility of bioindustrial manufacturing career pathways.*
 - b. *Working with an extensive network of partners to leverage the federal portfolio of existing bioscience manufacturing programs and resources.*
 - c. *Coordinating workforce initiatives between government, industry, academia, and community stakeholders to build an ecosystem for sustainable and transformative bioeconomic growth.*
 - d. *Positioning BioMADE EWD as a core resource for career and workforce readiness for the development of skilled technical workers to supervisory and management-level workers.*
 - e. *Building a strong and enduring workforce capacity through the lens of social impact, diversity, equity, and inclusion.*



Technology and Innovation

➤ BioMADE is moving the bioindustrial manufacturing industry forward by funding innovative research, reducing barriers to scaling-up and commercialization, and de-risking investment in relevant infrastructure

➤ Focus on strengthening capabilities at Manufacturing Readiness Levels (MRLs) 4-7

Focus Areas

Data and
Design

Scale up

Downstream
Processing

Testing and
Evaluation

Resilient
Bio-Manufacturing
Ecosystem

Commercial
Readiness

How to Help US Industrial Biomanufacturing Gain Traction?

Early innovation creates important tools or concepts but may not create business models necessary to sustain a thriving bio-based economy

- *Biomolecules are usually incorporated into complex products vs being products in themselves*
- *Market-maker strength is necessary to sustain the biomolecule producers long enough for the complex product to find its market legs*

Capital risks and business case risks need information that can only be gained by scaling

- *Drop-in replacements must meet complex existing production scenarios; integrators hesitant to invest their own capital if the biomolecule requires work, but the biomolecule often cannot be produced in large enough quantities due to its own capital limitations*

In Brief

- › Intermediate scaling capabilities (5K to 50K liters)
- › Suites of flexible downstream processing unit operations
- › Reliable feedstocks
- › Robust prototyping and analytical capabilities
- › Market making and market pull partnerships

Why is it Hard to Gain Traction for Industrial Biomanufacturing?

Bioindustrial manufacturing uses living organisms - bacteria, yeast, and algae – *and also*

- *cell free systems*
- *enzyme catalysts (semisynthesis)*
- *chemical transformation of biological feedstocks*
- *gas-phase feedstocks*
- *plants*
- *the list keeps growing...*

Bioindustrial manufacturing leverages long ties to

- *food production technologies (fermentation, downstream processing equipment),*
- *personal care (detergent enzymes, ingredients)*
- *traditional chemical production (distillation, semisynthesis, downstream catalytic conversion)*

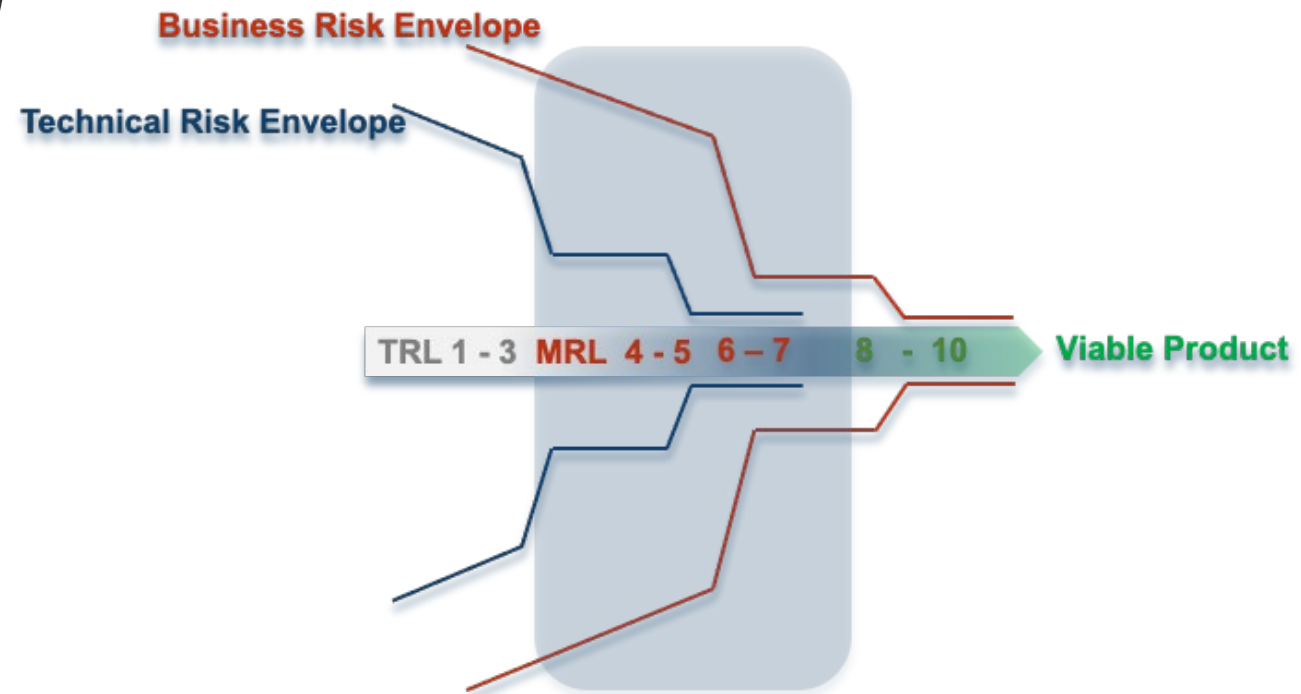
Challenges

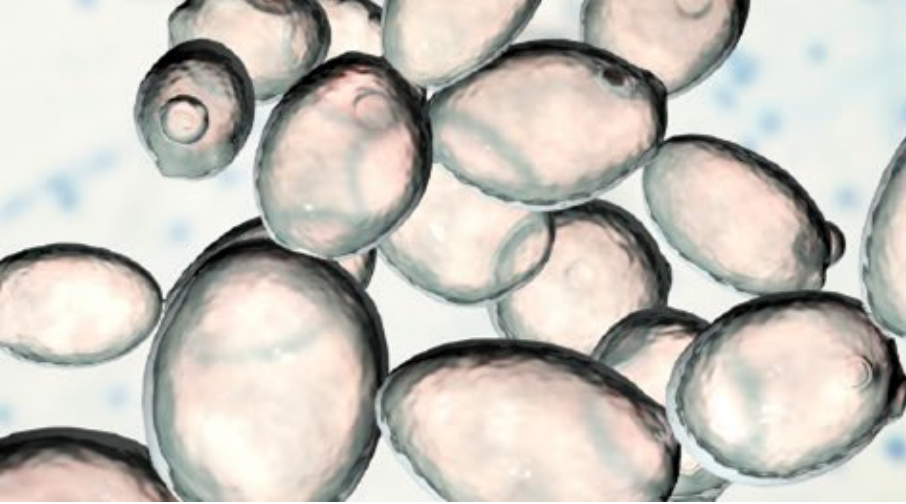
- › Technology remains in a state of evolutionary flux to address markets competitively;
 - › *but capital for evolving infrastructure is costly*
- › Benefits from adjacent technology spaces;
 - › *but suffers from lack of clear identity or definitions*
- › Can enable creating new products;
 - › *but the underlying bio-component often remains imperceptible to the consumer*

Risk Mitigation: What besides Technical Risk?

Product and Technology Development face substantial commercialization risks:

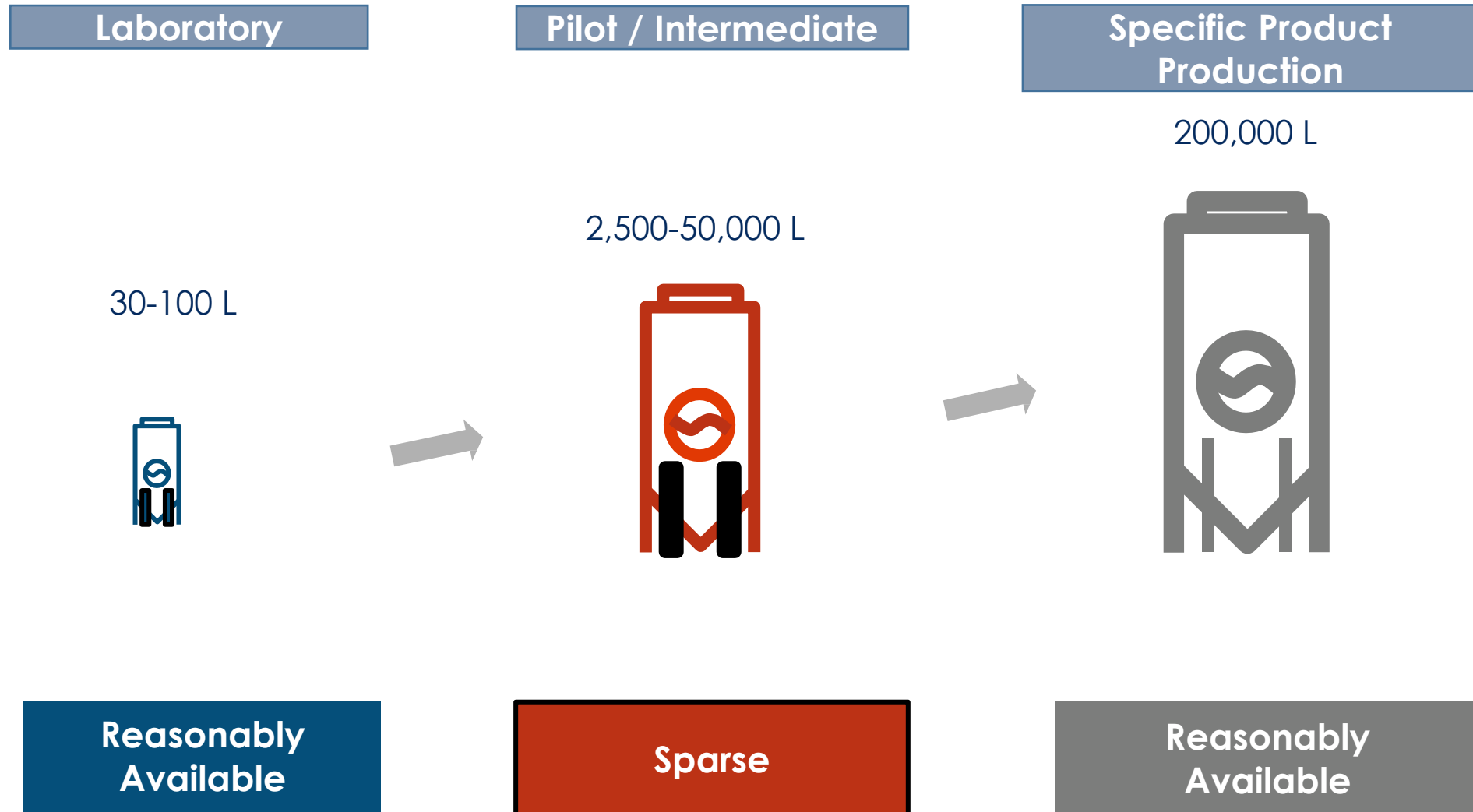
- *Product Demand and Pricing*
- *CapEx/OpEx*
- *Pilot scale availability*
- *Performance in systems*
- *Non-bio competition*
- *Regulatory / Legal*
- *Supply Chain*
- *IP theft*
- *Workforce*
- *And others*





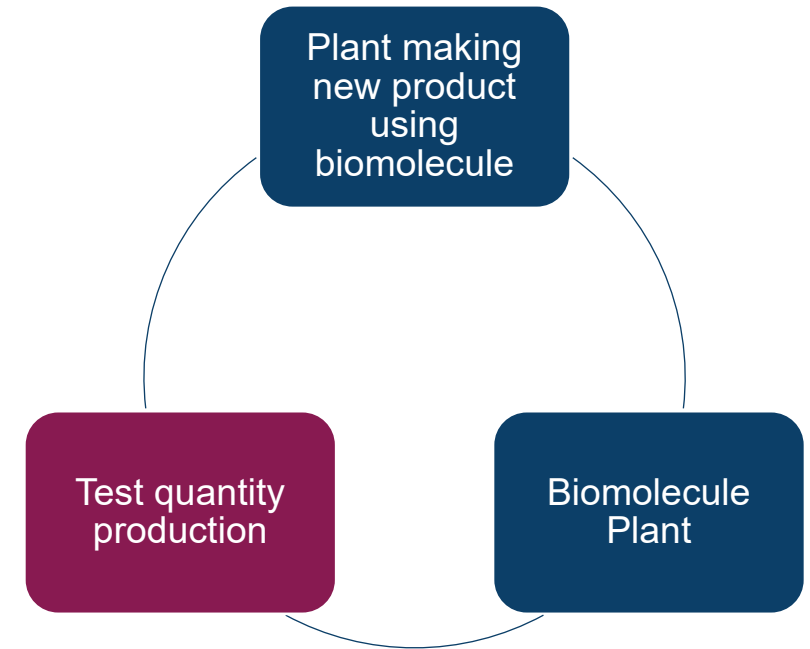
Infrastructure

There is a gap in existing domestic infrastructure



Reduction of the Triple Capital Threat

- › The capital needed to make sufficient test quantities of the biomolecule (often tons)
- › The capital needed to modify or build product facilities that incorporate the biomolecule (for instance using a new biomolecule to make a new fiber)
- › The capital needed to modify or build a biomolecule production facility that would supply the biomolecule



The weakest link; the lack of availability of initial test material makes the economics of the rest of the process untenable

Before private sector investments will be made on products using bio-derived intermediates, a 'bridge' to their production and integration testing is required.

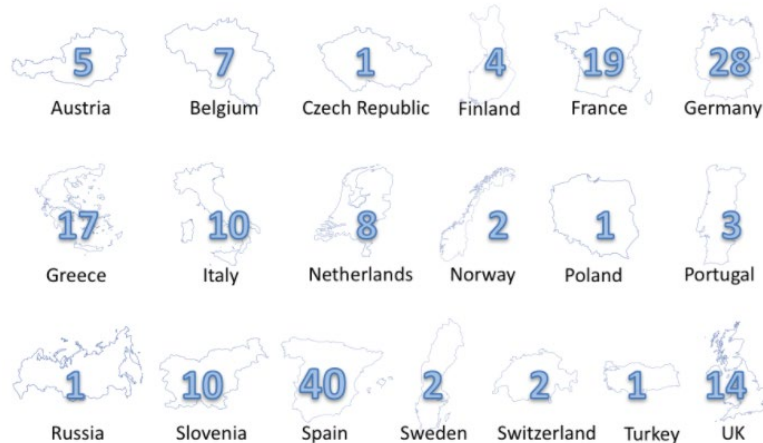


Europe has a highly developed network of pilot plant infrastructure for biomanufacturing.

EPPN is a network of fully connected and collaborating pilot lines to **boost European competitiveness** in advanced materials manufacturing (including biomanufacturing).

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NUMBER OF PILOT PLANTS BY COUNTRIES



EPPN

Pilot plant facilities:

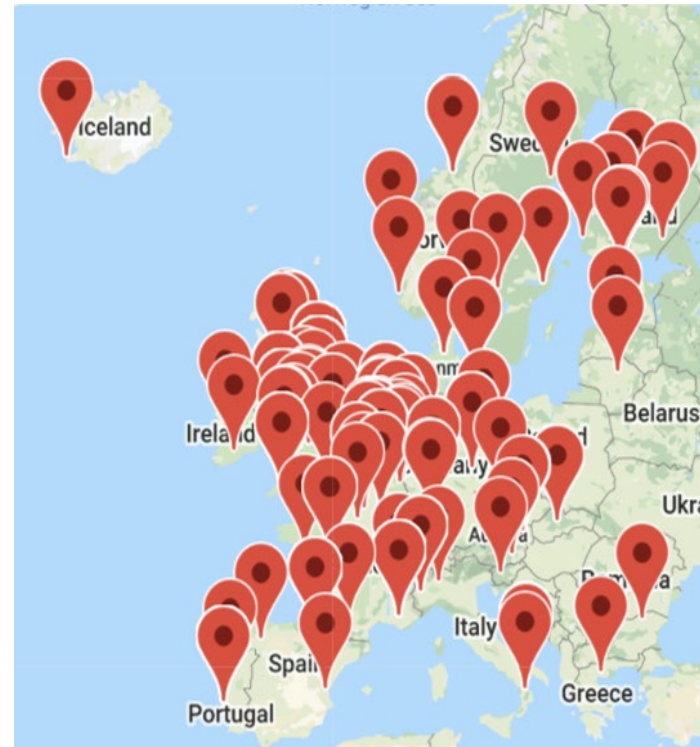
- Accelerate the product development and market entry.
- Help create new businesses and develop an **adaptable**, **resilient**, and **technically skilled** workforce.
- Increased return on investment in research.
- Enhances innovation ecosystem and attractive business environments.

But the US is falling behind in pilot plant infrastructure.

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Pilots4U (funded by the EU's Bio-based Industries Joint Undertaking) maps all existing open access pilot and demo-infrastructures across Europe, creating a **visible and easily accessible network** for the European bioeconomy.



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DATABASE ENTRIES



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ORGANISATIONS



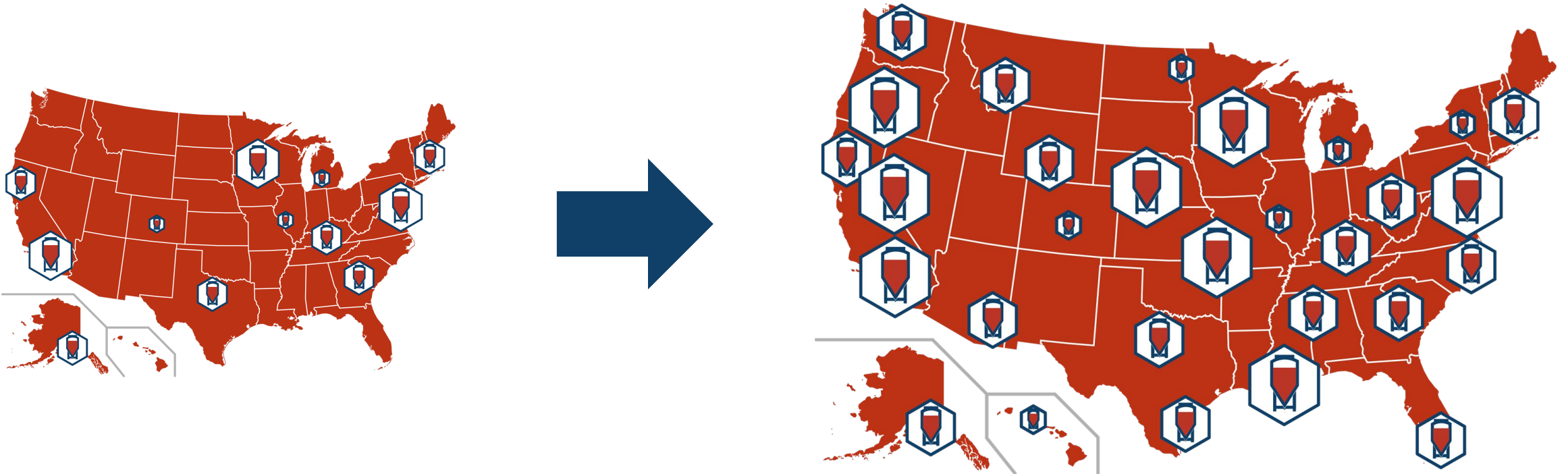
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DATABASE
SEARCHES
THIS WEEK

<https://biopilots4u.eu/>

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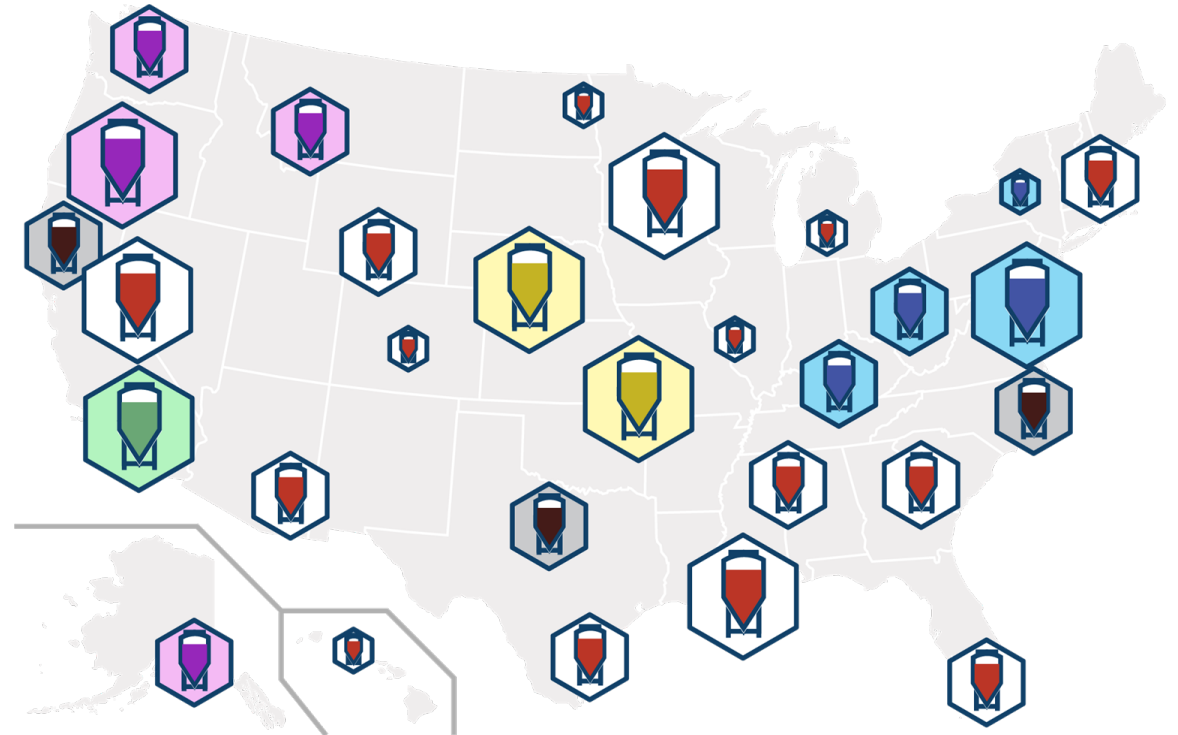
Growing bioindustrial manufacturing infrastructure at each scale where it makes sense to do so



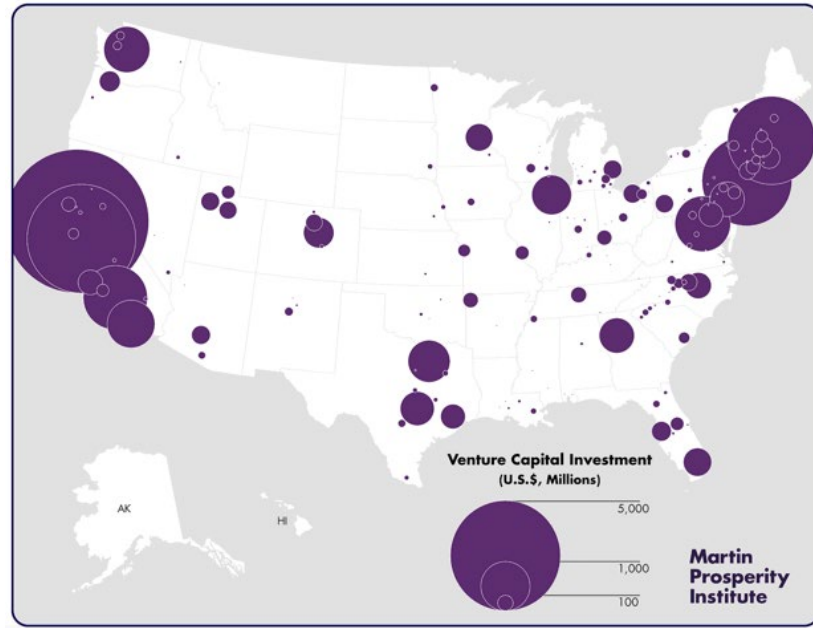
- Public-private funding for “bridges and roads” to product commercialization
- Organize for the greatest impact

Diversify and Specialize infrastructure for a robust and resilient network of manufacturing capabilities

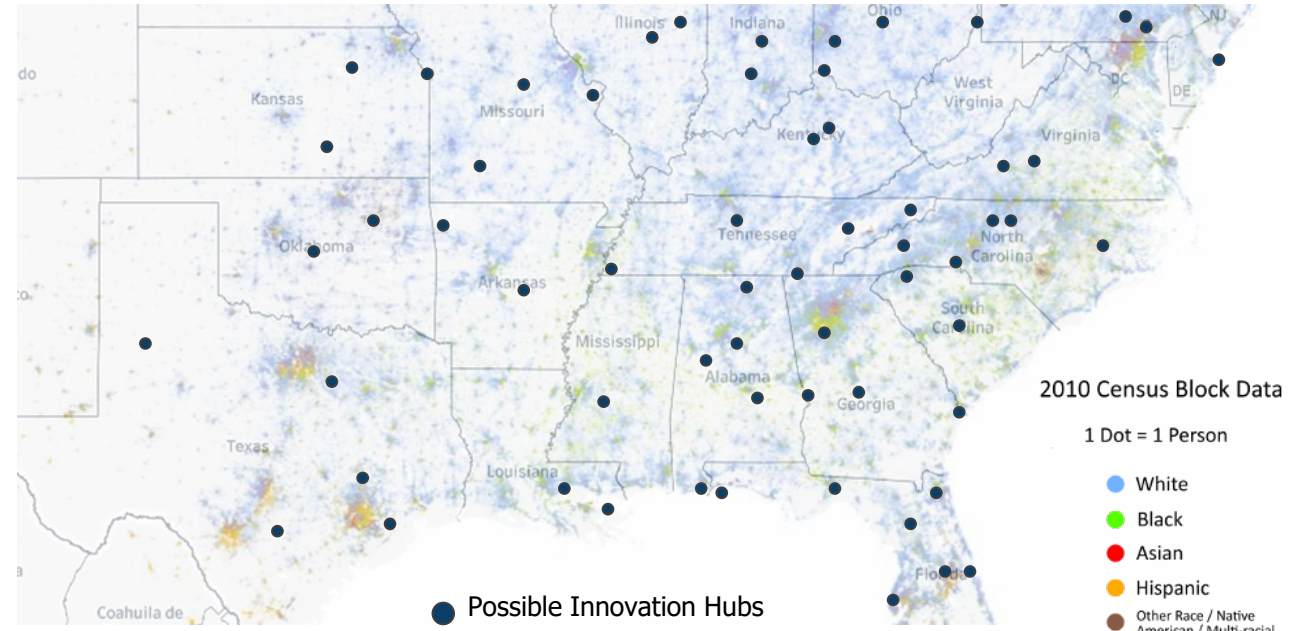
- Leverage regional feedstocks
- Couple with regional supply chains and manufacturing needs
- Proximity locations to customer markets for testing



The bioeconomy can bolster **equitable** rural development.



Distribution of venture capital across the US. **We propose to invest in infrastructure development more equitably across the south and midwest.** ([Martin Prosperity Institute, 2016](#)).



Proposed locations to develop domestic Innovation Hubs, overlaid on racial demographic data. **Many of these hubs are in predominantly underrepresented communities.** ([Jonathan Gruber and Simon Johnson, 2019](#)) (<http://racialdotmap.demographics.coopercenter.org/>)

- 75% of venture capital investment and startup activity is geographically concentrated - a rural bioeconomy can create new economic activity that **equitably distributes wealth and generates supply chain resilience**.
- The European Circular Bioeconomy Fund invests **€250 million** towards late-stage companies, **accelerating European startups to commercially compete globally**.
- China plans to expand its biological industry from **\$1.2T** to reach **\$1.6T** in 2020, effectively using **biomanufacturing as a pillar to build its economic power**.

The United States has a competitive portfolio of biomanufacturing companies:

- **Infrastructure** is needed to scale up production.
- **Bioeconomy VC funding** is needed to transform biotechnology and accelerate late-stage development.

This can be done in an **equitable, sustainable, and competitive** way to secure our economic resilience.

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General Questions:
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Membership Information:
membership@biomade.org



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A laptop screen displaying an aerial view of a lush green agricultural field with rows of crops. Overlaid on the image is the text 'BUILDING A SUSTAINABLE, DOMESTIC END-TO-END BIOINDUSTRIAL MANUFACTURING ECOSYSTEM' in white, bold, sans-serif capital letters.

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