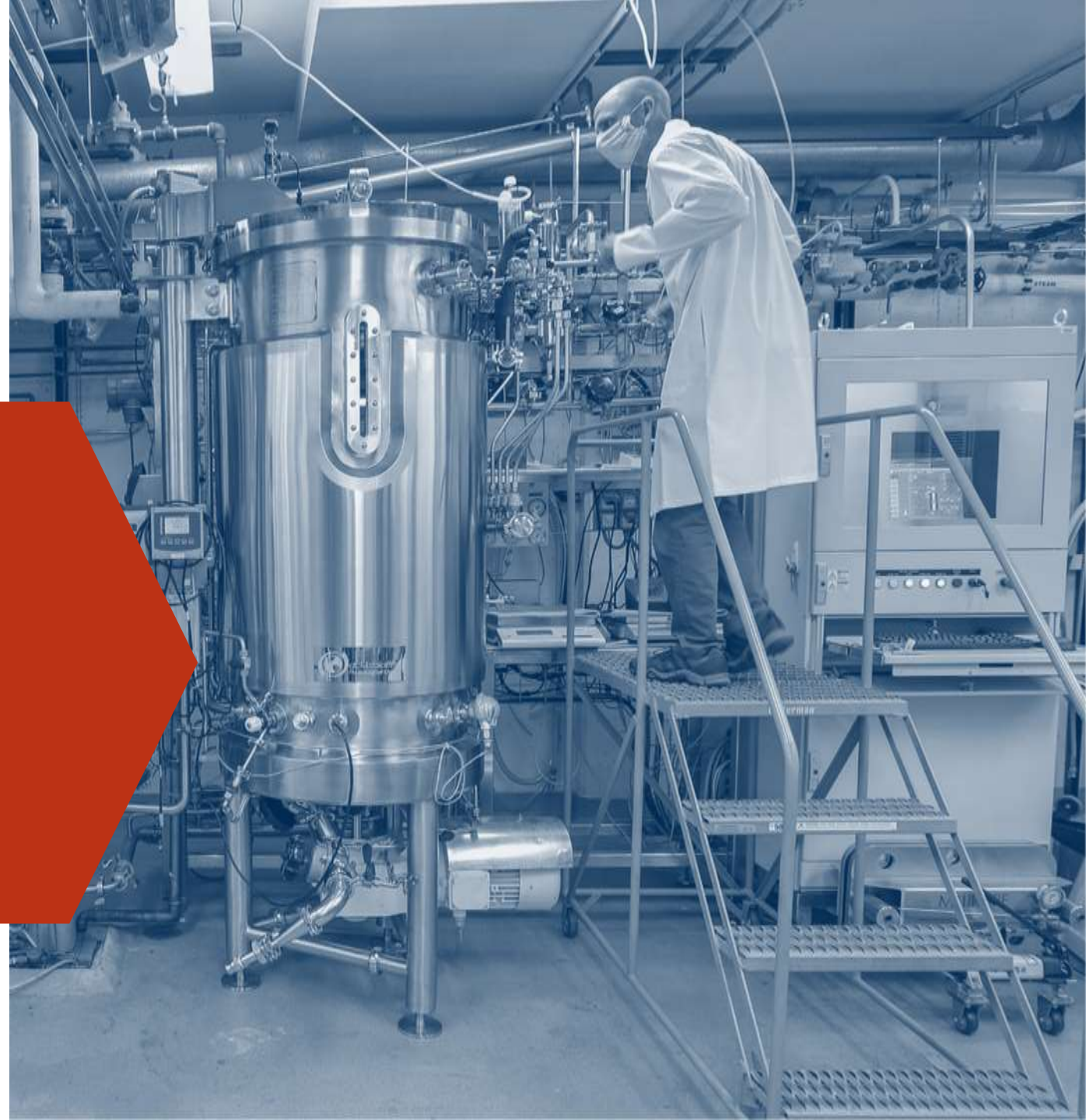
BioMADE

BioMADE: Building the U.S. bioindustrial manufacturing base



Doug Friedman

June 26, 2023

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

BioMADE: the Bioindustrial Manufacturing Innovation Institute

About Us

BioMADE launched in 2021 and is an independent non-profit, public-private partnership initiated 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 lab to market
- Creating resilient supply chains
- Enabling the workforce of the future

Vision & Mission

Vision

To build a sustainable, domestic end-to-end bioindustrial manufacturing ecosystem

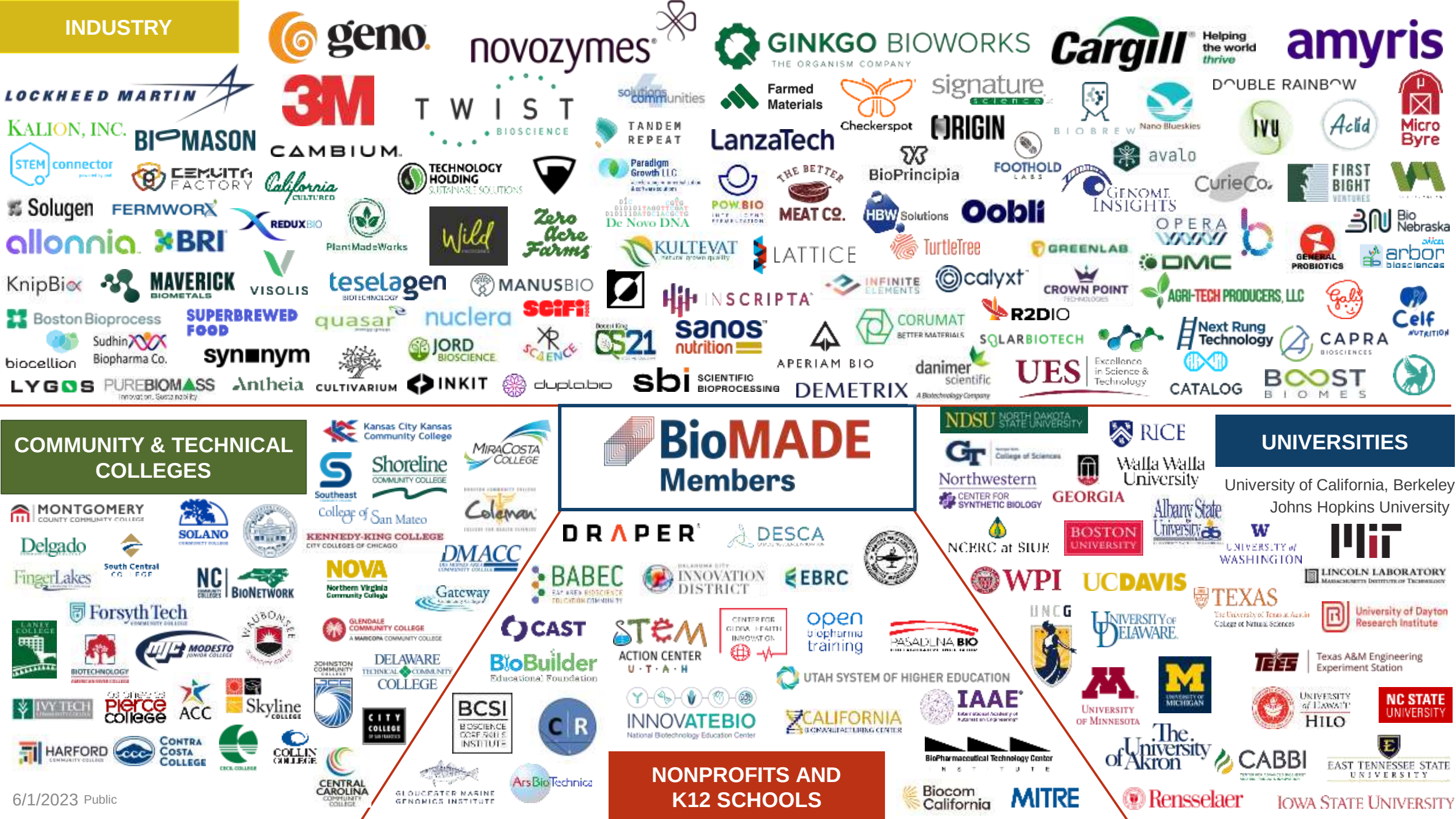
Mission

Our mission is to enable bioindustrial manufacturing at all scales, develop technologies to enhance U.S. bioindustrial competitiveness, de-risk investment in relevant infrastructure, and expand the bioindustrial workforce to realize the economic promise of industrial biotechnology

How BioMADE Accomplishes the Mission

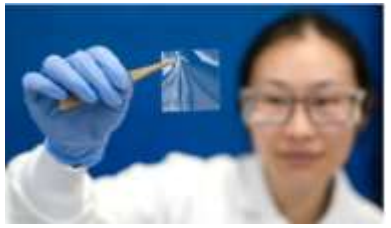
Strategies

- Create a dynamic member ecosystem
- Provide funding opportunities for members
  - *Technology & Innovation*
  - *Education & Workforce Development*
  - *4S – Safety, Security, Sustainability & Social Responsibility*
- Increase access to U.S. domestic scale up infrastructure


INDUSTRY
geno.
novozymes
GINKGO BIOWORKS
THE ORGANISM COMPANY
Cargill
Helping the world thrive
amyris
LOCKHEED MARTIN
KALION, INC.
BIOMASON
3M
CAMBIUM
TWIST BIOSCIENCE
solutions communities
TANDEM REPEAT
Paradigm Growth LLC
De Novo DNA
Farmed Materials
LanzaTech
Checkerspot
signature science
ORIGIN
BIOBREW
Nano Blueskies
DOUBLE RAINBOW
IVU
Acid
Micro Byre
STEM connector
CEMVITA FACTORY
California CULTURED
TECHNOLOGY HOLDING
SUSTAINABLE SOLUTIONS
POW.BIO
THE BETTER MEAT CO.
BioPrincipia
FOOTHOLD LABS
avalo
CurieCo.
FIRST BIGHT VENTURES
Solugen
FERMWORX
REDUXBIO
allonia
BRI
PlantMadeWorks
Wild
Zero Acre Farms
HBW Solutions
Oobli
GENOME INSIGHTS
OPERA
Bio Nebraska
arbor biosciences
GENERAL PROBIOTICS
DMC
KULTEVAT
LATTICE
TurtleTree
GREENLAB
KnipBio
MAVERICK BIOMETALS
VISOLIS
teselagen BIOTECHNOLOGY
MANUSBIO
SciFi
INSCRIPTA
INFINITE ELEMENTS
calyxt
CROWN POINT TECHNOLOGIES
AGRI-TECH PRODUCERS, LLC
Boston Bioprocess
SUPERBREWED FOOD
quasar
nuclera
R2DIO
CORUMAT BETTER MATERIALS
SOLARBIOTECH
Next Rung Technology
CAPRA BIOSCIENCES
Celf NUTRITION
biocellion
Sudhin Biopharma Co.
synonym
JORD BIOSCIENCE
OS21
sanos nutrition
APERIAM BIO
LYGOS
PUREBIOMASS
Antheia
CULTIVARIUM
INKIT
duplabio
sbi SCIENTIFIC BIOPROCESSING
DEMETRIX
danimer scientific
A Biotechnology Company
UES Excellence in Science & Technology
CATALOG
BOOST BIOMES
COMMUNITY & TECHNICAL COLLEGES
Kansas City Kansas Community College
MiraCosta College
Southeast
Shoreline COMMUNITY COLLEGE
College of San Mateo
Coleman
KENNEDY-KING COLLEGE
CITY COLLEGES OF CHICAGO
MONTGOMERY COUNTY COMMUNITY COLLEGE
SOLANO
Delgado
South Central
FingerLakes
NC BioNETWORK
DMACC
NOVA Northern Virginia Community College
Gateway
Forsyth Tech
GLENDALE COMMUNITY COLLEGE
A MARICOPA COMMUNITY COLLEGE
LANEY COLLEGE
BIOTECHNOLOGY
MODESTO JUNIOR COLLEGE
WAUBONSEE
JOHNSTON COMMUNITY COLLEGE
DELAWARE TECHNICAL COMMUNITY COLLEGE
IVY TECH
pierce college
ACC
Skyline COLLEGE
CITY COLLEGE
HARFORD
CONTRA COSTA COLLEGE
COLLIN COLLEGE
CENTRAL CAROLINA COMMUNITY COLLEGE
BioMADE Members
DRAPER
DESCA
BABEC
INNOVATION DISTRICT
EBRC
CAST
BioBuilder Educational Foundation
STEM ACTION CENTER U·T·A·H
CENTER FOR GLOBAL HEALTH INNOVATION
open biopharma training
PASADENA BIO
UTAH SYSTEM OF HIGHER EDUCATION
INNOVATEBIO
National Biotechnology Education Center
CALIFORNIA BIOMANUFACTURING CENTER
IAAE
BCSI BIOSCIENCE CORE SERVICES INSTITUTE
CR
BioPharmaceutical Technology Center INSTITUTE
GLOUCESTER MARINE GENOMICS INSTITUTE
ArsBioTechnica
NONPROFITS AND K12 SCHOOLS
Biocom California
MITRE
NDSU NORTH DAKOTA STATE UNIVERSITY
RICE
Northwestern
CENTER FOR SYNTHETIC BIOLOGY
Walla Walla University
GEORGIA
NCERC at SIUE
BOSTON UNIVERSITY
Albany State University
UNIVERSITY of WASHINGTON
WPI
UCDAVIS
LINCOLN LABORATORY
MASSACHUSETTS INSTITUTE OF TECHNOLOGY
UNCG
TEXAS
University of Dayton Research Institute
UNIVERSITY OF DELAWARE
TEES
Texas A&M Engineering Experiment Station
UNIVERSITY OF MINNESOTA
UNIVERSITY of MICHIGAN
UNIVERSITY of HAWAI'I HILO
NC STATE UNIVERSITY
The University of Akron
CABBI
EAST TENNESSEE STATE UNIVERSITY
Rensselaer
IOWA STATE UNIVERSITY
UNIVERSITIES
University of California, Berkeley
Johns Hopkins University


MycoComposite™ biobased packaging

ECOVATIVE DESIGN



zymergen

CRUZ FOAM

Cruz Foam Made From Shrimp Shells Could Help Keep Beaches Clean


Consumer packaging and shipping material


Biobased fire resistant materials

CAMBIUM BIOMATERIALS™

LanzaTech


Sustainable aviation fuel


JIVE Asphalt Rejuvenator

POET

bioMASON building with nature

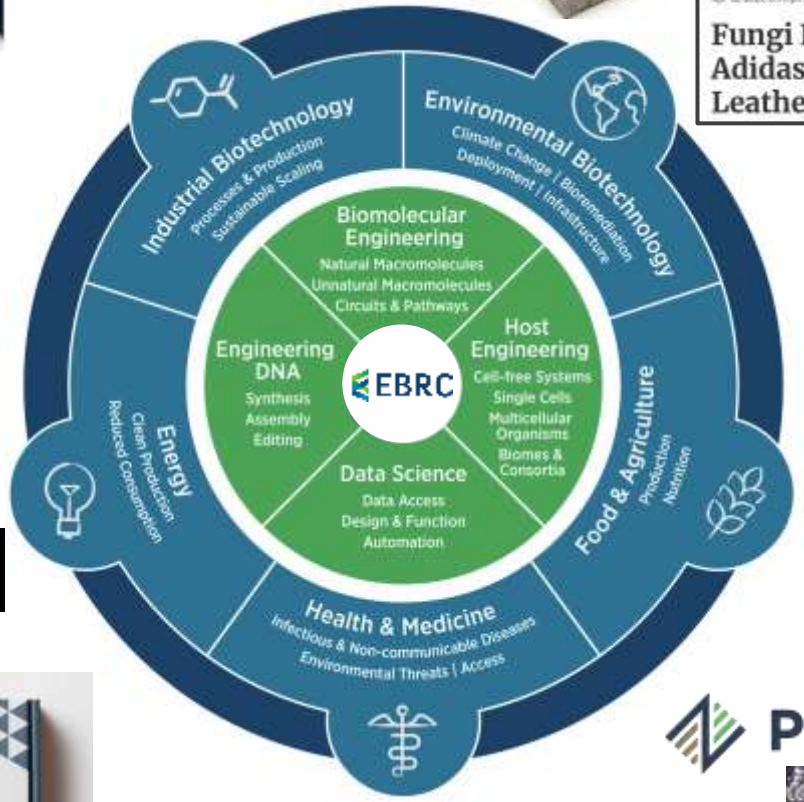

Sustainable building materials

BOLT THREADS

Fungi Fashion Is Booming As Adidas Launches New Mushroom Leather Shoe


Laundry pods made from industrial waste


Nitrogen-producing microbe for crops




Hermes x MycoWorks

Checkerspot


Cell Based Beef & Lamb

PIVOT BIO


microbial seed inoculant

indigo

MEMPHIS MEATS

Blood-based genomic profiling tests

FOUNDATION MEDICINE

GELTOR


Bioactive skincare

Cruelty-Free Beauty Products, Biodesigned In Silicon Valley


Perfect Day Fungi-Produced Dairy Proteins

What Can Bioindustrial Manufacturing Create?

Applications

- Carbon-negative chemicals that can be used for water treatment, concrete, fertilizers, and detergents
- PFAS alternatives and bio-based fire-resistant composite materials
- Bioplastics and durable fibers
- Chemicals used to make compostable tote bags, coffee capsules, and food packaging
- Growable cement and alternative natural rubber to make tires
- Proteins, probiotics, fragrances, and skincare products

bioMASON building with nature

Sustainable building materials

Perfect Day Fungi-Produced Dairy Proteins

Biobased fire resistant materials

Bioactive skincare

CAMBIUM BIOMATERIALS™

LanzaTech

Sustainable aviation fuel

Nitrogen-producing microbe for crops

microbial seed inoculant

Laundry pods made from industrial waste

Consumer packaging and shipping material

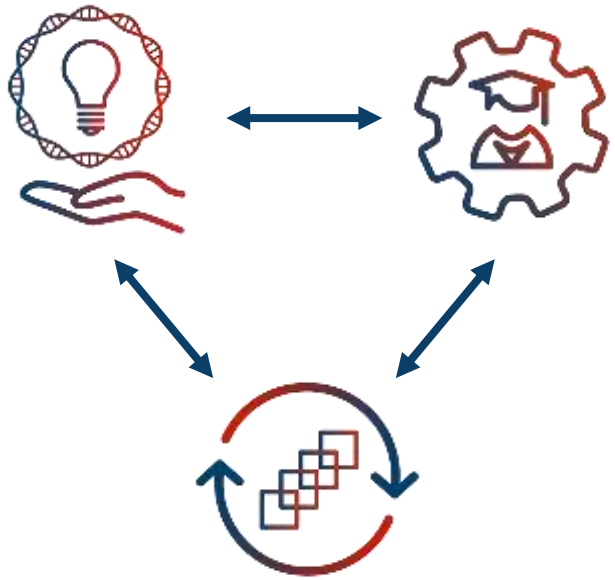
BioMADE Programs

Building a sustainable, domestic, end-to-end bioindustrial manufacturing ecosystem

Member Group Amyris

BioMADE

BioMADE Works Across Three Program Areas



BioMADE Projects

BioMADE co-invests with its members to advance projects in each of these three interconnected areas:

- 45 projects
- 58 members engaged in projects
- Project work in 16 states
- Over $100MM in funded work

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

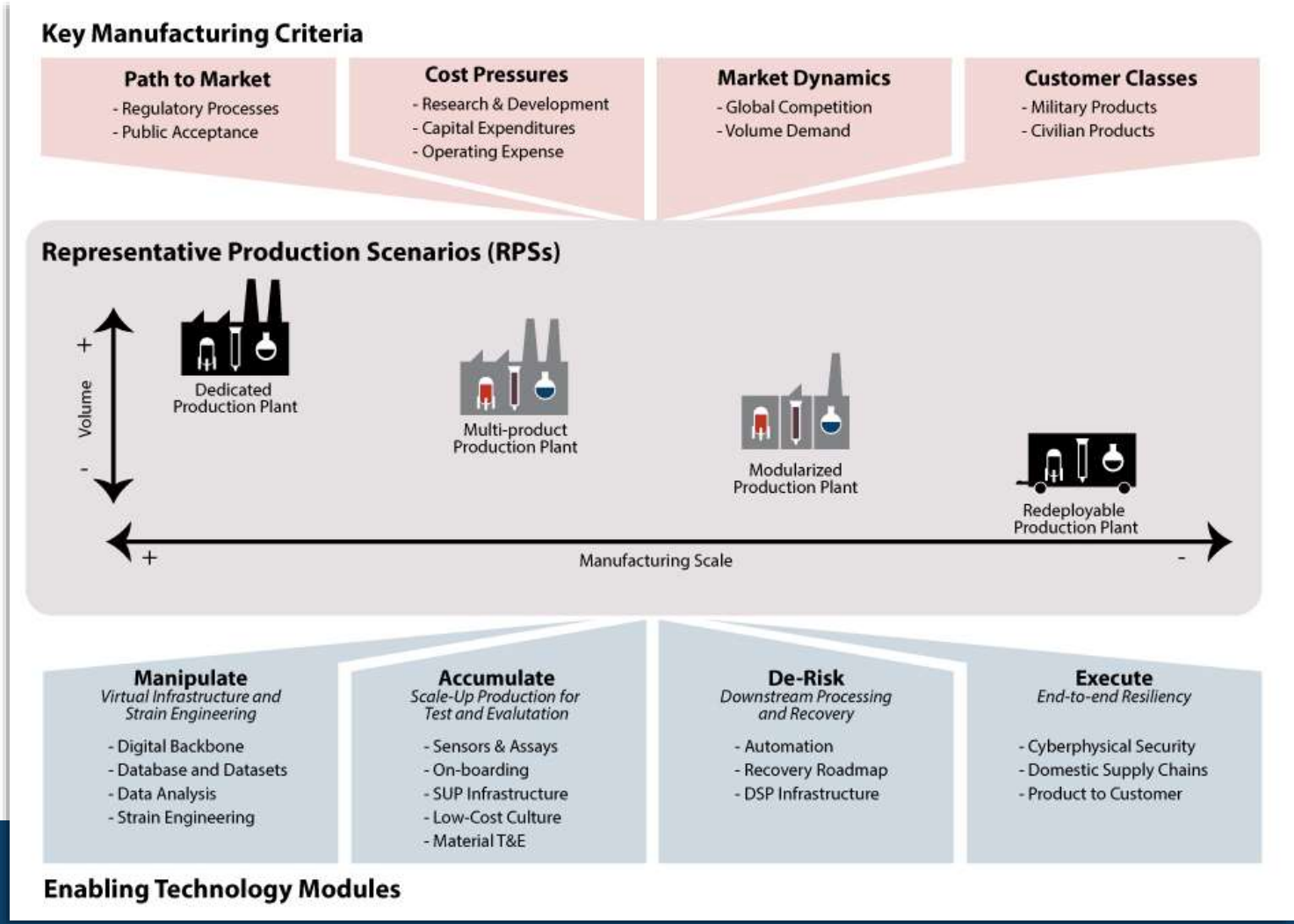
Focus on strengthening capabilities at Manufacturing Readiness Levels (MRLs) 4-7

Focus Areas

- Data and Design
- Scale up
- Downstream Processing
- Testing and Evaluation
- Resilient Bio-Manufacturing Ecosystem
- Commercial Readiness

BioMADE Technical Roadmap

Representative Production Scenarios



Selected Technology & Innovation Projects

Tandem Repeat is scaling upstream and downstream processes for producing Squitex, a sustainable high-performance fiber

PC: Tandem Repeat

Goodyear and **Farmed Materials** are accelerating commercialization of a domestic source of natural rubber sourced from TK dandelions

PC: Farmed Materials

PC: Farmed Materials

Selected Technology & Innovation Projects

Development of a Continuous Taylor Vortex Fermentor-Extractor-Separator

IOWA STATE UNIVERSITY

- This project will provide a flexible, modular, and redeployable bioreactor design that integrates product extraction and separation into the bioreactor itself.
- Researchers will develop a novel continuous-flow bioreactor-extractor-separator based upon Taylor vortex flow for use in small-volume, re-deployable production plants.

Accumulation of a Direct Precursor to Acrylic Acid from Dairy Waste Fermentation

MicroByre

- This project will leverage a previously un-engineered bacterium that consumes several unrefined byproducts from the dairy industry to generate a cheap and sustainable alternative to displace petroleum-based propylene as the feedstock used to make acrylic acid.

Stress Testing Supply Chains and their Ecosystems

Georgia Tech College of Sciences

- This project will design a simulation platform to stress test end-to-end bioindustrial manufacturing facilities and supply chains resiliency for levels of trust, security, resilience, agility, and competitiveness.
- Researchers will evaluate various bioindustrial supply chain risks, cost, productivity, and other performance metrics of interest to firms in the industry.

Education and 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.

Focus 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

Selected EWD Projects

ALAKA'I: Applied Life-Science Academy: Knowledge Advancing Industry

- The ALAKA'I project establishes a Hawaiian bioeconomy academy to develop industry-relevant training for delivery in Hawai'i and across the United States.
- The project will draw on traditional Hawaiian and Pacific Island cultural perspectives to provide insights and guiding principles for effective sustainability.

Regional Partnerships for Training the Biomanufacturing Workforce in Worcester, MA

- This project will launch an after-school program focused on training students for biomanufacturing careers.
- This program will be credit-bearing, industry-informed, and based on the successful Innovation Pathways framework through Worcester Public Schools.

Bioreactor Education, Setup, and Training (BEST)

- This project will increase access to advanced training and equipment for bioindustrial manufacturing, giving more students the appropriate training they need for careers in the industry.
- This project will develop a cost-effective DIY bioreactor with all the functionality of a commercially available, far more expensive bioreactor.

- 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

Zooming Back Out

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

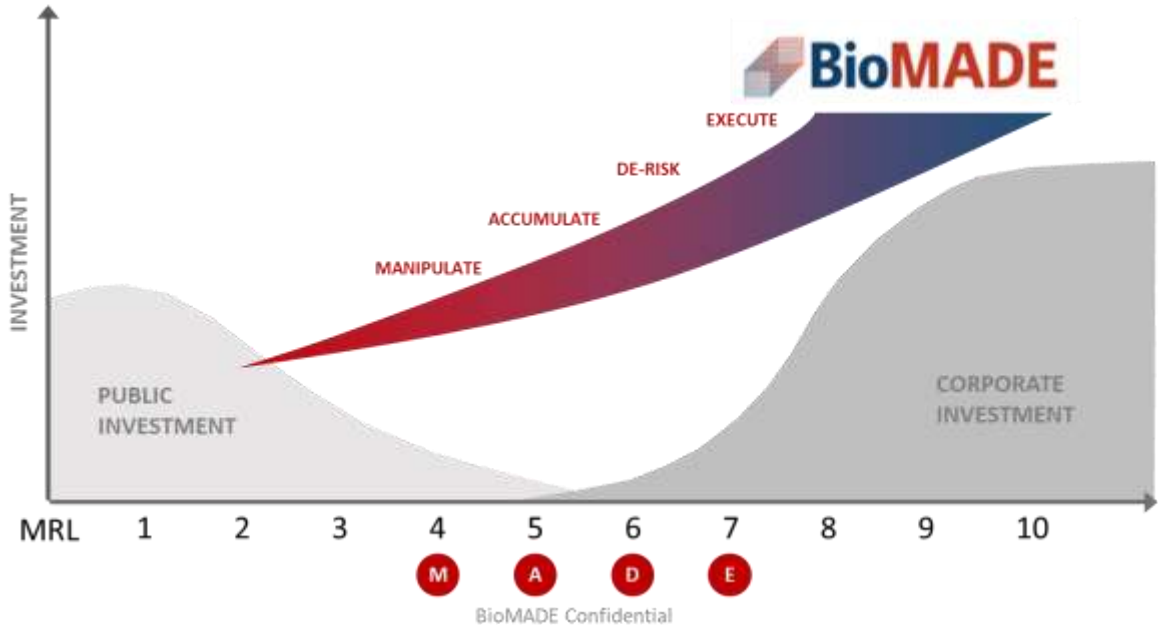
- *food production technologies (fermentation, downstream processing equipment),*
- *personal care (detergent enzymes, ingredients)*
- *traditional chemical production (distillation, semisynthesis, downstream catalytic conversion)*

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*

Biotech Commercialization is Challenging

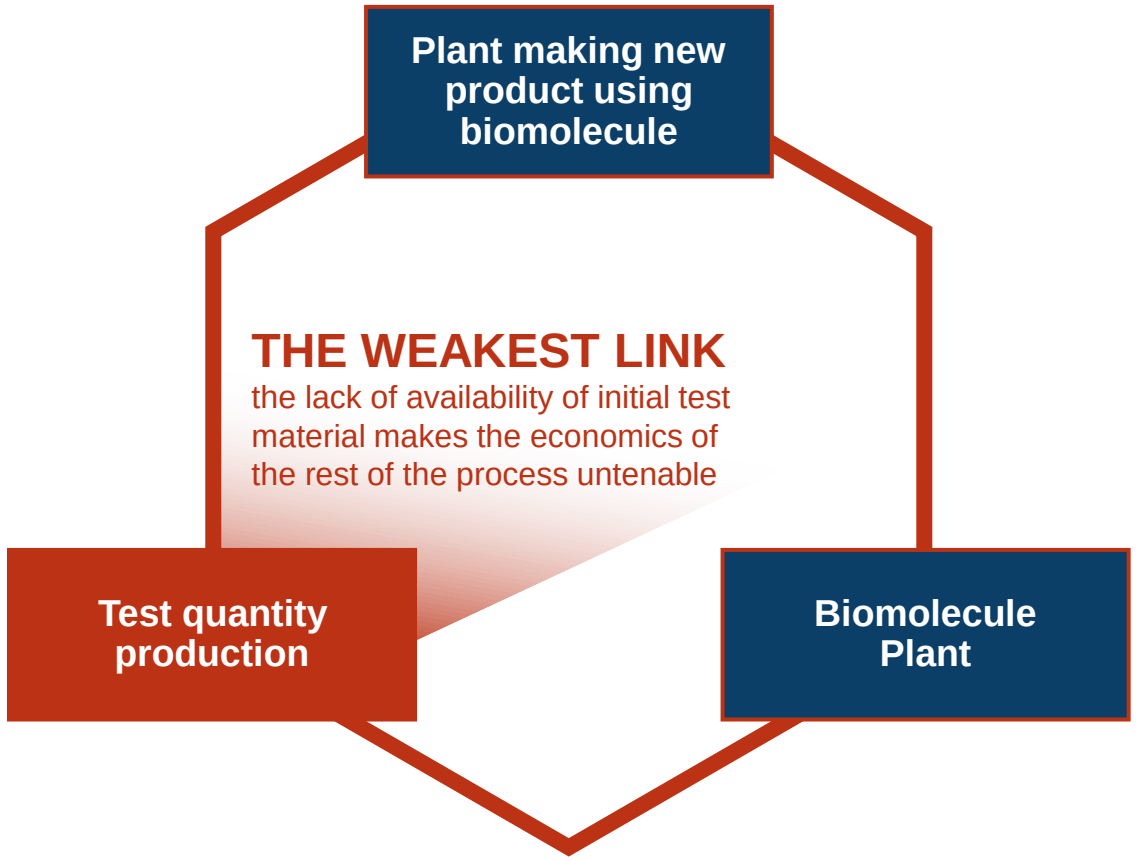
- The Valley of Death is wide
- Too applied for academia … too risky for industry
- Uncertainty in tech, production costs and markets hinders investment
- “Language barrier” between innovators and capitalists
- Startups unsure how to proceed with future R&D and business strategy



–Odds of success:1/5000 to 1/10000

Reduction of the Triple Capital Threat

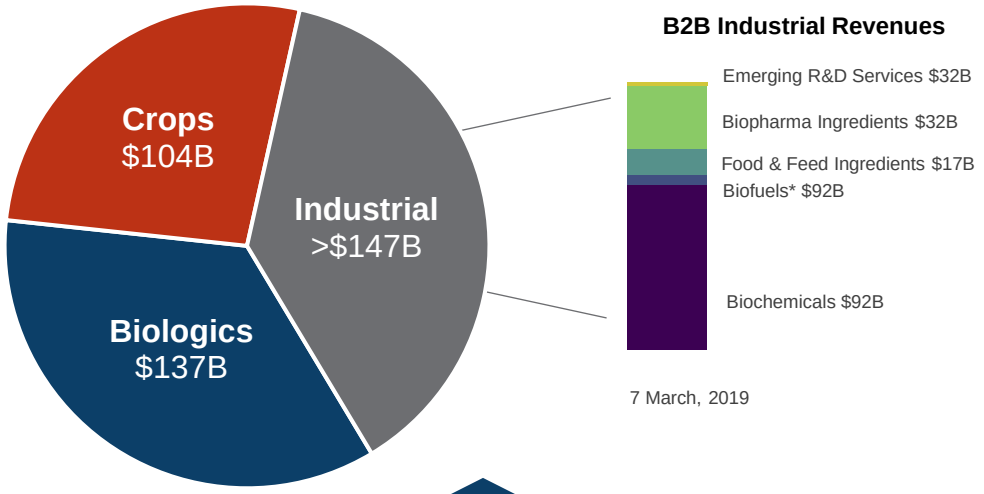
- The capital needed to make sufficient test quantities of the biomolecule (often tons)
- The capital needed to modify or build product facilities that incorporate the biomolecule (for instance using a new biomolecule to make a new fiber)
- The capital needed to modify or build a biomolecule production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



Opportunity to Accelerate a Strong Domestic Bioeconomy

Estimated 2017 U.S. Biotechnology Revenues: At Least $388 Billion, or 2% of GDP

(Sources: Bioeconomy Capital, Agilent)



U.S. Bioeconomy

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

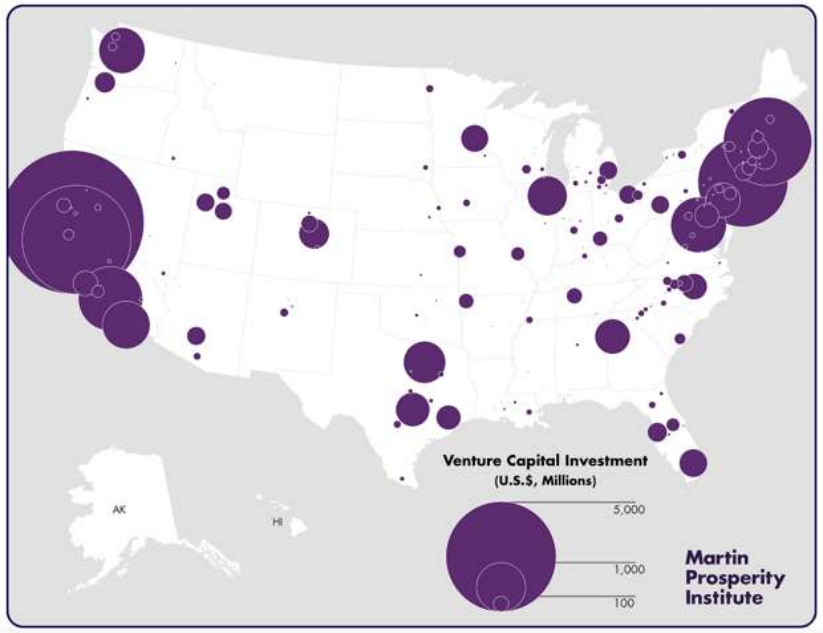
U.S. Strategic Bioeconomy Assets

- **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.

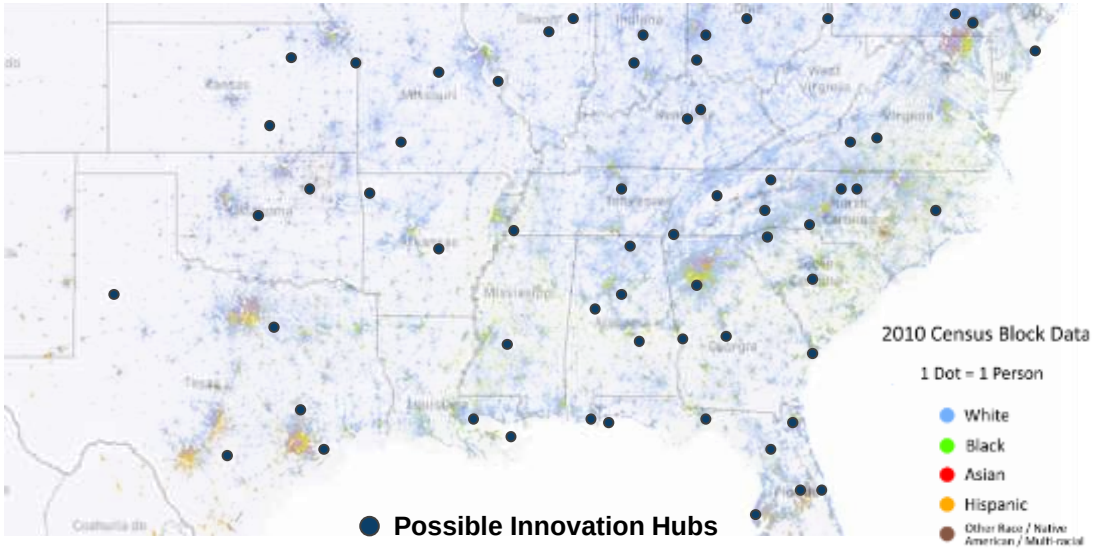
U.S. Bioeconomy is Robust and Growing

- **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.

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/)

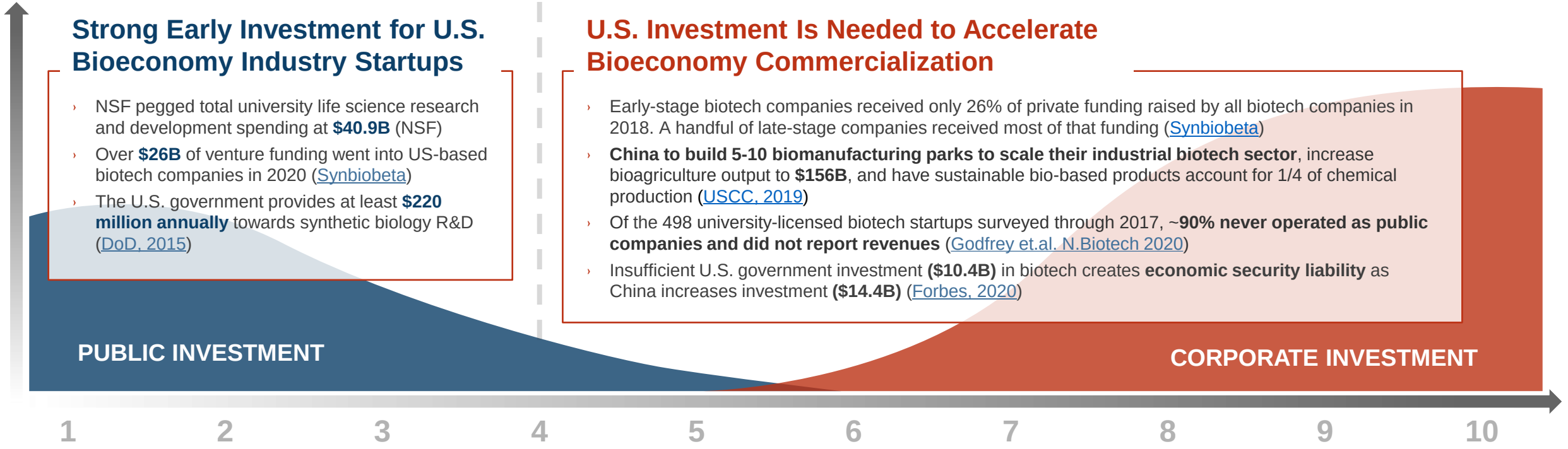
Investment is Needed to Accelerate Bioeconomy Commercialization

Strong Early Investment for U.S. Bioeconomy Industry Startups

- NSF pegged total university life science research and development spending at **$40.9B** (NSF)
- Over **$26B** of venture funding went into US-based biotech companies in 2020 (Synbiobeta)
- The U.S. government provides at least **$220 million annually** towards synthetic biology R&D (DoD, 2015)

U.S. Investment Is Needed to Accelerate Bioeconomy Commercialization

- Early-stage biotech companies received only 26% of private funding raised by all biotech companies in 2018. A handful of late-stage companies received most of that funding (Synbiobeta)
- **China to build 5-10 biomanufacturing parks to scale their industrial biotech sector**, increase bioagriculture output to **$156B**, and have sustainable bio-based products account for 1/4 of chemical production (USCC, 2019)
- Of the 498 university-licensed biotech startups surveyed through 2017, ~**90% never operated as public companies and did not report revenues** (Godfrey et.al. N.Biotech 2020)
- Insufficient U.S. government investment **($10.4B)** in biotech creates **economic security liability** as China increases investment **($14.4B)** (Forbes, 2020)



U.S. Investments that Enabled Bioeconomy Startups

3 Bioenergy Research Centers (DoE)	Increased Venture Capital	SynBERC (NSF)
Living Foundries (DARPA)	Somatic Cell Genome Editing (NIH)	Agile Biofoundry (DoE)
URoL - Syn Cell (NSF)	Cell Manufacturing (NSF)	Center for Biorenewable Chemicals (NSF)

U.S. and Foreign Biotech Commercialization Efforts

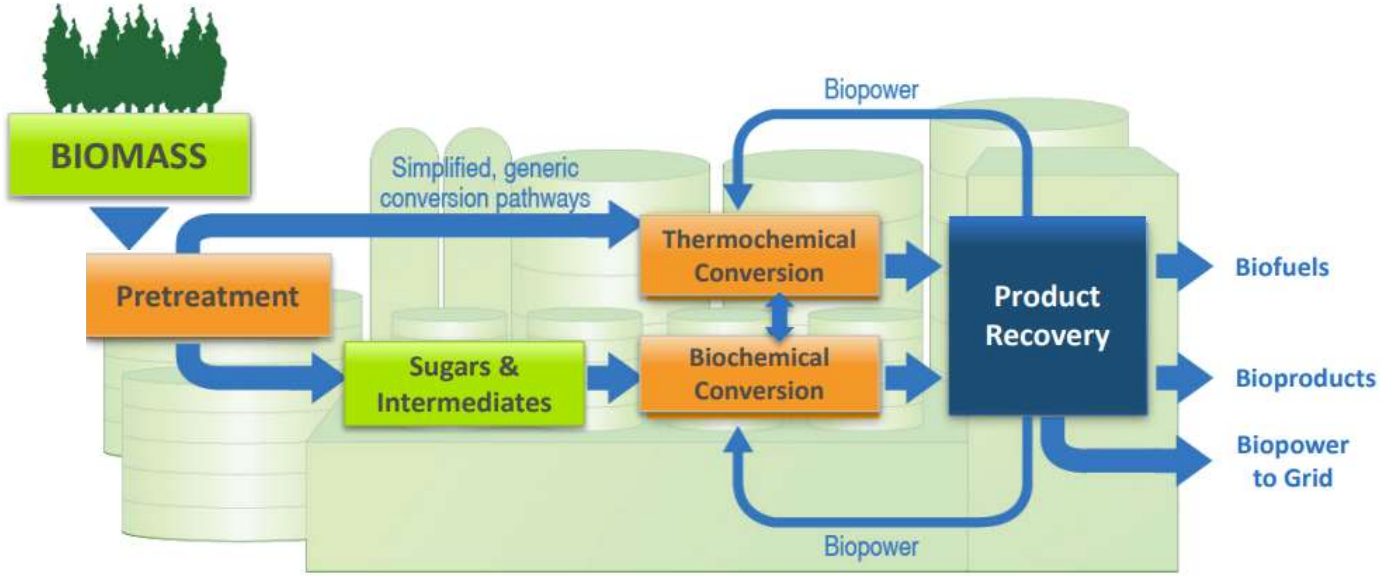
BioMADE (USA)	National Biologics Manufacturing Centre (UK)	Pilots4U (EU)
Industrial Biotechnology Innovation Centre (UK)	Shared Pilot Facilities (EU)	BioFabUSA (USA)
NIIMBL (NIST)	Biotechnology Innovation Platforms (CN)	Institute of Synthetic Biology (CN)

BioMADE

From Farm to Manufacturing Floor

Building in Feedstocks

- Biomass preprocessing and feedstock utilization has not always been directly linked to bioindustrial manufacturing.
- Farmers and manufacturers need a clear and reliable understanding of the full value chain to maximize utility for all.
- Technology improvements for moving, storing, and processing biomass can benefit the bioindustrial manufacturing sector.



Key Challenges			
Biomass	**Pretreatment**	**Conversion**	**Product**
• Reliable supply • Consistent quality • Affordable delivery	• Biomass feeding, sizing and moisture • Solids handling • Construction materials	• Products Yields • Construction materials • Catalysts • Fermentation organisms	• Separations • Catalytic upgrading • Recycle loops

Source: U.S. Department of Energy Bioenergy Technologies Office

BioMADE is Developing New Feedstocks for Bioindustrial Manufacturing

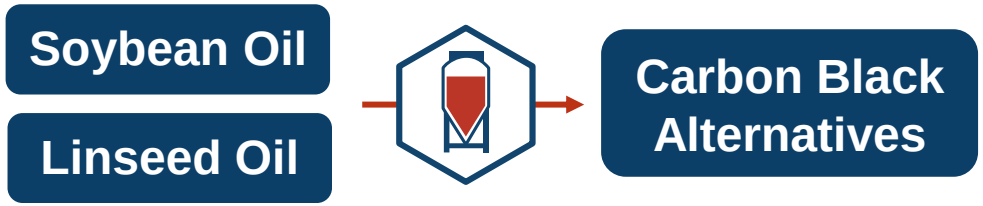
Valorizing Dairy Waste

Bio-based alternatives to petroleum-derived acrylic acid

MicroByre

New Uses for Plant Oils

Light-weight and eco-friendly composites for aerospace, automotive, and other applications



AGRI-TECH PRODUCERS, LLC

The University of Akron

Biomanufacturing Hubs Support Rural Development

Case Study: **Iowa Bioprocessing Center** (Eddyville, IA) – 2016 Estimates

Commercial hub for manufacturing legacy products; no pilot facility (not innovation-focused)

Commercial Production at Bioindustrial Manufacturing Complex

90M bushels corn

↓

5 companies

↓

Value-added products

Starch	Lysine
Sweetener	Food and feed supplements
Alcohol	
Corn oil	Pharma products
Gluten meal	

Nearly 100 Million Bushels of corn generate **Billions of $ in Output** and **1,000s of Jobs**

54% more earnings for workers at the Center than the regional norm

$1-5M in premiums to local farmers for reduced feedstock transport costs

		Jobs	Labor Income	Value Added	Output
Economic impacts for 3-county region	Direct	822	$ 56.6 M	$ 177.6 M	$ 1,792.8 M
	Indirect	2,085	$ 95.6 M	$ 157.5 M	$ 375.5 M
	Induced	700	$ 21.6 M	$ 40.2 M	$ 73.5 M
	Total	**3,608**	**$ 173.8 M**	**$ 375.3 M**	**$ 2,241.8 M**

Table and information reproduced from *Estimating the Economic Impact of the Iowa Bioprocessing Center in Eddyville, Iowa by* Dave Swenson, Associate Scientist, Department of Economics, Iowa State University (April 2016)

U.S. Government is Prioritizing Bioeconomy and Biomanufacturing

August 2022


TITLE IV—BIOECONOMY RESEARCH AND DEVELOPMENT

CHIPS and Science Act

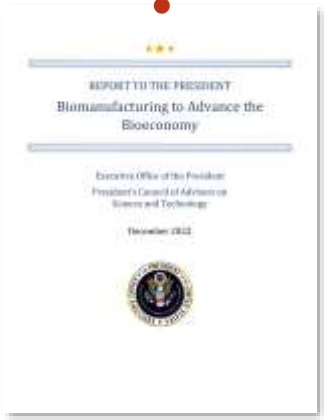
September 2022


Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy

Executive Order

White House Summit

December 2022


REPORT TO THE PRESIDENT
Biomanufacturing to Advance the Bioeconomy

PCAST Report


SEC. 213. SUPPORT FOR RESEARCH AND DEVELOPMENT OF BIOINDUSTRIAL MANUFACTURING PROCESSES.

FY23 NDAA

March 2023


BOLD GOALS FOR U.S. BIOTECHNOLOGY AND BIOMANUFACTURING

Bold Goals Report


U.S. Department of Defense Biomanufacturing Strategy

Defense Biomanufacturing Strategy

BioMADE Infrastructure

Establishing a Network of Pilot Innovation Facilities

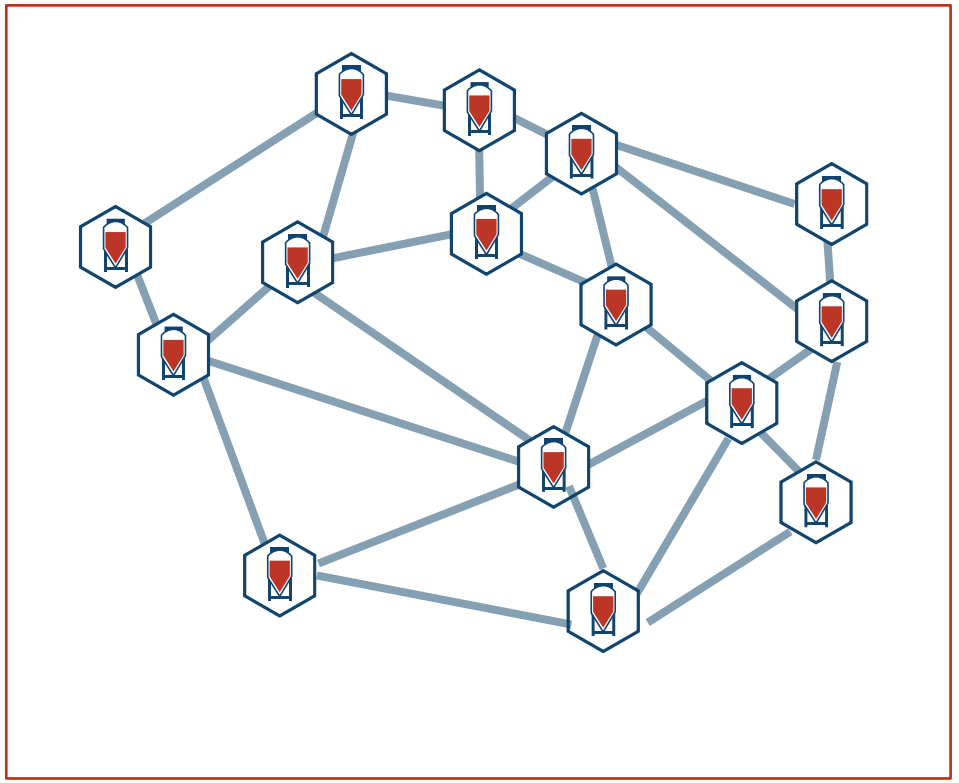
BioMADE

Growing Domestic Scale Up Infrastructure

Facilities Overseas

Domestic Need

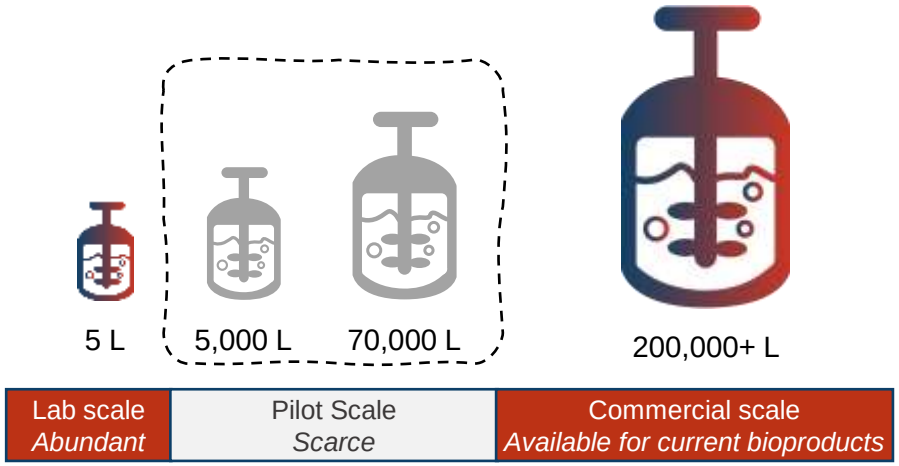
Vision for BioMADE Network in the U.S.



The Domestic Scale-Up Infrastructure Gap

Today, a gap in domestic pilot-scale infrastructure is filled by going overseas

Lack of domestic scale-up facilities *forces* U.S. innovators to look elsewhere to scale or manufacture their biotechnology products



An Existing Network of National Pilot Facilities

An Exemplar Pilot Plant

Facility needs

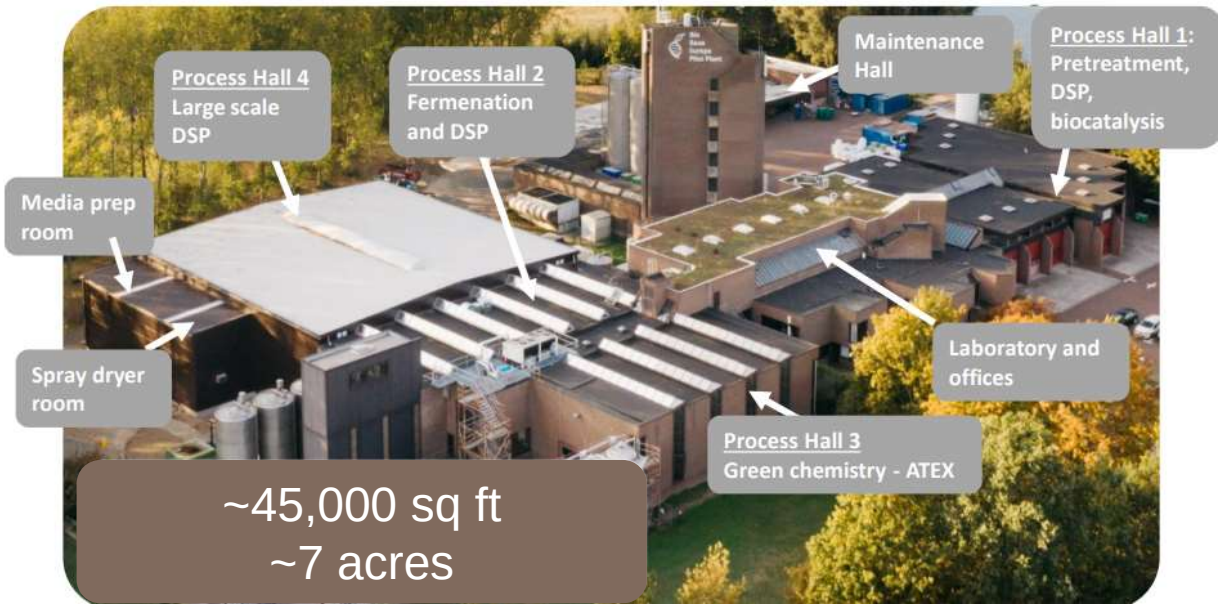
- Intermediate scaling capabilities (5K to 50K liters)
- Suites of flexible downstream processing unit operations
- Reliable feedstocks
- Robust prototyping and analytical capabilities
- Market making and market pull partnerships

Products

Focus on products that meet defense needs

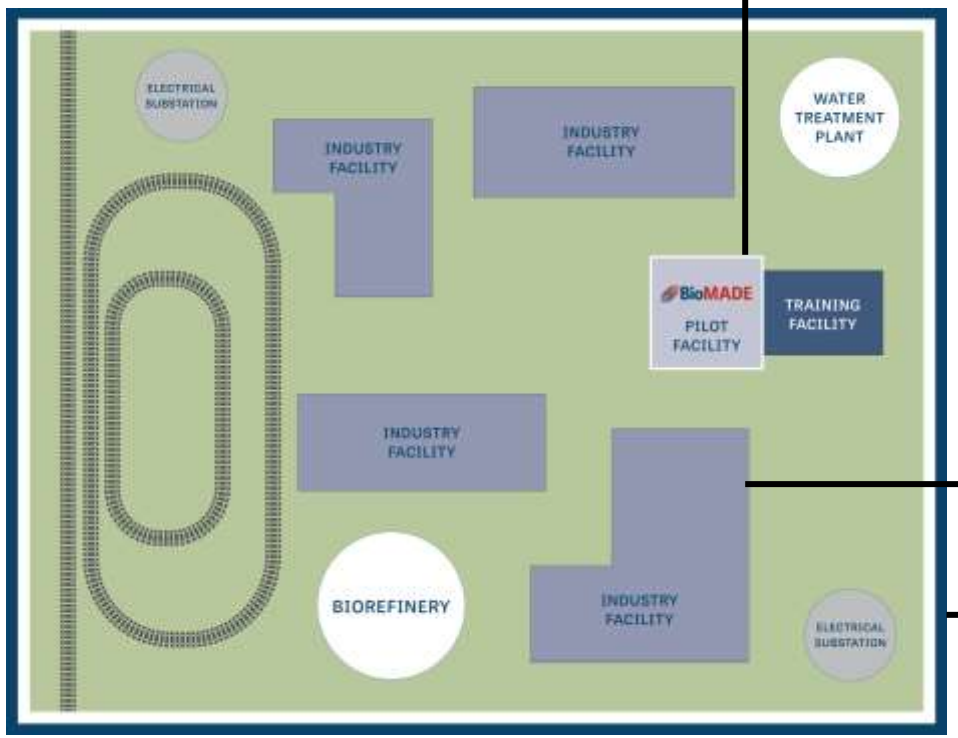
Top Product Examples
Melanin
Biomanufactured motor oil
Bacteria that secrete calcium carbonate
Squitex fibers

Example of flexible pilot facility layout



Example Campus Model: Pilot Facilities Seed Biomanufacturing Hubs

Initial pilot facility



Fermenters at Bio Base Europe with volumes of 100 L, 4,500 L and 15,000 L.

Private investment in commercial facilities
Relevant utilities, partnerships, workforce availability, and business conditions drive private business to co-locate with pilot plant

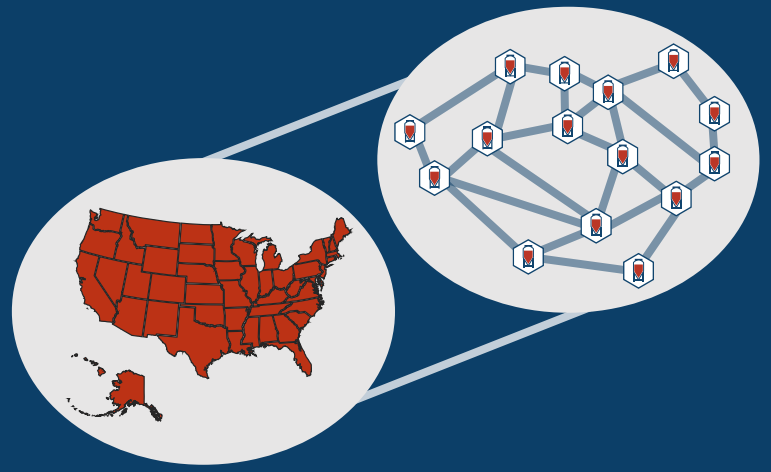
Commercial biomanufacturing park
Creates jobs and brings revenue to state and local community

350 Acre Core | Cargill Campus Blair, NE

BioMADE is Establishing a National Network of Bioindustrial Manufacturing Pilot Innovation Facilities

Respond to the Request for Statements of Interest with ideas for potential facilities

Building a network of 12-15 bioindustrial manufacturing pilot innovation facilities located across the United States



Key Deliverables for the Network

- Provide scale-up process development and pilot-scale to intermediate-scale manufacturing services to catalyze the bioindustrial manufacturing base
- Contribute to local jobs and economic development
- Advance U.S. economic, national security, and sustainability goals

Access the Request for Statements of Interest: https://www.biomade.org/infrastructure-statements

Site Selection & Facility Development

- Facilities will interoperate in a network and can offer unique capabilities and leverage local or regional strengths
- Facility development may involve partnerships spanning industry, educational institutions, government, and other stakeholders
- Plans for co-located private commercial development can be optionally included but are not required
- Approach to co-investment and access to state and local incentives may influence facility placement