INTERBIOME

Transforming Bio-Manufacturing

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What We Do - Highlights

Transforming biologics manufacturing

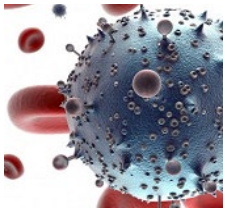
- Large, underserved market - >$12 billion per year in the USA alone
- Wait times for challenging bio-manufacturing slots ~18 months
- $2 million in pre-existing assets secured
- Management team possesses extensive business, regulatory, and marketing experience
- First facility ready in 9-12 months

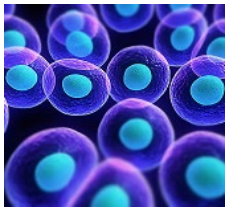
What We Do: Biologics

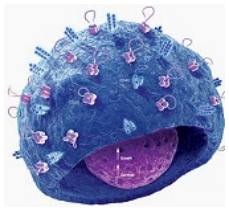
The Interbiome Biologics Division solves demanding, difficult, bio-manufacturing tasks. We provide cGMP-quality manufacturing of mammalian-cell-line, biologic Investigative New Drugs (INDs) in a BSL-3 ready facility.

Example products :


Vaccines


Gene Therapies


Stem Cells


Monoclonal Antibodies

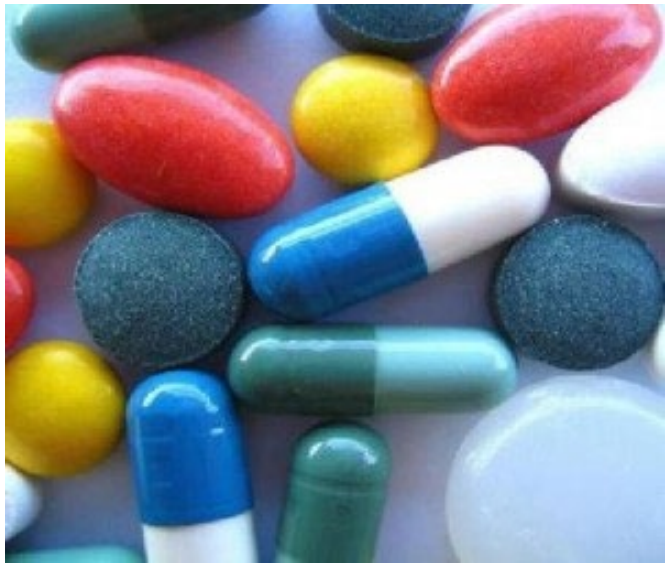

Immunotherapy


Spores

If you have an FDA license to use an "IND" in clinical trials, we have a biologics-manufacturing time slot available, and we can find a way to scale up and manufacture the product you want to deliver.

What We Do: Abandoned Drugs

The Interbiome Drug Shortage Division provides bulk manufacturing of off-patent drugs “abandoned” by pharma firms as low margin, yet still required by clinicians, for persisting, rare or off-label patient needs, starting with oncology drugs of last resort. *(Small-molecule drugs as well as biologics.)*



If you have an “abandoned” drug you wish to retain access to, we can arrange commercial manufacturing of the small-molecule or biologics product you need.

First Bio-Manufacturing Facility

Founded: 2016
Headquarters: Rockville, MD
Business Model: Contract-Driven Bio-Mfg

State of Facility:

- 1100 sq ft labs/clean rooms
  - 2 large clean rooms: cell culture, production
  - Both with Single-Pass, HEPA-filtered airflow
- 3000 sq ft office/conference rooms
- Pre-built BSL-3 capable facility
- HVAC already in place
- Undergoing mostly cosmetic remodeling
- Clean rooms pre-built
- Ample facility space
- 9-12 months for 1st facility regulatory validation

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Management

Strong lifescience research/industry/patient advocacy relations and deep experience in lifescience systems, GMP facility management, bio-process development and health product sales and marketing.

Roger Erickson *CEO & Founder*

Entrepreneur and neuroscientist with 40 years of experience in lifescience research and human systems coordination. BA Reed College; PhD SUNY/Buffalo

Andra Miller *Sr. VP QA & Regulatory Affairs*

Entrepreneur & molecular biologist with 20 years of experience in lifescience research, FDA audits, and bio-process consulting. BS/PhD GWU.

Peter Probst *Sr. VP Quality Systems*

With 40 years of experience in lifescience research, FDA facility audits, and facility process consulting. BA Catholic University.

Dan Miller *Sr. VP Marketing*

Entrepreneur with 20 years of experience in health-IT product & services marketing & development. BA Brandeis University.

INDUSTRY CHALLENGES

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The Problems

- Biologics manufacturing remains a under-optimized industry, with **lagging capacity, high construction & facility operation costs, costly failures**, & local/global supply-chain optimization needs

- Growing **capacity crunch** based on multiple factors:
  - Inadequate physical biologics-CMO capacity (high cost-basis)
  - Team training delayed by facility shortage

- **Neglected internal logistics** limit CMO margins

- **Neglected external logistics limit CMO productivity**
  Patient advocates, scientists and clinicians wait far too long to consult with GMP-manufacturing and other expert stakeholders
  - Adding to **costs, delays and failures**

Blockers to Drug Development

BLOCKER #1:

Client wants an FDA "IND" license to run a Clinical Trial on human subjects.

- When introducing a new biologics drug, a CMO is not immediately available to provide reliable Process Development and scale-up services.

- Client: *"We need this work done immediately, without failures or delays, to prove that the biologics drug we designed can be made to cGMP and clinical requirements."*

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Blockers to Drug Development

BLOCKER # 2:

A drug candidate has finally been awarded FDA IND status. A Phase 1 (or 2 or 3) clinical trial site partner has been negotiated and the trial has been scheduled.

- A company is not immediately available to successfully manufacture the experimental drug to cGMP standards.

- Client: *"We need a CMO to immediately provide the manufacturing capacity needed for a multi-million dollar trial."*

Blockers to Drug Development

BLOCKER #3:

Extremely costly process development and manufacturing failures occur, delaying or even preventing market introduction of new drugs.

- The return on investment for reducing errors, delays and failures is exceptionally high.

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Blockers to Drug Development

BLOCKER # 4:

Those who suffer from rare illnesses cannot access desperately needed therapeutics.

- More than 7500 rare diseases are now defined, with approximately two new rare diseases defined each month
- Patient advocacy groups are driving the most - and fastest - change in Public Health policy
- Only ~1100 patient advocacy groups have been formed; there is a huge organizational backlog for defining and producing needed new therapeutic variants

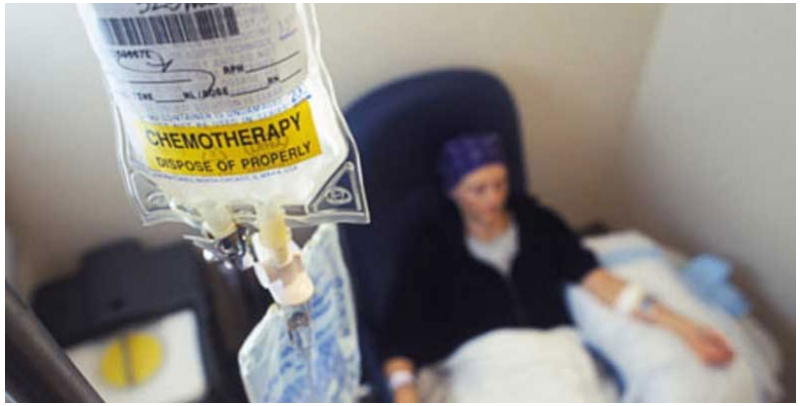
Plus, there is no clear border between rare diseases and personalized medicine. A beneficial tsunami of market segmentation is coming, since progress in rare/personalized health insights drives discovery of new leads for diverse, new therapeutic applications.

Blockers to Drug [Availability]

BLOCKER #5:

A drug still required for care of particular or diverse patients has been abandoned by a pharma company.

- Who will now manufacture this much-needed, off-patent product?
- Abandoned oncology drugs of last resort are a particular need, yet so are off-label prescription drugs for patients with diverse needs.



The “abandoned drug” market guarantees mfg income against the ups and downs of IND bio-manufacturing, and also solves a humanitarian need.

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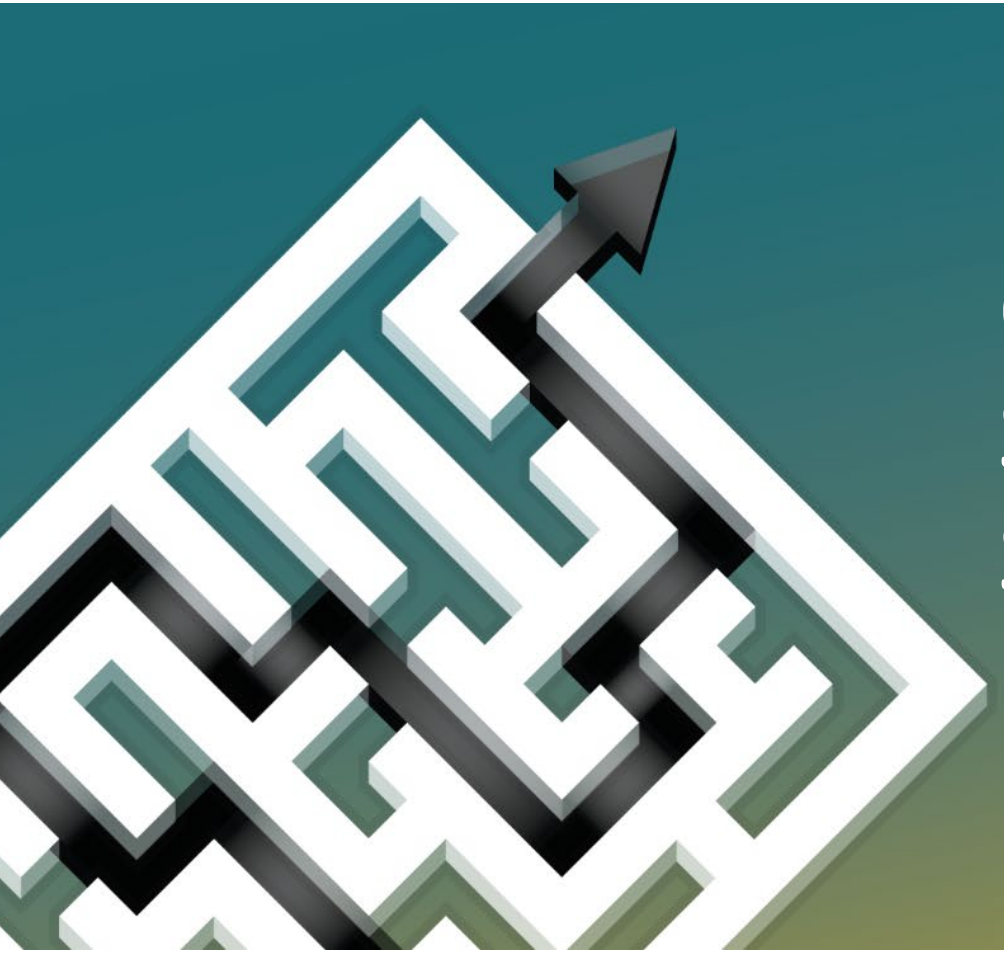

OUR SHORT-RANGE SOLUTIONS

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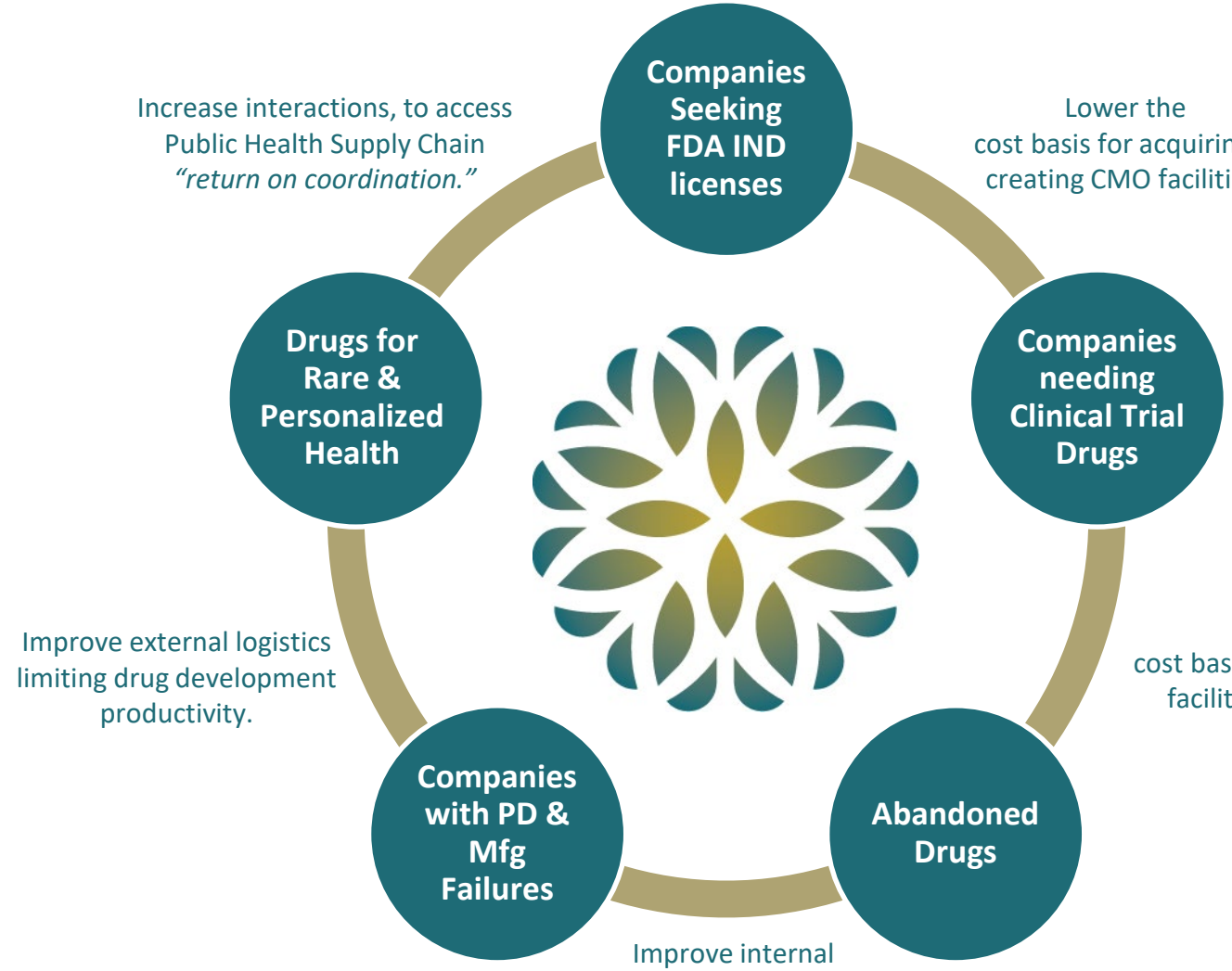
Challenges & Opportunities



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Interbiome Product Overview

First Facility

- Secure spaces for receiving, material, quarantine, QA records, and product storage
- Lab area for process development (PD)
- 1 clean room for GMP cell culture
- 1 clean room for BSL-3 GMP bio-mfg
- QC lab for environmental assays
- Ample room to add more clean rooms
- Conference rooms and offices for client consulting
- HVAC for single-pass, HEPA-filtered airflow
- Generator backup power

Services

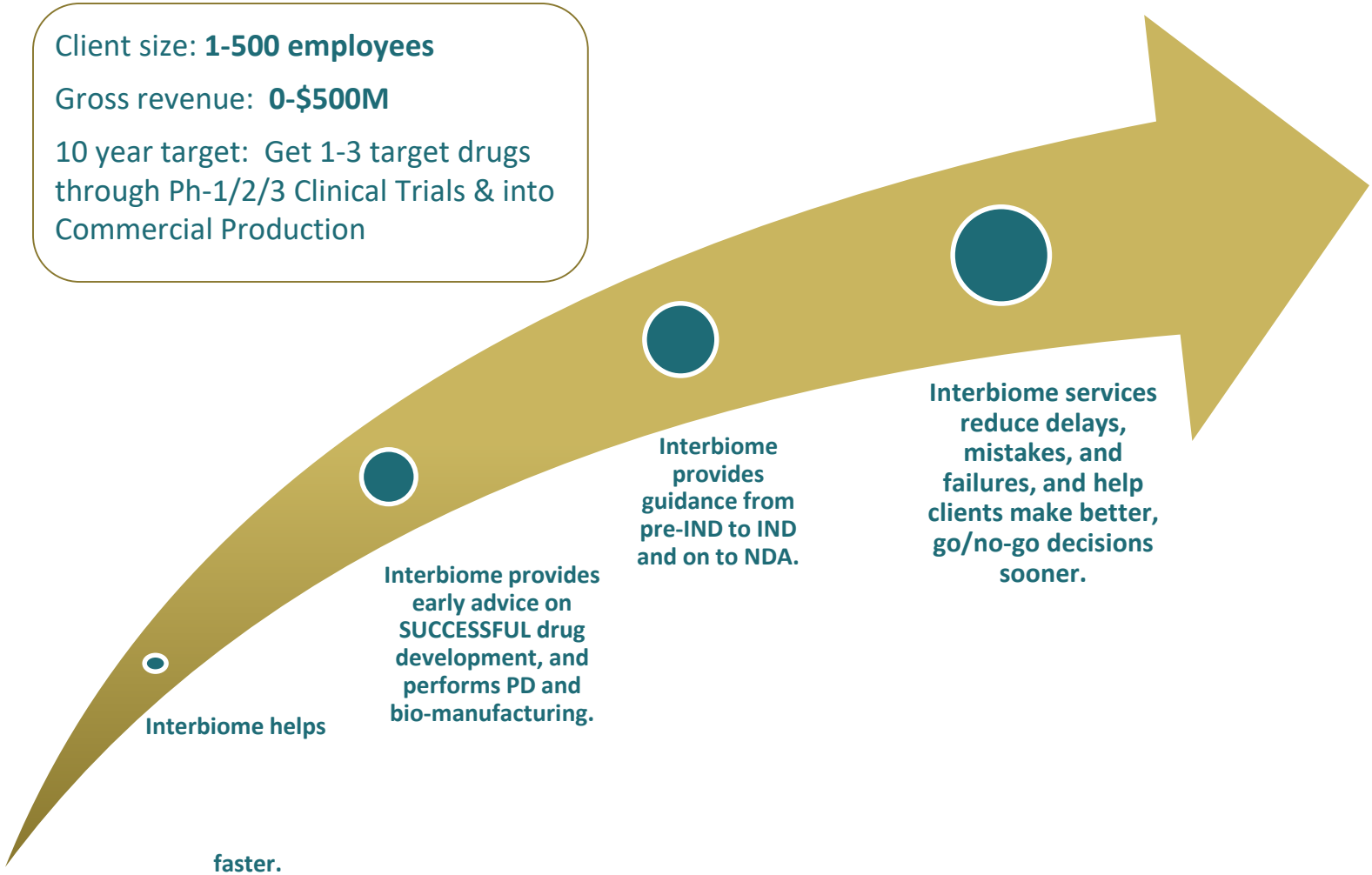
- Consulting with clients for IND applications
- PD and scale-up services for pre- and post-IND applications
- Process optimization
- Master cell line development & storage
- Ph-1/2/3 BSL-3 biologics manufacturing
- Consulting with clients for NDA applications
- Technology transfer to client post scale-up
- Graduation to commercial production
- Pre-arranged facility expansion path (real estate)
- Highly trained staff

Prototype Bio-Pharma Engagement

Client size: **1-500 employees**

Gross revenue: **0-$500M**

10 year target: Get 1-3 target drugs through Ph-1/2/3 Clinical Trials & into Commercial Production



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Why Interbiome Succeeds

- Focus on high-margin biologics contracts improves long-term margins
- Established, low cost-basis for capacity expansion provides advantage
- BSL-3 capability cements unique positioning for high-margin contracts
- Mfg of abandoned drugs mitigates our operating risks & helps patients
- Internal/external logistics improvements lower costs & improve service
- Integrated, consultative, high-end systems approach benefits clients

Market, Size and Drivers

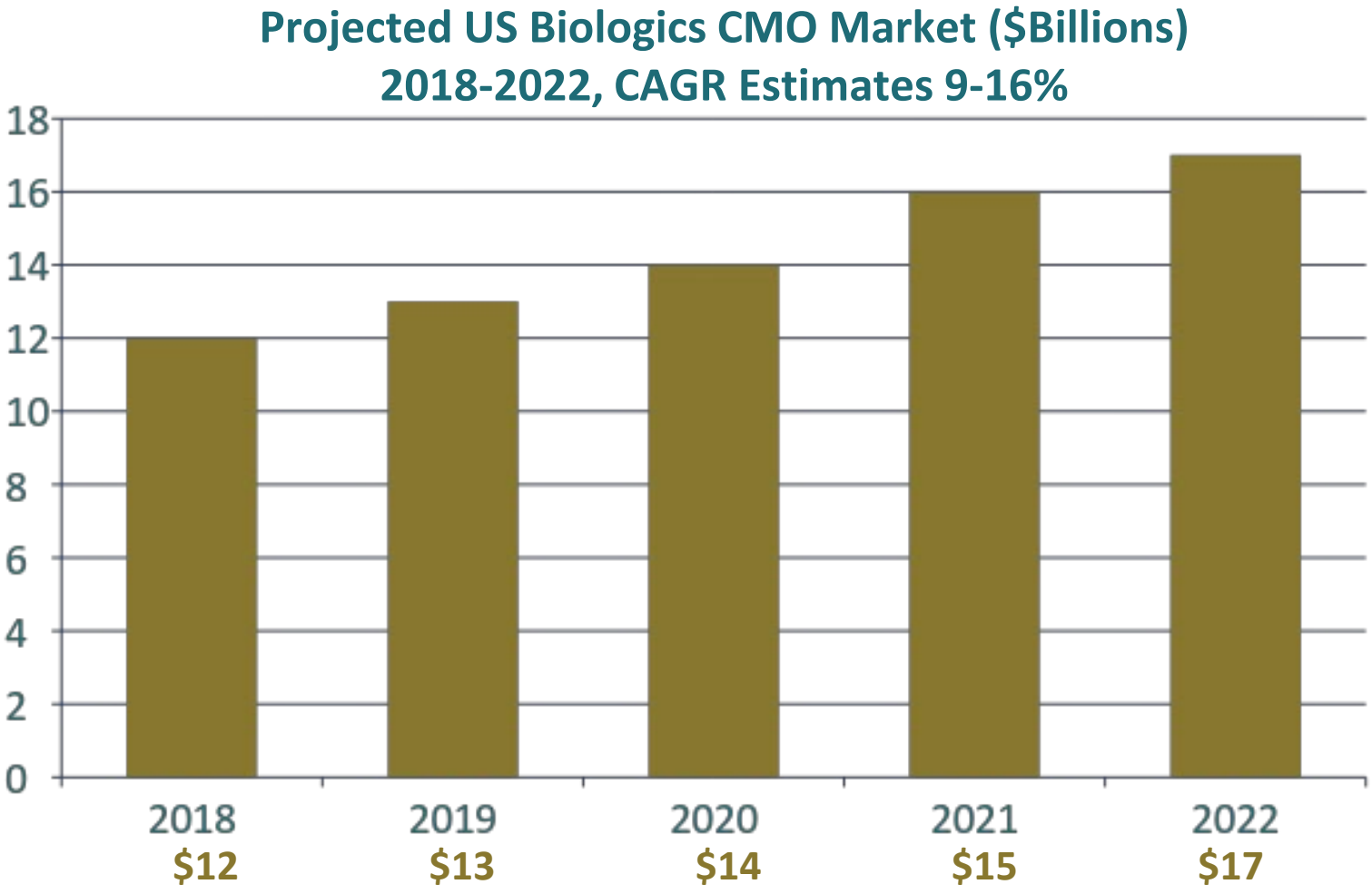
MARKET REVENUE	CONTRACT TYPE	NUMBER OF CONTRACTS
>$11 billion/yr Mkt	Biologics Mfg for Clinical Trials (USA)	6,000/year with 4% increase/year
>$400 million/year	Biologics Process Development Contracts	>2,000 per year
>$1 billion/year	Ph-1 Biologics Manufacturing Contracts	>1,500 per year
>$3 billion/year	Ph-2 Biologics Manufacturing Contracts	>2,500 per year
>$7.5 billion/year	Ph-3 Biologics Manufacturing Contracts	>2,000 per year

Plus thousands of “abandoned drugs” in demand as treatments of last resort and for rare-disease patients (size of this market difficult to estimate; > $10Billion/yr)

Slowly growing BSL-3 biologics competition and BSL-3, Ph-3 competition

Source:

Market Projections



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BioManufacturing Facility Roadmap

- Validate/certify current facility (and plan additional facilities)
- Add consulting services to support resource-center demand
- Add captive analytical assay division
- Increase partner support & co-education

2017	2018	2019	2020	2021	2022

Validate First Mfg Facility

- Minor remodeling
- Facility master plan
- Write facility SOPs
- Writing of facility use and engineering documentation (outsourced)

Facility Launch

- Expand staff
- Initial PD and Ph-1 Mfg Contracts
- Improve supplier contracts
- Host Resource Center Interaction Conferences

Facility Enhancement

- Further integrate supplier logistics
- Add Ph-2 contracts
- Extend advisory services to investor and early-state R&D groups

Expansion

- Add facility capacity
- More Ph-1-2 contracts
- Enhance advisory services
- Add Ph-3 contracts
- Add Commercial Production of Abandoned Drugs

Revenue Model

- Services are delivered via an in-house, contract-service model
- Unique, extensive interaction and coordination is essential for driving business in ALL these areas

TYPE	TYPE AND COST
Process Development (PD)	**Pre-requisite to Ph-1 Mfg Biologics Contract $400K median cost (+/- 50%)**
Bio-Manufacturing	
Phase-1 Biologics Contracts	**cGMP batch manufacturing of client IND $1.5M median cost (+/- 50%)**
Phase-2 Biologics Contracts	**cGMP batch manufacturing of client IND $2.5M median cost (+/- 50%)**
Phase-3 Biologics Contracts	**cGMP batch manufacturing of client IND $7.5M median cost (+/- 50%)**
Commercial Mfg of Abandoned Small Molecule Drugs (or biologics)	**cGMP batch/continuous commercial mfg of client's existing drug $10M+ (highly variable and case dependent)**

Sources:

Go-to-Market Strategy

Three Approaches to Driving Growth

Direct Sales	Indirect Sales + Marketing Programs	Partnerships
• Hunter-forager model • 0 to 18 month sales cycle for PD and mfg IND Clients • Higher margin slot reservation fees for those willing to pay to secure facility use schedule slots in advance	• Channel sales (referrals) • Public relations • Industry conferences	• Channel sales (referrals) • Public relations • Industry conferences

Traction with Clients and Partners

Initial key partners from nine segments:

- Funders – NIH, Private Investors (Foundations, VCs)
- Bio-Pharma Firms
- Patient Advocacy Groups
- Regulators (FDA)
- Researchers
- Payers
- Insurers
- Clinicians and Hospitals
- Employers

Traction with Clients and Partners

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Competition

	Mass Biologics	LFB BioMfg	KBI Biopharma	Florida Biologix	Interbiome YE2017	Interbiome YE2018	Interbiome YE2019
Biologics PD	x	x	x	x	x	x	x
BSL-2 PH-1,2 Mfg	x	x	x	x	x	x	x
BSL-3 PH-1,2 Mfg						x	x
PH-3 Mfg						x	x
Capacity Expansion						x	x
Facility Expansion Roadmap					x	x	x
Commercial Production of Abandoned Drugs							(2021)
	**	**	**	**	**	*** ***	*** ****

~540 US drug manufacturing facilities total *(most capacity is dedicated to commercial production)*

~160 CMOs (contract manufacturing organizations)

~68 US Biologics CMOs **~62 BSL-2* **~6 BSL-3* **~4 Support Phase-3 trial mfg* Source: www.CMOlocater.com

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Financials

First biologics mfg facility alone; (*excluding abandoned drug mfg*)

	2017	2018	2019	2020	2021	2022
Revenue	0	$1.9M	$6.7M	$10.7M	$13.6M	$17.1M
Gross Margin		$1.7M	$6.0M	$9.6M	$12.2M	$15.4M
Expenses	($300K)	$3.4M	$4.9M	$7.5M	$9.2M	$11.3M
EBITDA	($300K)	($1.7M)	$1.1M	$2.1M	$3.0M	$4.1M

Revenue Drivers:

- Close more Ph-1 mfg contracts/year, to max
- Add Ph-2 mfg contracts
- Eventually add Ph-3 mfg contracts
- Move up-margin from BSL-2 to to BSL-3 contracts
- Add additional facilities
- Add commercial mfg of abandoned drugs *(2020 & beyond)*

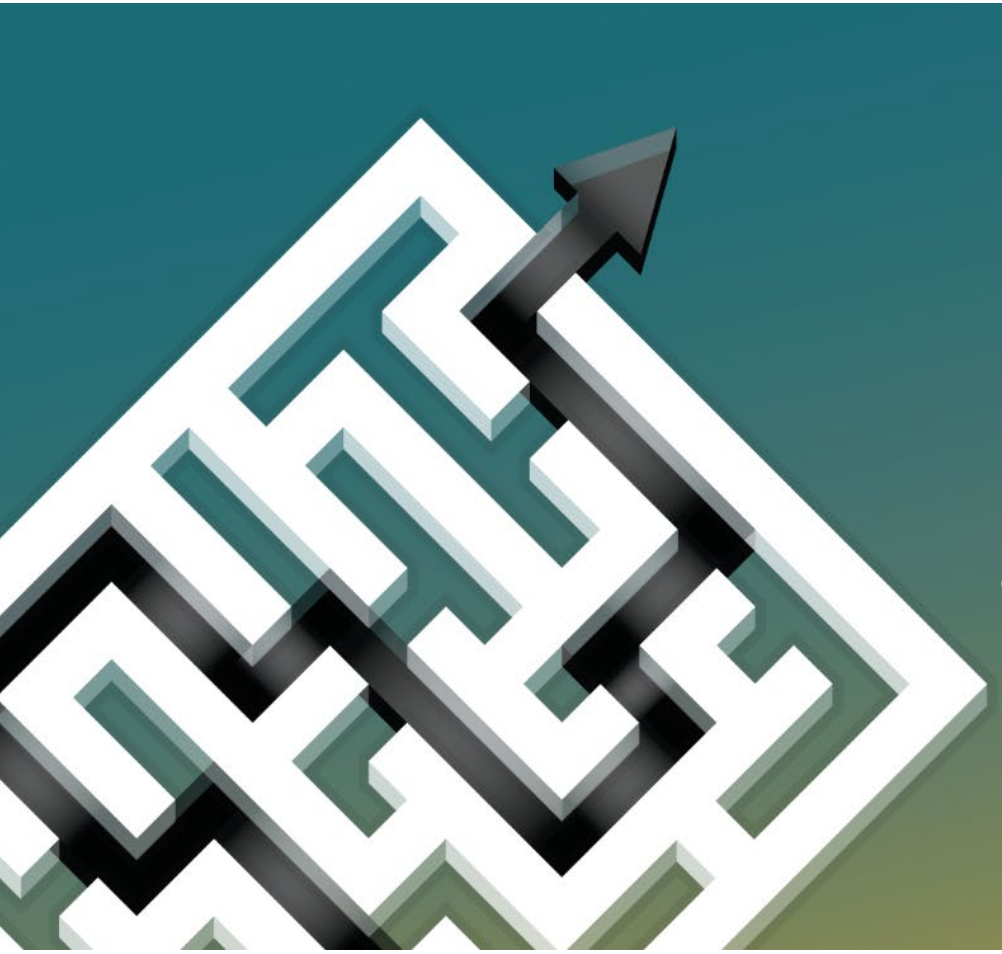
Cost Drivers:

- Securing, building-out, validating new facilities
- Recruiting, training and retaining key staff
- Developing client/supplier partnerships
- Marketing/sales
- Added regulatory cost for commercial manufacturing of Abandoned Drugs

Use of Initial Funds

Seeking $2 million in investment to bring first facility on-line, hire/train initial staff, close first bio-mfg contracts, and launch resource-center conferences:

- Sales and Business Development
  - Build an inside sales force to pursue bio-pharma clients with high-margin biologics manufacturing needs
  - Attract charter partners to extend reach at a low cost of sales
- Marketing
  - Launch industry resource center conference programs, to deeply integrate with patient advocacy groups, researchers, providers, payers, regulators and employers
- Technology
  - Expand capacity in our first facility, and plan opening of additional facilities



OUR LONG-RANGE SOLUTIONS

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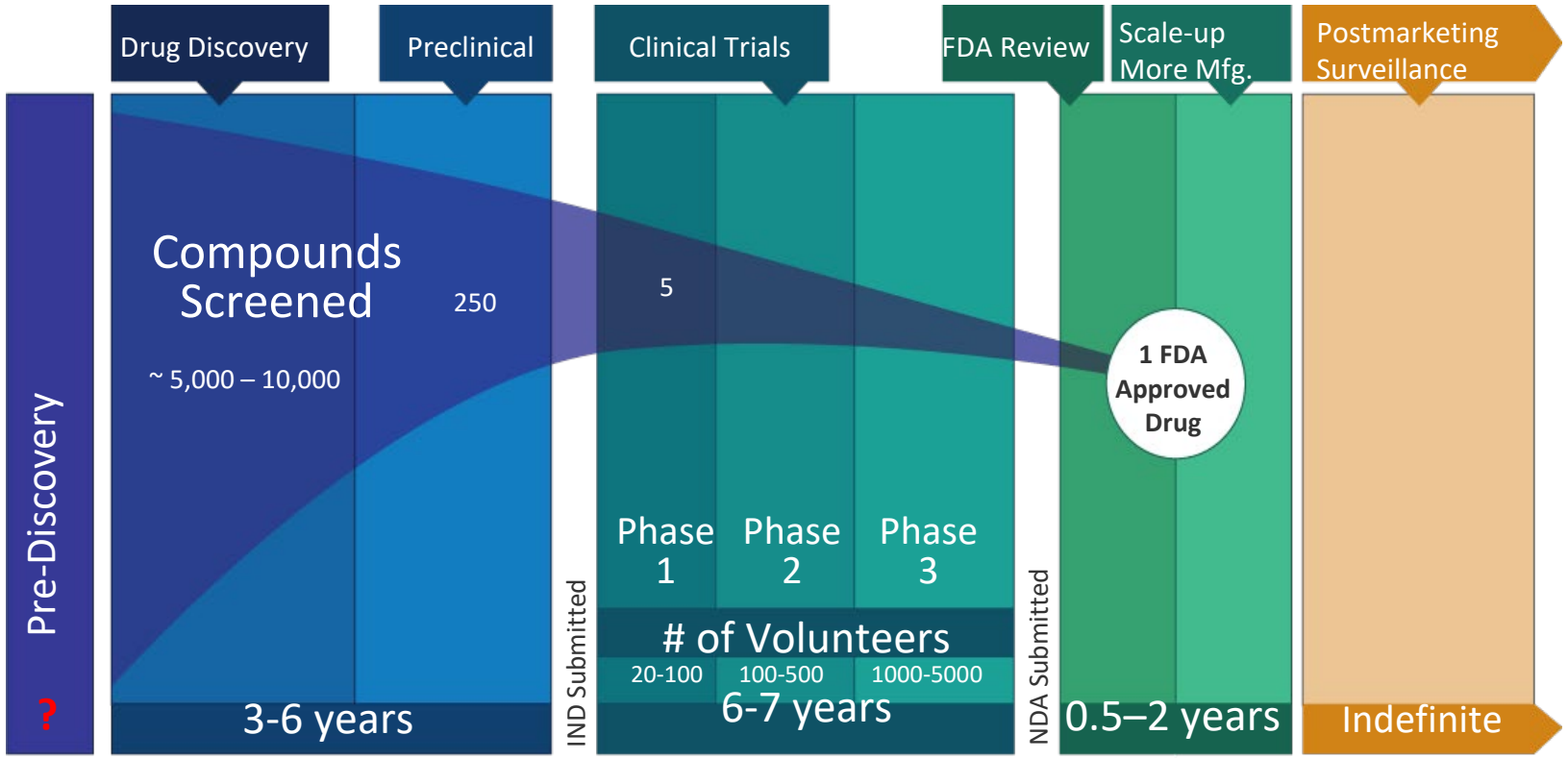
Pharma Industry Today Sees Public Health Management as *"Drug Development"*

This illustrates part of a *Public Health Supply Chain* with lagging throughput.
Therapies cost too much (>$2Bil/drug), and take too long.
The net process is plagued with uncertainties, so quality is expensive to manage.



Largest knowledge trove? Held in the minds of hundreds of thousands of researchers/clinicians, and tens of millions of patients

CMO

Biggest opportunity, BY FAR? Accelerated Pre-Discovery. HOW?

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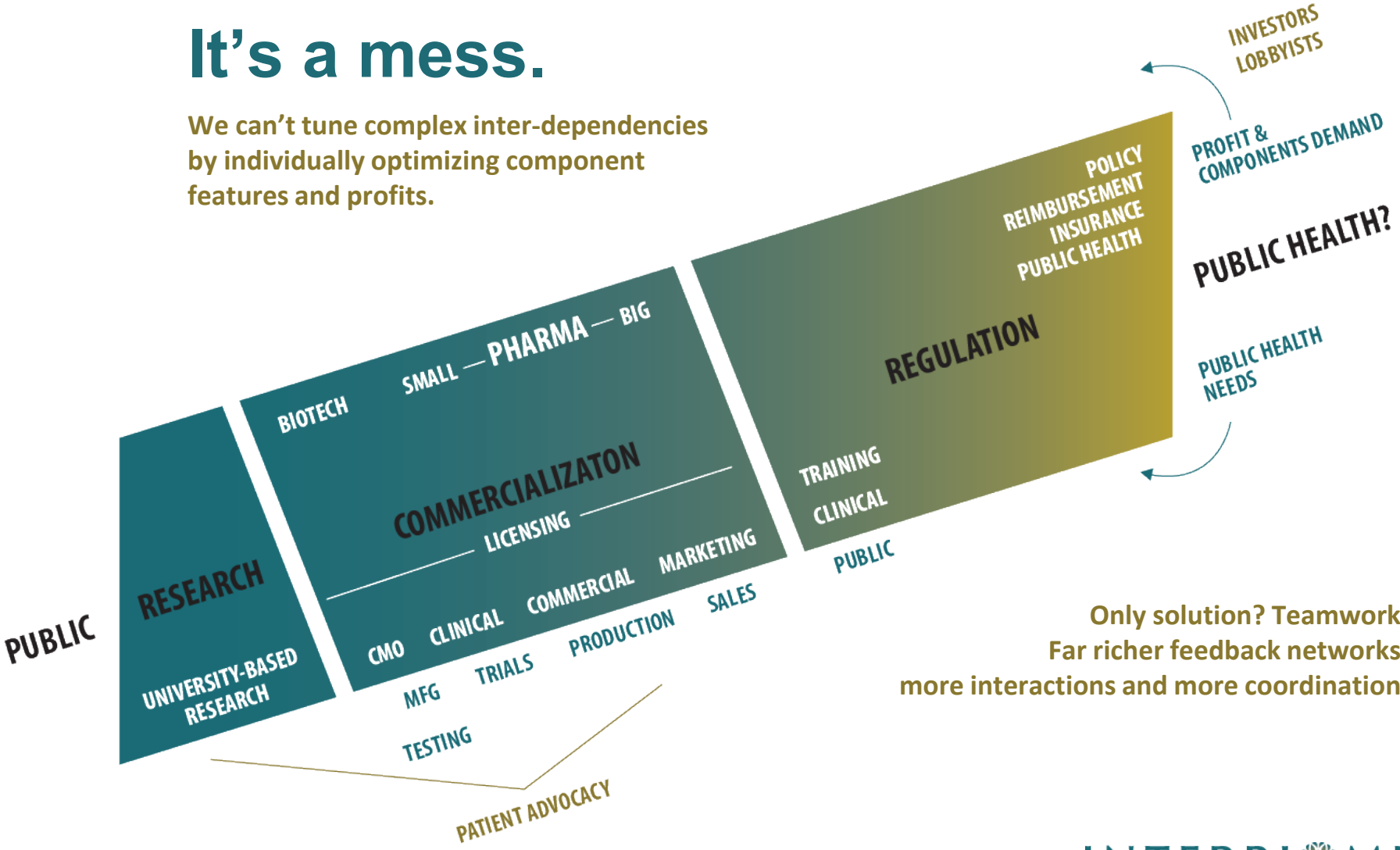
Drug Development: A More Realistic View

It's a mess.

We can't tune complex inter-dependencies by individually optimizing component features and profits.



Only solution? Teamwork.
Far richer feedback networks, more interactions and more coordination.

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Industry Coordination

- Industry Coordination is needed even more than component services! We don't know what our Public Health Supply Chain will look like in another generation, but whatever it evolves to, WE can help get there faster, through adequate interactions.

- More, and earlier, interactions and coordination are needed, **EVERYWHERE**, to counter declining coordination among growing numbers of specialists

- Interbiome is responding with unique, ongoing integration of all services

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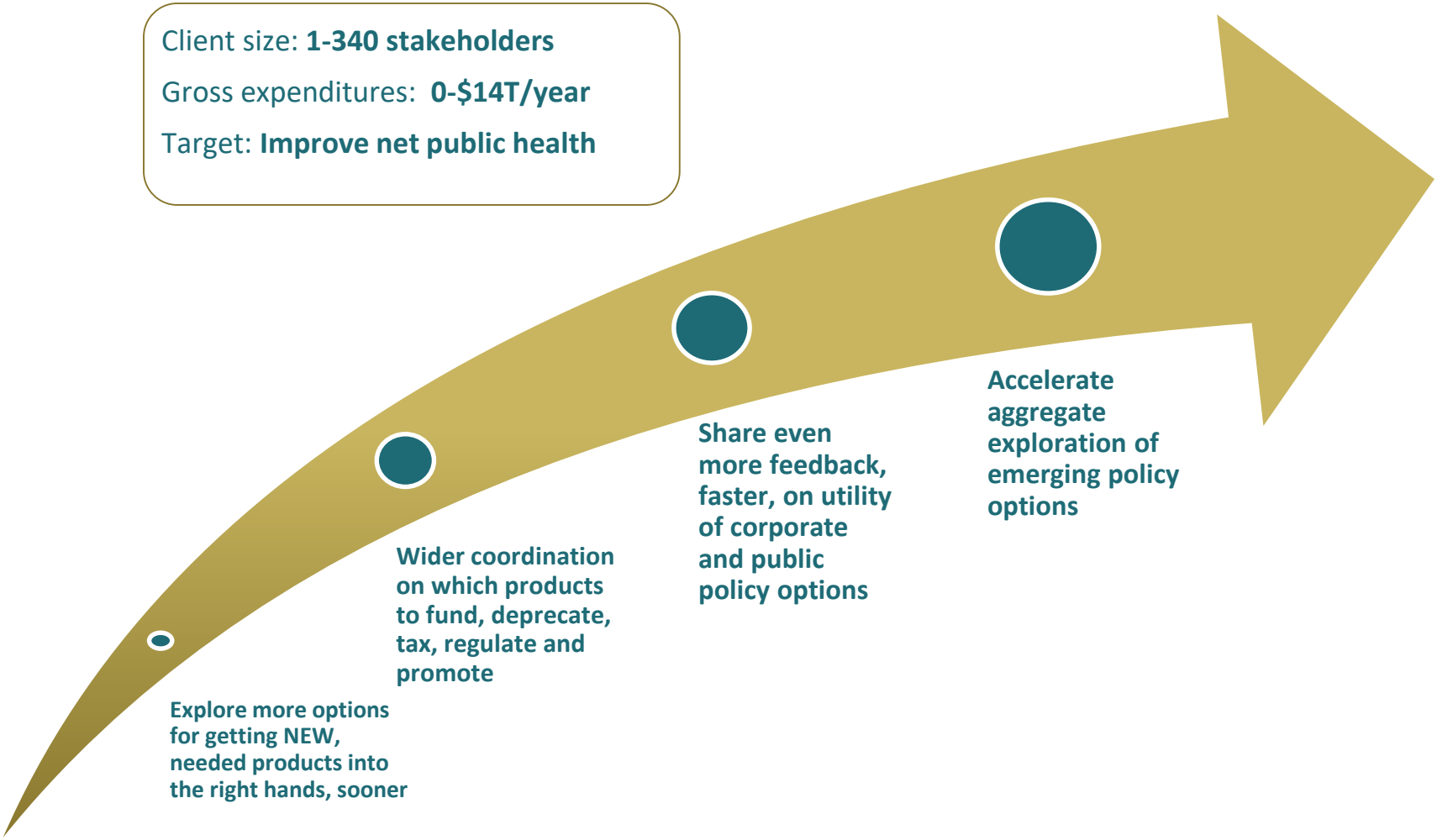
Prototype Stakeholder Partner

Client size: **1-340 stakeholders**

Gross expenditures: **0-$14T/year**

Target: **Improve net public health**



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End-to-End PD->IND->NDA Process Management

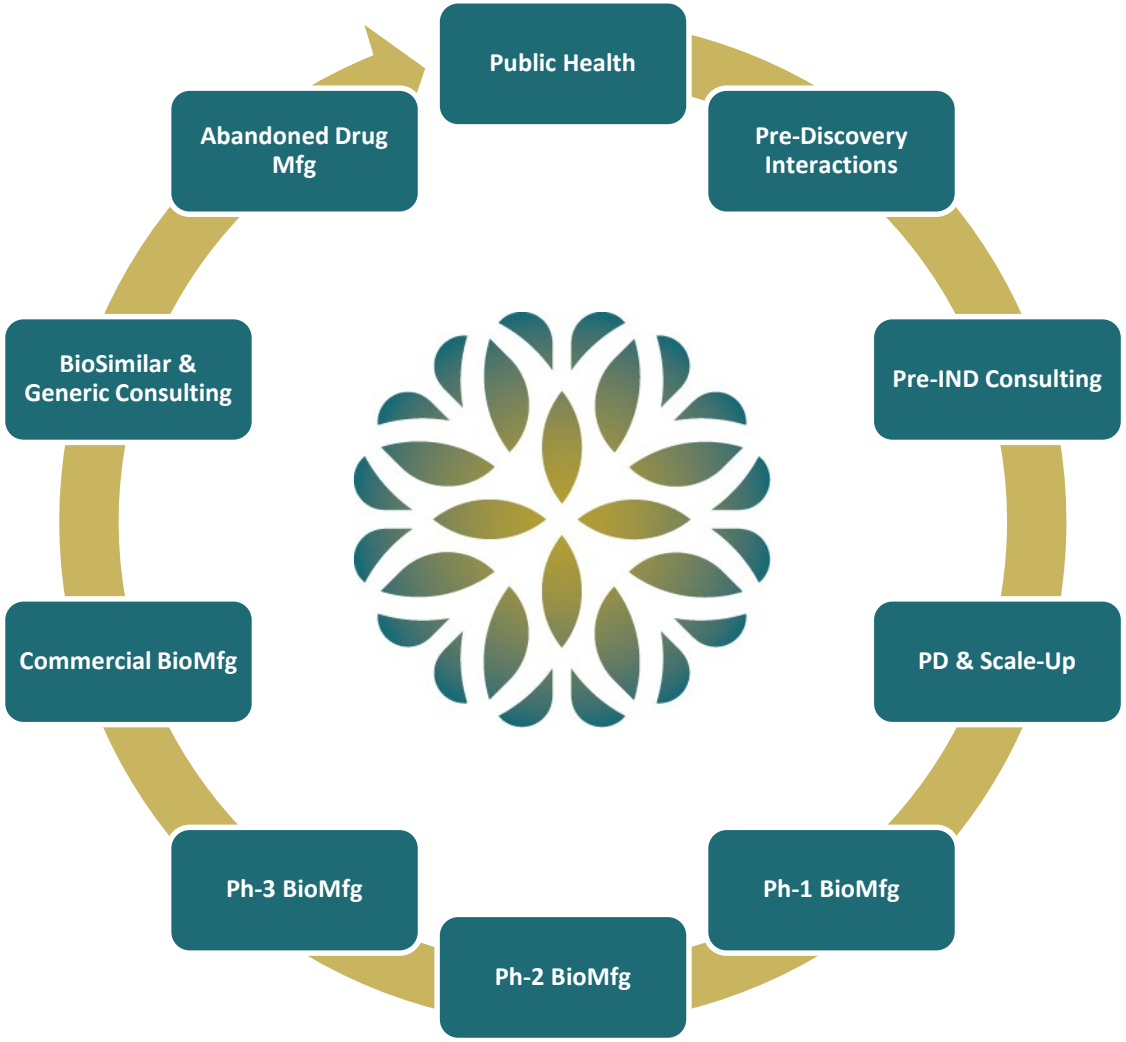
Patient Groups, Bio-Pharma, Providers

- Early needs assessment and process consulting
- Rapid decisions on bio-mfg scheduling and pricing
- Advanced procurement planning
- Advanced consulting on FDA evaluations and IND/NDA applications
- Host for Pt/R&D/Business/Clinical coordination
- Better/faster/earlier communication with all stakeholders

Regulators, Payers, Buyers, Insurers

- Public Health Supply Chain consulting
- Feedback on bio-mfg advances
- Reliable service and sustainable success, NOT just short-term profits
- Capacity planning to meet projections
- Advisory services for investors
- Coordination with R&D funding agencies

End-to-End PD->IND->NDA Process Management



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