# Dyadic International, Inc. (NASDAQ: DYAI)

"Proteins for World Health"

## Unlocking Scalable Biomanufacturing: C1 and Dapibus™ Platforms

Joe Hazelton
President & COO
Dyadic International (USA) Inc.
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# Industrial heritage provides expertise for rapid scalability & high productivity…

### 1980

**The journey begins in cellulase enzymes**

- Pioneered use of pumice stones in stonewashing
- Transitioned to cellulose enzymes to textile

### 1990

**Discovery of C1 System**

- R&D of the novel Thermothelomyces heterothallica filamentous fungal protein production system (C1)
- Bioindustrial applications

### 2000

**GRAS Certification & Expanded Applications**

- Building toolkit and commercializing industrial
- Expanded application of industrial enzymes in biofuels, animal feed, textiles, paper, food and beverage industries

### 2015

**Re-engineered C1 System for Biopharmaceuticals**

- Sale of industrial business to DuPont.
- Glycoengineering
- Production of human and animal bioligic vaccines and therapeutic

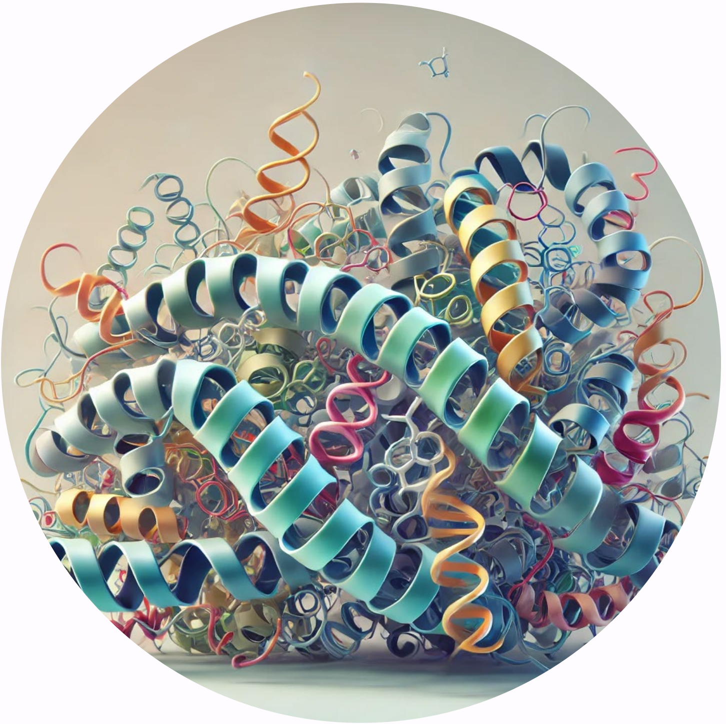
### 2022+

**Expanded Dyadic Adoption & Pipeline**

- Phase I validates platform
- Pharma partnerships
- Dapibus™ platform for food/nutrition

# Dyadic Mission: Proteins for World Health

Reducing time and cost, while increasing productivity in protein production…



Enabling faster, broader, sustainable access to crucial bioproducts…

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# Dyadic Platforms at a Glance: High productivity, Low cost, Scalable

## Proven at Scale

- Fermentation at >**150,000L** capacity
- Industrial conditions validated

## Regulatory Ready

- **Phase I** human data
- **FDA GRAS** designation

## Commercial Track Record

- Used to make **10,000s of tons** of enzymes
- Trusted in **small, mid, large-scale production**

## Versatile Expression System

- High-yield **biologics & reagent** production
- Supports **rapid strain optimization**

## GMP-Compatible & Transferable

- Direct **tech transfer** to cGMP sites
- Proven **lab-to-commercial** scalability
- First reagent product launch 2025
    - **Recombinant human albumin**

## Clean & Sustainable

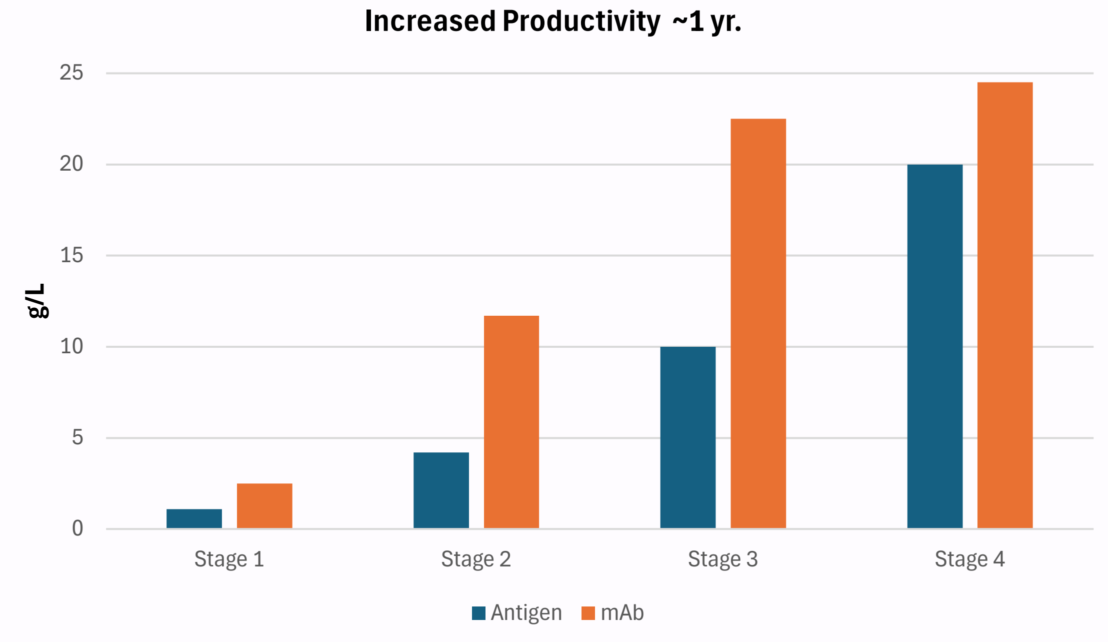
- No viruses or endotoxin; low carbon footprint

## Quality & Scale

- Phase I data w/cGMP material; production scales >100,000L

## Rapid & Low Cost

- Shorter processing times; high titers with inexpensive media



# Dyadic Platforms Have Distinct Production Advantages vs. Today's Technology

| Limitation | Baculovirus Cells | CHO Cells | C1 Cells |
|---|---|---|---|
| Viral Clearance for DS Release | Required | Required | ☑ Not required — inherently safe |
| Upstream/Downstream Complexity | Lengthy & expensive | Lengthy & expensive | ☑ Streamlined and cost-effective |
| Doubling Time | >20 hrs | >20 hrs | ☑ Fast-growing (≈2 hrs) |
| Production Flexibility | Narrow temp & pH range | Narrow temp & pH range | ☑ Broad operational range |
| Production Cycle Time | Up to 3–4× longer | Up to 3–4× longer | ☑ Rapid expression cycle |
| Molecule Size Constraints | Size-limited (e.g. HIV NP) | Size-limited | ☑ Handles large, complex proteins |
| Antigen Productivity | Low | Low | ☑ High-yield antigen output |

## C1 Cell Line Key Advantages

- **Faster stable cell line development**
- **Shorter drug substance production**
- **Quicker release of more doses with a smaller, cheaper footprint**

# Recombinant Proteins Hold Advantages Over Animal Derived, Except Cost

**Dyadic strengths align with shortfalls in current recombinant and animal derived proteins**

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**Dyadic Enhances Value Across:**
***Pharma, Life Sciences & Nutrition***

Improved Regulatory

**✓ Regulatory Advantages**

- No viruses, pathogens, or endotoxins
- GRAS certification
- Phase I clinical data
- Supports complex protein expression

**Production & Scale Benefits**

- Scales to >100K L
- Higher productivity
- Operates under wide conditions
- Cost-efficient media

Lower Cost

# Dyadic Platforms Positioned to Deliver Efficient Products in High Value Markets

- C1: GMP-ready, high-yield recombinant system
- Dapibus™: GRAS, scalable, food-grade production

- Rapid strain development
- Enzyme & protein expression
- High scalability & low cost
- Animal-free production

Therapeutic Proteins/Antibodies – $61B

Molecular Biology Enzymes – $6B+

Cell Culture Media – $4.7B

Vaccines – $200B

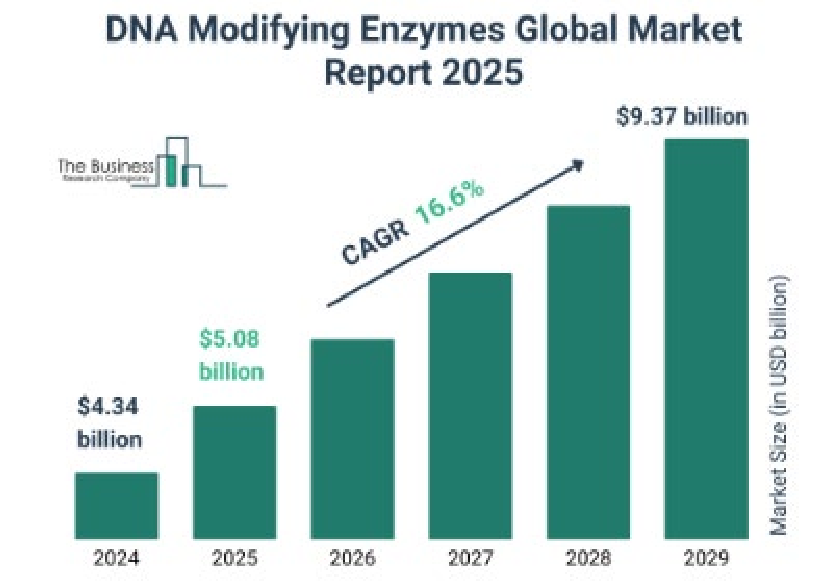
Reagents – $72B

Non-Animal Dairy – $26.5B

Biofuels/Industrial Enzymes – $155B

# Dyadic DNA/RNA Product Portfolio for Rapidly Growing mRNA Enzyme Market

| Product | Application | Status |
|---|---|---|
| DNASE-1 | Removes DNA from RNA prep | Commercial – Available now |
| TdT Transferase | Adds nucleotides to DNA templates | In Development |
| T4 DNA Ligase | Used in cloning/template prep | In Development |
| RNase Inhibitor | RNA protection from degradation | In Development |
| T7 RNA Polymerase | Core for in vitro transcription | In Development |

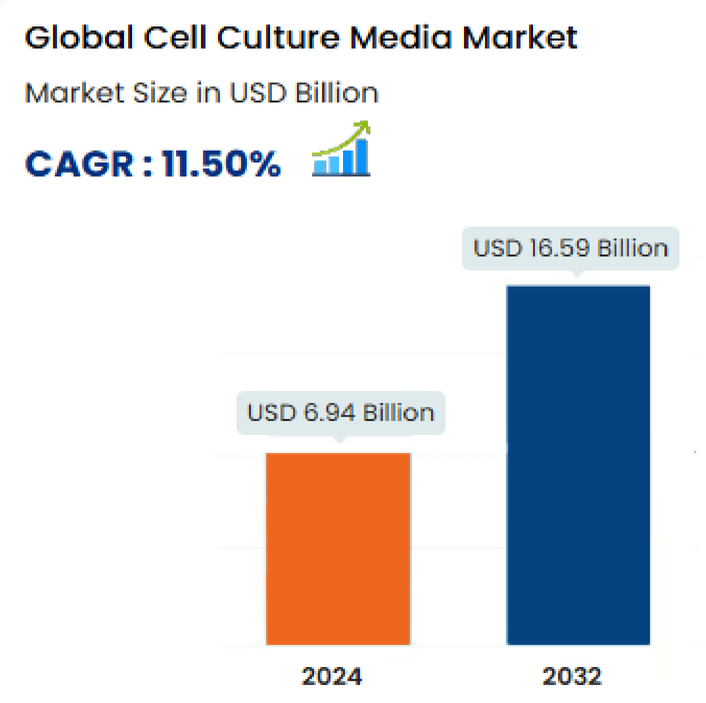



- **Increasing demand for mRNA therapeutics & vaccines**
- **Personalized medicine & in vitro tools growth**
- **Current supply challenges: high cost, production capacity**

**Dyadic is building a targeted, high-impact enzyme portfolio to serve the $4B+ molecular biology reagent market *— starting with DNASE-1 in 2025.***

# Dyadic Cell Culture Media (CCM) Product Portfolio of High Value Targets

| Product | Application | Status |
|---|---|---|
| ☑ Human Albumin | Support cell growth and protein production | 2H 2025 |
| Human Transferrin | Regulates the supply of iron to cells | In Development |
| Human FGF | Stimulate cellular processes | In Development |
| ☑ Bovine Transferrin | Regulates the supply of iron to cells | Samples available now |
| ☑ Bovine FGF | Stimulate cellular processes | Samples available now |




- Global CCM Market: $4.7B (2023) at 12.5% CAGR
- Cost Drivers: Albumin, transferrin, and GF = up to 80% CCM cost
- Recombinant CCM more expensive than animal-derived

**Dyadic is unlocking scalable, affordable cell culture media with recombinant albumin, transferrin, and growth factors**
***— addressing high value segment with unmet cost and supply challenges.***

# C1 Platform: End-to-End Bioproduction – Faster, Cheaper, Scalable

**From R&D to Full-Scale Therapeutics**

**→ Lower-cost reagents for early development**

**→ High-yield therapeutic manufacturing at commercial scale**

## Affordable, Scalable Reagents

**Streamlines assay & platform development at lower cost**

- Diagnostics: Antigens & Antibodies
- Development Tools: Human & Bovine Serum Albumin
- Enzyme Catalysts: DNase I, Hyaluronidase

## High-Volume, Low-Cost Therapeutics

**Monoclonal Antibodies (mAbs):**

- CHO-like binding, 22.5 g/L in 7 days
- Faster production, lower cost

**Complex Subunit Vaccines:**

- Ferritin NP: 3.5 g/L in 5 days (Wuhan), 2.0 g/L (H5N1/H5N8)
- Poultry: 20 g/L in 7 days
- Multivalent RBDs (8 VOCs), SP2 Spike (1 g/L)

**Therapeutic Proteins:**

- Multi-specific Abs, Cholinesterase, Insulin

# Partnering with Dyadic: Flexible Access to High-Performance Bioproduction

## "Simple Starts. Scalable Success”

*Flat-priced feasibility, flexible commercial paths*

### 1. Platform Licensing

- Access to C1 or Dapibus™ for in-house biomanufacturing
- Tech transfer, process optimization support
- Scalable from lab bench to 150,000L

### 2. Strain L:icensing

- Use of pre-developed Dyadic production strains
- Customization options available
- Royalty-based or upfront/milestone agreements

### 3. Product Supply

- Purchase of recombinant proteins or enzymes
- Examples: FGF, DNase I, transferrin, alpha-lactalbumin
- GMP or food-grade formats

**“Let's build the next generation of affordable biologics—together.”**

# Thank You

Contact us: ir@dyadic.com

# Appendix

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**Let's build the next generation of affordable biologics—together...**

DYADIC INSIDE

# Dyadic C1 Platform Multiple Revenue Paths for Human Health

| | Recombinant Protein Vaccines | Antibodies/Therapeutic proteins | Reagent/Excipient Products |
|---|---|---|---|
| **Internal Portfolio** | • H5 Bird Flu<br>• Seasonal Influenza<br>• mPox<br>• COVID | • Certolizumab<br>• Nivolumab<br>• Other NME or Biosimilar potentials | • DNA/RNA products<br>• Cell Culture Media products<br>• Alpha-lactalbumin<br>• Hyaluronidase |
| **External Partners** | • Fondazione Biotecnopolo di Siena<br>• 2 Top 10 Pharma companies<br>• Rubic One Health | • Gates Foundation<br>• Top 10 Pharma company<br>• Multiple mid-sized pharma projects<br>• Fondazione Biotecnopolo di Siena | • Proliant Health and Biologics<br>• Multiple ongoing opportunities |

**Revenue Models**

- Platform/Product Licensing
- 3rd Party product revenue
- Dyadic branded products

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# Dyadic Path to Revenue Through Reagent Products

## ALBUMIN

**Product ID and development**

- Recombinant human albumin
- C1 strains >20g/L
- USP & non-USP sequences for diagnostic and CCM applications

**Testing and Analysis**

- Certificate of Analysis
- Cell media application testing
- Analytical and activity testing

**Commercialization**

- Options: Produce or Partner
  - Partnered with Proliant Health and Biologics
    - Upfront/Profit Sharing
    - PHB has current distribution and customer base for rapid launch and uptake in diagnostics and CCM

**Licensed Products**

- Time from development to contract ~12 months
- Time from development to launch ~15 months
- rHSA stable revenue generation for Dyadic in 2025

## DNASE-1

**Product ID and Development**

- DNASE-1 (Rnase-free)
- C1 strains >1g/L (2x eColi)
- Research and cGMP applications
- Identified from previous project

**Testing and Analysis**

- Certificate of Analysis
- Analytical and activity testing
- Product sampling to 3rd Parties

**Commercialization**

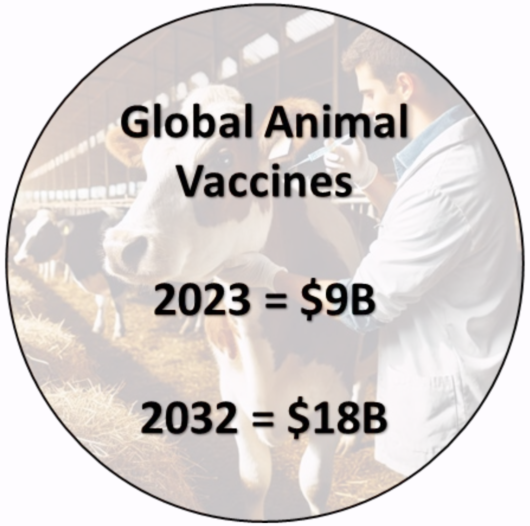
- Options: Produce or Partner
  - Evaluating ISO production of research grade product
  - Seeking cGMP partner for licensing
  - Bulk supply of non-GMP material

**Product/Portfolio Products**

- Time from development to supply agreement ~6-8 months
- Time from development to launch ~12 months
- DNASE-1 expected stable revenue generation for Dyadic in 2025

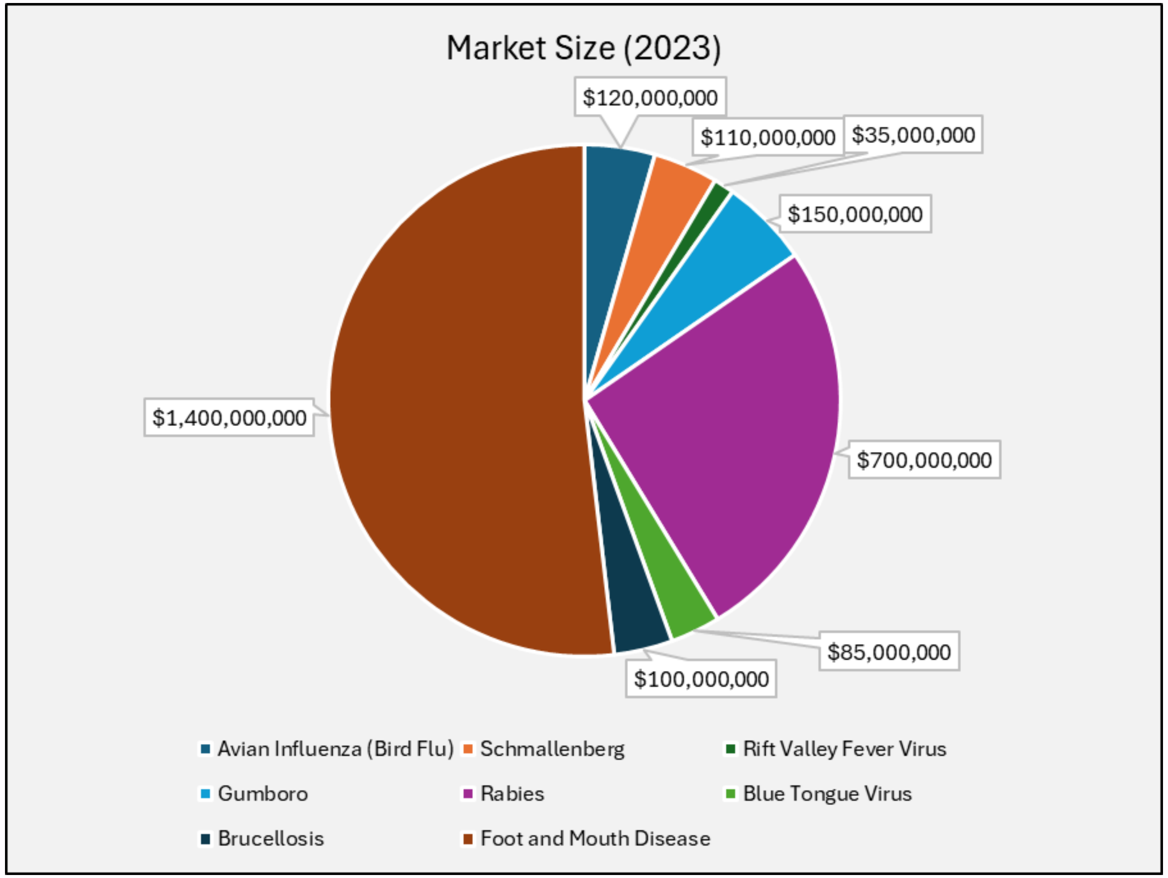
# Dyadic Market Opportunities: Animal Health

# Dyadic C1 Advantages Provide Opportunity Within Animal Health




TAM of ~$3.4B for Recombinant Vaccine Segment (2030)

**Potential Animal Health Vaccines**

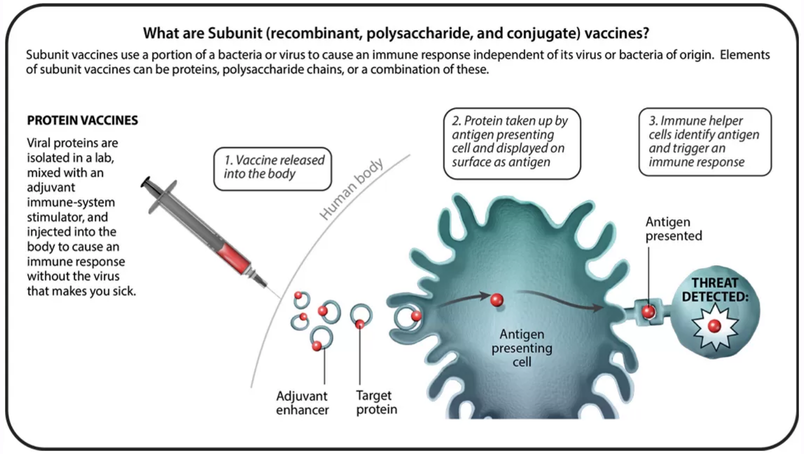



## Higher yields with lower overall costs

| Protein-base Antigens | Total Yield | Yield Per Day |
|---|---|---|
| Avian Livestock -1 | 20.0 g/L | 2.85g/L/d |
| Avian Livestock -2 | 1.9 g/L | 0.27g/L/d |
| Rift Valley Fever Virus (RVFV) | 1.6 g/L | 0.32 g/L/d |
| H5 Influenza A/Astrakhan/2020 (Ferritin) | 1970 mg/L | 281 mg/L/d |
| Schmallenberg Virus (SBV) | 1.8 g/L | 0.3 g/L/d |

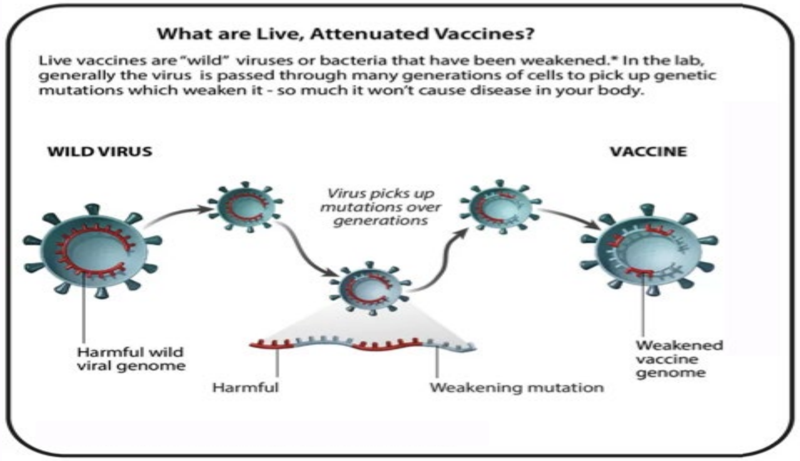
# Affordable Recombinant Vaccines Advantages vs. Live Attenuated

R E C O M B I N A N T




- ❑ **Reduced Risk of Reversion & No Risk of Disease**
- ❑ **Targeted Immunity & Minimal Side Effects**
- ❑ **Heat Stability & Long Shelf Life**
- ❑ **Customization & DIVA Capability**

A T T E N U A T E D




- ❑ **Comprehensive & Cell-Mediated Immunity**
- ❑ **Rapid Onset**
- ❑ **Lower Production Costs**
- ❑ **Fewer Boosters Required**

Dyadic yields can change cost model

*References are found on file

# Dyadic Path to Revenue in Animal Health

## Vaccines

**Product Development**

- Poultry vaccine
- C1 strains ~20g/L
- External project fully funded

**Testing and Analysis**

- Pre-clinical animal studies
- Improving yield and DSP
- Planned clinical trials

**Commercialization**

- Collaborator evaluation
  - Expected launch in poultry 2027-28
  - Dyadic receives milestone and royalty
  - Additional products in development

**Pharmaceutical Opportunities**

- 3rd party funded vaccine or antibody development
- Lower costs enable better margins in sensitive segment
- Current 3rd party vaccine project to launch in ~2 years

## Product/Platform

**Product ID & Development**

- H5 Astrakaan (Bird Flu)
- C1 ferritin nanoparticle strain
- Initial yield 1.9 g/L before optimization

**Testing and Analysis**

- Pre-clinical animal studies showed efficacy across species (avian, human, bovine)
- Positive independent analysis
- Sampling to 3rd Party animal health

**Commercialization**

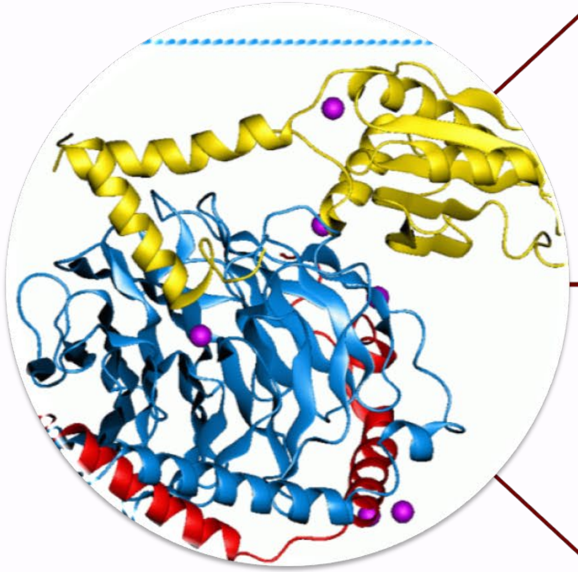
- Options:
  - Antigen production for animal (and human) testing kits
  - License of antigen for animal vaccine
  - License of platform for animal health

**Product or Platform Opportunities**

- Potential for reagent or diagnostic product opportunities
- Platform licensing for pandemic or therapeutic preparedness

# Dyadic Market Opportunities: Alternative Proteins

# Dyadic Alternative Proteins Represent Significant Potential Value



**Life Science**

**$5-10Bn**

- Cell culture media
- Personal Care

**Food & Nutrition**

**$30-50Bn**

- Non-animal dairy
- Food and Beverage

**Industrial**

**$50-200Bn**

- Biofuels
- Manufacturing
  - Textiles
  - Feed
  - Detergent

| Legend | |
|---|---|
| Available | <3-6 Months |

# Dyadic Alternative Protein Product Portfolio Growing Rapidly

- Global CCM market estimated at $4.7B with >12% CAGR
- The Good Food Institute (GFI) estimates albumin, transferrin, and growth factors make up >95% serum-free cell culture media costs
  Recombinant CCM products are significantly more expensive than animal derived

## Cell Culture Media (Food)

| Product | Total Addressable Market | Application | Status |
|---|---|---|---|
| **Bovine albumin** | $100-300MM | Support cell growth and protein production | C of A complete; Partnered with Proliant Health |
| **Bovine transferrin** | $100-300MM | Regulates the supply of iron to cells | C of A complete; application testing 12/2024 |
| **Bovine growth factors** | $1.6B | Stimulate cellular processes like proliferation | Sampling initiated in Q4 2024 |

## Food & Nutrition; Industrial Applications

| Product | Total Addressable Market | Application | Status |
|---|---|---|---|
| **Bovine Alpha-lactalbumin** | $300-400MM | Food/Nutrition/Reagent | C of A complete; sampling initiated |
| **Dairy enzyme** | $110MM | Cheese production | Licensed to Inzymes; Q2 2025 launch |
| **Hyaluronidase** | $900MM | Cosmetics | Sampling initiated; testing ongoing |
| **Cellulosic Enzymes** | $1.1Bn | Biofuels | Partnered with Fermbox; 1H 2025 launch |

- Bovine alpha-lactalbumin has potential markets in food and as a research grade material; current yields achieve research grade margins
- Sustainable revenue from Alternative Proteins estimated for 2025 as both product supply and licensing agreements underway

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# Summary

# Dyadic Near- and Long-Term Potential Opportunities are Viable




| | PLATFORM | PORTFOLIO | PRODUCT |
|---|---|---|---|
| Pharmaceutical | - Pandemic & infectious disease vaccines and antibodies<br>- Clinical-grade reagents and excipient suppliers | - Cell culture media<br>- DNA/RNA products<br>- Therapeutic proteins (e.g., alpha-lactalbumin, transferrin) | - Vaccines and antibodies (e.g., H5, mPox, Nivolumab)<br>- Clinical-grade reagents (e.g., DNASE-1, transferrin)<br>- Diagnostics (e.g., antigens) |
| Non-Pharma | - Alternative protein companies in food, nutrition, and industrial sectors | - Cell culture media<br>- Food proteins (e.g., non-animal dairy proteins)<br>- Biofuels (e.g., cellulosic enzymes) | - Cell culture media (e.g., transferrin, growth factors)<br>- Industrial applications (e.g., cellulosic enzymes, proteases |

# Strong leadership with diverse pharmaceutical and industrial experience

**Mark Emalfarb,** Founder/CEO

Entrepreneur, Inventor 25+ U.S. and foreign biotechnology patents, filamentous fugal enzyme product commercialization

**Ping Rawson,** CFO

20+ years of finance, accounting & international trade and business development experience

**Joe Hazelton,** COO

25 Years in Pharmaceutical Industry, commercialization, regulatory, business and clinical development

**Ronen Tchelet,** CSO

20+ years in Biopharmaceutical Industry & Recombinant Product Commercialization

## Board Members

### Michael Tarnok

Board Member

Seasoned pharma industry finance and operational executive

### Dr. Arin Bose

Board Member

34 years bioprocess development and clinical manufacturing

### Patrick Lucy

Chairman of the Board

20+ years of bioprocess biotech and business development

# Protease Production in C1 Expression Platform (53 of >100 Identified)

**1. Serine Proteases:**
- Diagnostics: Used in clotting disorders (e.g., assays for thrombin and plasmin activity in coagulation).
- Research: Study of protein degradation and signaling pathways, including immune system responses

**2. Cysteine Proteases:**
- Diagnostics: Detection of diseases (e.g., cancer or inflammatory) for role in apoptosis and protein degradation.
- Research: Studying cell death mechanisms, antigen processing, and lysosomal functions.

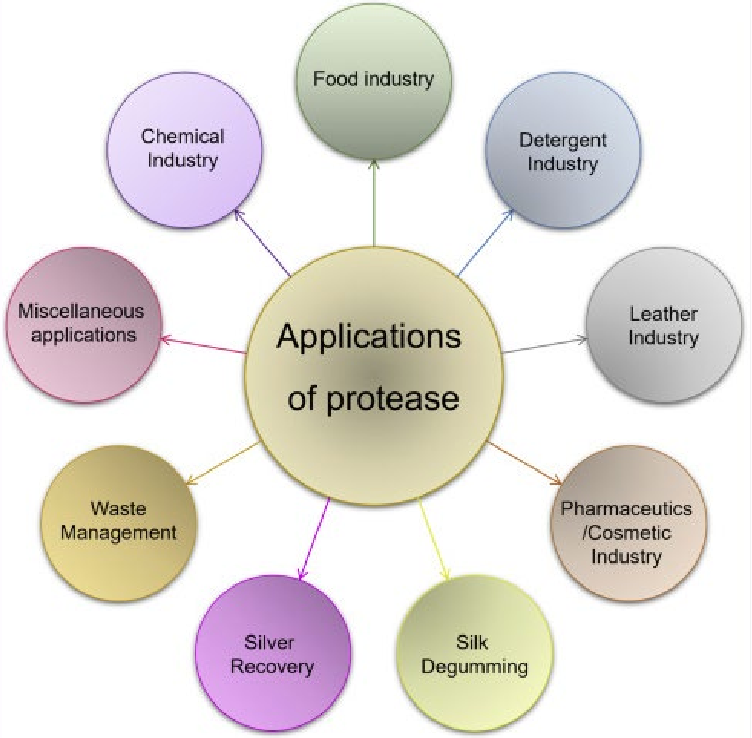
**3. Aspartic Proteases:**
- Diagnostics: Biomarker detection for neurodegenerative diseases (e.g., β-secretase in ALZ).
- Research: Investigating protein cleavage involved in viral replication and lysosomal degradation.

**4. Glutamic Proteases:**
- Diagnostics: Less common but used in specific enzymatic assays for fungal infections.
- Research: Exploring fungal biology and enzyme engineering for industrial applications.

**5. Metalloproteases:**
- Diagnostics: Key markers for cancer metastasis (e.g., matrix metalloproteinases).
- Research: Study of extracellular matrix remodeling, cancer progression, and angiogenesis.

**6. Asparagine Peptide Lyases:**
- Diagnostics: Emerging use in protein sequencing and diagnostics due to their specificity.
- Research: Protein structure analysis, particularly in mass spectrometry and proteomics.

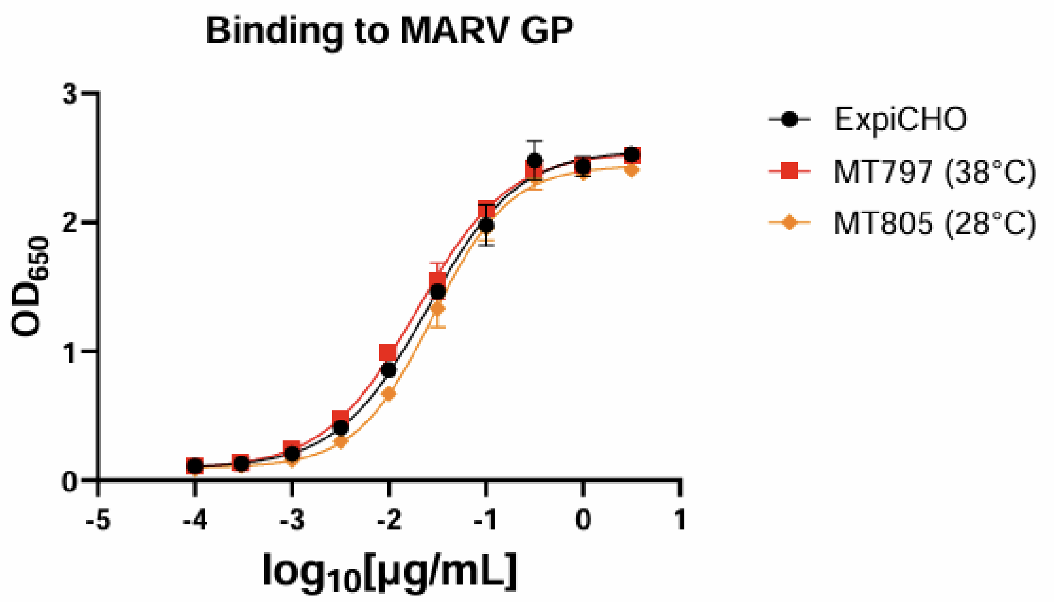
**Protease Applications**



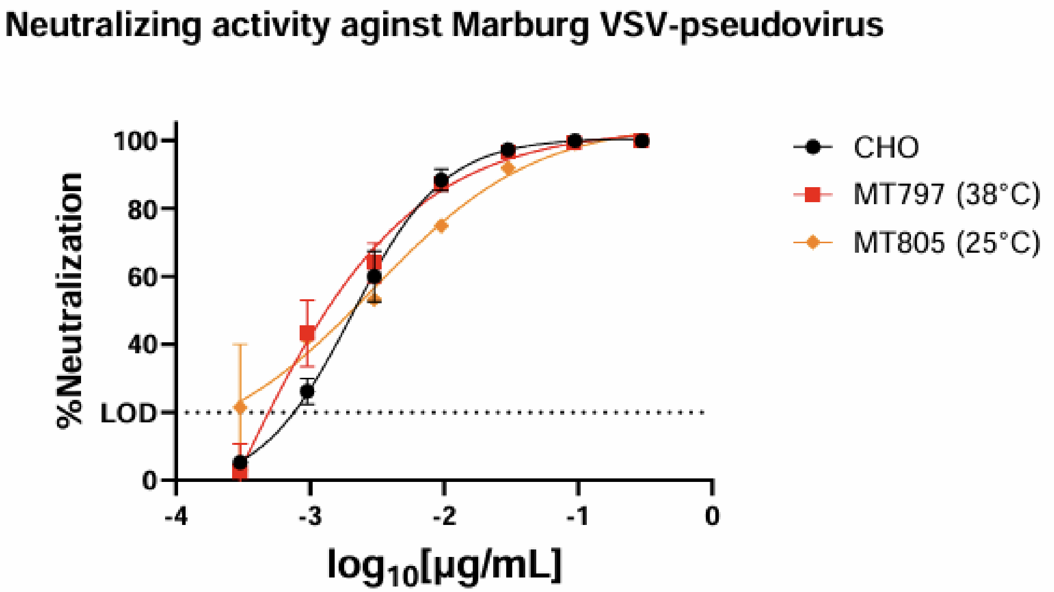

Spiking library for protease screening for C1/Dapibus

# CHO-Like Neutralization and Binding, but Faster and More Affordable

## Marburg VIRUS




Binding of CHO produced and C1-produced (2 clones) of anti-MARV mAb ABV-04 to Marburg glycoprotein




Neutralizing activity of CHO produced and C1- produced (2 clones) of anti-MARV mAb ABV-04 using a MARV GP-VSV pseudotype Virus

DYADIC

# Demonstrated Consistent Successful Expression of Broad Array of Potent Antigens & mAbs from C1-Cells

- **Infectious Disease Monoclonal Antibodies**
  - **COVID-19**
    - Neutralizes All SARS-CoV-2 Variants of Concern, Including Omicron BA.1/2.
    - Hamster & Non-Human Primate Studies
  - ZIKA
  - RVFV
  - ANDV (Andes Hantavirus)

- **CORONAVIRUS**
  - **SARS-CoV-2 S-RBD**
    - Alpha (B.1.1.7), Beta (B.1.351)
    - Gamma (P.1), Delta B.1.617.2
    - Omicron B.1.1.529, Omicron BA.5
  - **MERS (Middle East Respiratory Syndrome)**
  - **SARS-CoV-2 gRBD Ferritin Nanoparticles**
    - Wuhan gRBD Ferritin nanoparticle
    - Omicron gRBD Ferritin nanoparticle

**Robust Capability**

- **Infectious Disease Antigens**
  - **Now available: H5 (bird flu); mPox***
  - **FLU**
    - INFLUENZA HA & NA
    - INFLUENZA H1N1, H5, H7
  - **FLAVIVIRUS**
    - WN (West Nile)
    - POWASSAN
    - ZIKA
  - **SELECT LIVESTOCK & HUMAN**
    - RABIES
    - SBV (Schmallenberg)
    - RVFV (Rift Valley Fever)
    - IBVD-VLPs (Infectious Bursal Virus Disease)

- **Complex molecules & Others:**
  - Full Spike (SP2)
  - H5N1 (Bird Flu) Ferritin Nanoparticles
  - aMHCII Delta RBD
  - Fc-RBD
  - Others in Development