

Dyadic International (NASDAQ: DYAI)

Next Generation Proteins for the World's Health

H.C. Wainwright Global Investment Conference May 2022

# **Safe Harbor Regarding Forward-looking Statements**

Certain statements contained in this presentation are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including those regarding Dyadic's expectations, intentions, strategies and beliefs pertaining to future events or future financial performance. Actual events or results may differ materially from those in the forward-looking statements as a result of various important factors, including those described in Dyadic's most recent filings with the SEC. Undue reliance should not be placed on the forward-looking statements in this presentation, which are based on information available to us on the date hereof. Dyadic assumes no obligation to update publicly any such forward-looking statements, whether as a result of new information, future events or otherwise. For a more complete description of the risks that could cause our actual results to differ from our current expectations, please see the section entitled "Risk Factors" in Dyadic's annual reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, as such factors may be updated from time to time in Dyadic's periodic filings with the SEC, which are accessible on the SEC's website and at <a href="https://www.dyadic.com">www.dyadic.com</a>

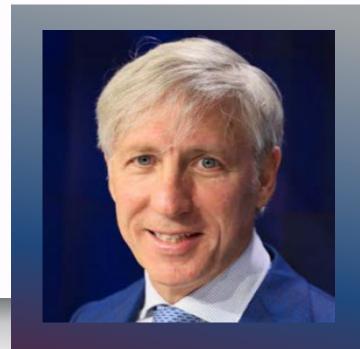


# **Dyadic's Mission**

To improve how we feed, fuel, and heal the world by utilizing modern biotechnology to revolutionize science, medicine, agriculture.

We are delivering a proven, cost-effective, industrial protein expression platform, which can fulfill the promise of affordable biologic drugs, vaccines and biologic products and processes across our core verticals.

Dyadic has achieved certain ports of the above "Mission" through its twenty plus years of experience in industrial biotech. Currently, we are primarily focused on animal and human health applications while opportunistically exploring if and how we may enter/re-enter certain industrial biotechnology applications.



# Mark Emalfarb Founder, CEO

Proven entrepreneur, inventor 25+ U.S. and foreign biotechnology patents, filamentous fungal enzyme product commercialization

# **Dyadic At-a-Glance**

**Re-engineering GMP Vaccine & Drug Production:** Proprietary & patented protein expression platform focused on biologic and vaccine production (the "C1 Platform"), designed to bring products requiring protein expression to market faster, in greater volumes, at lower cost. The C1 platform is de-risked, with a safe and long track record in industrial protein manufacturing

Value Creation Through De-risked Technology Licensing, Co-Development Partnering and Wholly Owned Product Development

Market Capitalization	\$60.0 million (as of 5/18/2022)
Cash & Investment-grade securities, including accrued interest	\$17.5 million (as of 3/31/2022)
Shares Outstanding	~ 28.3 million (as of 5/11/2022)
Debt and Warrants	None
Insider Ownership	~30%
2021 R&D Revenue	\$2.4 million (YoY 50% increase)



NASDAQ DYAI



HEADQUARTERS
Jupiter, Florida



HISTORY Founded In 1979



RESEARCH LOCATIONS
Finland, Spain, US & Others



# **Proven Leaders to Execute Dyadic Keys to Success**



DYADIC

Mark Emalfarb, Founder/CEO

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



Deloitte.

Ping Rawson, CFO

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



**U** NOVARTIS

Joe Hazelton, CBO

20+ Years in Pharmaceutical Industry, commercialization, regulatory, business and clinical development



CODEXIS® teva

Ronen Tchelet, CSO

20+ years in Biopharmaceutical Industry & Recombinant Product Commercialization



**Michael Tarnok** 

Chairman of Board
Seasoned pharma industry finance and operational executive



#### Dr. Barry Buckland

Board Member
29 years R&D leadership | US National Academy of Engineering



#### **Patrick Lucy**

**Board Member** 

20+ years of bioprocess biotech and business development



#### **Dr. Arin Bose**

**Board Member** 

34 years bioprocess development and clinical manufacturing



## **C1 Uniquely Positioned to Address Vaccine and Biologic Challenges**

### **Manufacturing Challenges**

Material and Equipment

Shortened timeframes and shortage of raw materials, equipment, consumables, lipid nanoparticles due to high demand Examples: Cell culture media, Bioreactor bags, vials, tangential flow filters

Process Complexity

Inherent challenges include time to produce new cell lines, drug substance, process optimization, aseptic techniques

Capacity Constraints

Inherent challenges include time to produce new cell lines, drug substance, process optimization, aseptic techniques

#### **C1 Manufacturing Advantages**

20+ years of proven industrial large-scale manufacturing

Conventional stainless-steel fermenters or bioreactor bags

Low cost, widely available media

Stable cell lines in ~ 60 days: From gene synthesis to stable strain for pre-clinical testing

Broad conditions for growth & High Yield

No unique cold storage requirements for manufacture or distribution

-Unparalleled scalable capacity from 5L to 500K L



## **Key Advantages: C1 Protein Production Capability**

## Potential to disrupt conventional manufacturing platforms by overcoming key production limitations



#### **Purity**

- High retention of target secreted protein through downstream processing
- No requirement for viral (i.e., CHO) or endotoxin (i.e., E.coli) inactivation



### **Productivity**

- Robust & versatile growth conditions
- High yields of secreted protein
- Low viscosity due to C1's unique morphology



## Robustness

- Broad commercial scale size, ranging from laboratory microtiter plates, shake flasks, single use and/or stainless-steel
  microbial bioreactors.
- Stable and correctly folded mAbs; Binding and neutralizing properties similar to CHO cells



#### **Speed**

- Develop stable C1 cell lines in ~ 7 weeks
- Production time savings of ~30 days over CHO-cell production (C1: 12-14 days vs CHO: 41-54 days)
- Potential to make ~ 3-4 batches of mAbs in the same time it takes to make 1 batch using CHO cells



#### Cost

- High yields and rapid production cycle times reduce cost and shrink manufacturing footprint
- Requires only low-cost cGMP synthetic media; C1 media <1/20 of the cost of CHO media</li>
- No requirement for viral or endotoxin inactivation, simplifies processing compared to CHO & E.coli saving time, money



## C1 is the Foundation for Our Core Business Segments

## C1-cell Protein Production Platform

#### **Human Health**

Phase 1 Clinical Trial of DYAI-100, COVID-19 (RBD) recombinant protein vaccine candidate:

Demonstrate human safety & preliminary efficacy

Execution of Janssen and other research collaborations with top tier biopharma

Advancing and expanding antigens & mAbs for infectious diseases: Potential SARS-CoV-2 mAb collaboration with EU scientists

Advancing mAbs with registrational potential in oncology, neurodegenerative and other diseases with top tier biopharma, biotech and academia

Glycoengineering effort for potential biosimilar mAb– Nivolumab (Opdivo®)

#### **Animal Health**

Advance commercial recombinant antigen vaccine candidates in poultry animal trials with Phibro/Abic animal health

Expand pipeline and develop C1 expressed biologic products for farm animals and companion animals

Zoonotic diseases from animal to human, including salmonellosis, zoonotic influenza, West Nile virus, coronavirus, plague, rabies, lyme disease, and brucellosis

#### **Other Biomolecules**

Strategic partnership with a Global Food Ingredient Company

WO2020161682 - PRODUCTION OF CANNABINOIDS IN FILAMENTOUS FUNGI

Primary and secondary metabolites

Explore partnerships within the nutraceutical, alternative food and other protein market opportunities



## C1-cell Protein Production Platform Has Been Validated by ZAPI



#### \$20MM PROGRAM OVER 5 YEAR S

EU sponsored Zoonosis Anticipation Preparedness Initiative (ZAPI)

Zoonoses, like Ebola and influenza, represent a serious threat to both human and animal health

Experts in human and animal health

New platforms and technologies facilitating fast, coordinated, and practical response to new emerging infectious disease

DYADIC played a pivotal role in accelerating bio-manufacturing



Dyadic and its C1 cell line far exceeded our initial expectations at the start of the program, turning in record antigen productivity for both the SBV and RVFV antigens ...their C1 technology can be used to churn out vaccines and antibodies in unprecedented amounts... has the potential to further accelerate biologic manufacturing processes

-Dr. Jean-Christophe Audonnet

# **Key Milestone**

# Phase I C1-cell SARS-CoV-2 RBD Recombinant Vaccine. Prove Safety and Efficacy of DYAI-100 Vaccine Candidate in Humans

		✓ = Completed ✓ = Ongoing
	DYADIC	Developed the C1 –SARS-CoV-2 RBD protein based rVaccine (DYAI-100 Vaccine Candidate)
	Universiteit Utrecht	Development of Monovalent RBD characterization / evaluation
	Erasmus MC	Collaboration on preclinical evaluation of the vaccine candidates in small animal
	++++ ENVIGO	Toxicology Study
	BTG A FERRING COMPANY	cGMP manufacturing of Drug Substance for Clinical Trial
	eurofins	cGMP manufacturing of Drug Product for Clinical Trial
<b>②</b>	parexel.	Support with regulatory & CMC consultation towards accelerated licensure
	CR()	Coordination of clinical trials



## Key Partners: Establishing Global Presence with Leading Organizations

Co-developing C1 enabled vaccines, antibodies & other therapeutics for human and animal health

# Research, License and Collaboration Agreement with Janssen



Under the terms of the agreement, Dyadic will receive the following:

- \$500K upfront payment for non-exclusive right and up to €1.6 million R&D funding to develop and assess Janssen product candidates
- Option payment mid-seven figure for exclusive license 1 specific target
- Option payment mid-seven figure for additional non-exclusive targets
- Potential for Dev & Reg milestones in the mid-seven figures per product
- · Potential for additional seven figure payment
- Potential for commercial milestone in the low nine figures per product based on cumulative amount of pharmaceutical product produced

# Dyadic announces development of COVID-19 Vaccine in India

Syngene

Mahesh Bhalgat, COO, Syngene International stated, "We look forward to our collaboration with Dyadic to initially explore the development of a COVID-19 vaccine, and to further evaluate the potential of developing a differentiated vaccine platform based on Dyadic's proprietary C1- cell line."

#### <u>Dyadic Announces Technology Transfer and Licensing</u> <u>Agreement With South Africa's Rubic Consortium</u>



"The need to quickly acquire and commercialize technology and manufacturing capabilities, which addresses the infrastructure necessary to deploy vaccinations for broad populations affordably and timeously has never been a more strategic imperative of African nations than today," said Shabir Madhi, professor of vaccinology, Dean Faculty of Health Sciences at the University of the Witwatersrand, Johannesburg, who is leading COVID-19 vaccine trials in South Africa.

# Dyadic and Phibro Animal Health Announce Exclusive License Agreement to Develop and Commercialize Animal Health Vaccine



Avner Finger, Phibro's Vice President of Research and Development commented, "Following the successful animal testing of antigens produced by Dyadic's C1 expression system for a targeted disease, we are pleased to be moving into the next stage of development to produce a viable vaccine candidate. Phibro remains committed to innovation and supplying superior animal health vaccines and feed solutions. Our commitment extends to not only consumers but to the ethical global supply chain of farmers and animals under their care, in order to provide a healthy source of protein."



# 2022 Year-to-Date Agreements / Events

Development of C1-cell Protein Production Platform for Commercial Use Matures

Date	Agreement / Events
5/22	Research, license and collaboration for the manufacture of animal free ingredients, fully funded (€3.6M) by a global food ingredients company
5/22	3rd peer-reviewed publication in 2022 relating to antigens produced from C1-cells showing safety and efficacy in animal models published in <i>Toxicology Pathology</i>
4/22	Dyadic development partner, Epygen Biotech, secures funding from Government of India to continue development, manufacture and conduct Phase 1 and Phase 2 clinical trial(s) using C1-derived COVID vaccine candidate with goal of commercial production up to 100 million initial doses at \$2 per dose
2/22	Granted Phibro/Abic Animal Health an exclusive license to produce C1-produced specific targeted antigens for development and commercialization of a poultry vaccine for a specific disease
1/22	Patented new method to produce synthetic cannabinoids and precursors from filamentous fungi, including C1-cell protein production platform



## **Key Focus: Infectious Disease Strategy For Animal and Human Health**

## Potential to Develop Multi-Valent Recombinant Variant Antigens (i.e., SARS-CoV-2 and Influenza) Vaccine Candidates

All variants of concern SARS-CoV-2 Receptor Binding Domain (RBD) have been expressed from C1-cells, including the Delta and Omicron variant antigens

1 week

Univ. Oslo HA mice trial supports previous Sanofi HA mice trial for potential use of C1 for producing influenza vaccines

Vaccines – The Highly Productive

Thermothelomyces heterothallica C1

Expression System as a Host for Rapid

Development of Influenza Vaccines

3 weeks

C1 Monoclonal antibodies (mAbs) expressed for potential use in treating infectious diseases

2 weeks

MTP ferm., DSP and Strain construction and 1-30 I scale fermentation Gene synthesis Plasmid construction re-isolation for analytics & RCB from RCB. DSP and monoclonality analytics generation cGMP grade strain and Sending samples for process characterization, evaluation, animal studies MCB

1 week

# **Key Attributes: C1-Cell Recombinant Protein Production for Biologics**

C1-Cells Enable Commercial Manufacture Of Rapid, Cost-Effective, High Value, Safe, Effective Protein Products

High Yields and Purities Demonstrated for Therapeutic Monoclonal Antibodies (mAbs) and Vaccine Antigen GlycoProteins<sup>1</sup>

Fc-Fusion Products
15.3 g/l <sup>1</sup>
168 Hours
2.58 g/l/day

mAb Products
24.5 g/l <sup>1</sup>
168 Hours
3.1 g/l/day

Fab (Certolizumab) Product
14.5 g/l <sup>1</sup>
164 Hours
2.1 g/l/day

Tri-specific Products	
6.12 g/l <sup>1</sup>	
144 Hours	
1.02 g/l/day	

High Productivity for Recombinant Protein Antigen Classes Routinely Used in Vaccines

Influenza HemAgglutinin (HA) Products	
413 g/l <sup>1</sup>	
137 Hours	
72 mg/l/day	

Coronavirus Antigen (S-RBD) Products	
2,000/3,000 mg/ <sup>1</sup>	
129 Hours	
400/600 mg/l/day	

Virus-Like Particle (VLP) Products	
2,200 mg/l <sup>1</sup>	
110 Hours	
500 g/l/day	

## Rising Interest in Pharma for Acquisition of Platform Technologies<sup>1</sup>

Recent acquisitions of cell-based gene expression and recombinant protein platforms

#### 2006

Merck & Co., Inc. To Acquire GlycoFi, Inc. For \$400 Million <sup>2</sup> Yeast cell





#### 2011

Johnson & Johnson Acquires Vaccine Developer Crucell - \$2.4 billion dollars, moving J&J prominently into the arena of vaccine development 3 Human cell

#### 2017

Sanofi completes acquisition of Protein Science for \$750 Million 4 Baculovirus expression system





#### 2020

Ligand Buys Pfenex in \$516 Million Deal to Access Protein Production Platform 5 Bacterial cell

<sup>1.</sup> https://www.forbes.com/sites/mergermarket/2018/10/26/pharma-ma-slumps-as-buyers-seek-platforms-instead-of-single-products/?sh=6fed8c266848/

<sup>2.</sup> https://www.biospace.com/article/releases/merck-and-co-inc-to-acquire-glycofi-inc-for-400-million-/

<sup>3.</sup> https://www.biopharminternational.com/view/johnson-johnson-acquires-vaccine-developer-crucell/

<sup>4.</sup> https://www.pharmaceutical-technology.com/news/newsanofi-completes-acquisition-of-protein-sciences-for-750m-5910136/

<sup>5.</sup> https://www.biospace.com/article/ligand-buys-pfenex-for-516-million/

# **Key Takeaways**

#### Next Generation Protein Production Biotech with Well-established Global Partners

# Lead asset: DYAI-100, COVID-19 Vaccine Candidate

"Pre-IND" first-in-human clinical trial application ("CTA") for Dyadic's recombinant SARS-CoV-2 RBD COVID vaccine

Supported by South Africa's RUBIC consortium and overseen by the University of the Witwatersrand, Johannesburg ("Wits") academic team, part of the Wits Health Consortium (WHC).

Agreement in place to potentially externally fund Phase 2 and Phase 3 of clinical development

## Multiple shots on goal

High demand for R&D collaborations investigating the application of C1 protein production system in:

human and animal health

Alternative food manufacturing and nutraceuticals

Existing and upcoming license agreements and collaborations include upfront, milestone and commercial stage payments

## **Strong cash position**

\$17.5 million in cash and investment securities as of 3/31/2022

No debt or warrants

Conservative cash-burn strategy supported by partner funded on-going R&D collaborations





# THANK YOU

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