

Dyadic International, Inc.**(DYAI: NASDAQ)****DYAI: Catching Up With Dyadic**

Our valuation approach employs a DCF model and a 15% discount rate. We assume a 22.5% probability of ultimate success for C1, based on historical drug approval rates and number of projects in the pipeline. The model assumes revenue contributions from sources worldwide.

Current Price (2/16/2024) **\$1.32**
Valuation \$9.00

OUTLOOK

Dyadic has developed C1, its proprietary fungal expression system that can produce a variety of recombinant proteins. C1 has been commercialized in industrial applications and is in development for production of pharmaceutical grade proteins. C1 exhibits potential to economically produce biologic vaccines, virus like particles, antibodies, Fc-fusion, enzymes, AAVs and other biopharmaceuticals.

In 2015, the company sold its industrial business to DuPont for \$75 million and retained the exclusive right to sublicense C1 for use in animal and human pharmaceutical applications. Proceeds from the DuPont sale provided cash for further development of the C1 platform for production of biologics. Additional R&D funding is provided by partners. Dyadic is working with several biopharmaceutical companies and government organizations to validate the technology and completed a Phase I trial evaluating the effectiveness of its COVID vaccine in 2023.

In the near term, we expect growing R&D revenue as additional partners are added with C1 and Dapibus.

SUMMARY DATA

52-Week High **2.40**
 52-Week Low **1.19**
 One-Year Return (%) **-16.5**
 Beta **0.6**
 Average Daily Volume (sh) **25,359**

Shares Outstanding (mil) **28.8**
 Market Capitalization (\$mil) **38.0**
 Short Interest Ratio (days) **8.5**
 Institutional Ownership (%) **15.7**
 Insider Ownership (%) **30.3**

Annual Cash Dividend **\$0.00**
 Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
 Sales (%) **186**
 Earnings Per Share (%) **N/A**
 Dividend (%) **N/A**

P/E using TTM EPS **N/A**
 P/E using 2023 Estimate **N/A**
 P/E using 2024 Estimate **N/A**

Zacks Rank **N/A**

Risk Level
Type of Stock
Industry
Above Average
Small-Growth
Med-Biomed/Gene

ZACKS ESTIMATES**Revenue**

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2022	\$0.6 A	\$0.7 A	\$0.9 A	\$0.7 A	\$2.9 A
2023	\$1.0 A	\$0.8 A	\$0.4 A	\$0.8 E	\$3.0 E
2024					\$4.2 E
2025					\$6.1 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-\$0.09 A	-\$0.12 A	-\$0.06 A	-\$0.08 A	-\$0.34 A
2023	-\$0.03 A	-\$0.07 A	-\$0.06 A	-\$0.08 E	-\$0.24 E
2024					-\$0.29 E
2025					-\$0.37 E

WHAT'S NEW

Since the report of third quarter results in early November, Dyadic International Inc. (NASDAQ: DYAI) has been active attending investor conferences, reading out clinical trial results and securing further partnerships. Some of the key partnership work that has been accomplished in the last three months includes an expansion of the work with Dyadic's Africa licensee, Rubic One Health, to work with Afreximabank to fund the build of manufacturing capacity. A new agreement with a global biopharmaceutical company was signed and partnership with Cygnus Technologies was forged to provide testing for C1-produced product.

New Collaborations and Partnerships

Rubic and Afreximabank

Dyadic has generated a steady flow of collaborations and partnerships and has continued this progression into 2024. Last November, the company [announced](#) an expansion of development efforts with its African licensee, Rubic One Health with funding entity Afreximabank. Afreximabank has signed an agreement with Rubic that will fund the vaccine manufacturing facility using the C1 platform in South Africa. Production from this facility will supply the entire continent of Africa. The presence of a biologics manufacturing facility will provide a base for production of many therapeutic proteins that can be expressed using Dyadic's C1 platform.

Global Biopharmaceutical Company

An unidentified global biopharmaceutical company [signed](#) a new research and development collaboration agreement with Dyadic, as shared on February 6th. The fully funded agreement includes a commercial option and will support the development and design of four recombinant proteins produced by C1.

Cygnus Technologies

On February 13th, Dyadic [announced](#) that it is working with Cygnus Technologies to develop an enzyme-linked immunosorbent assay (ELISA) test to evaluate C1 derived proteins for impurities and to quantify host cell proteins (HCPs). [Cygnus](#), which was acquired by Maravai LifeSciences in 2016, develops a wide variety of assays, kits and other biologics testing products. It has been working with Dyadic to develop an ELISA test which is critical for evaluating monoclonal antibody outputs from C1 to determine if there are any contaminants that may produce an undesired immune response or impact drug stability. While this type of testing is not necessary for vaccines, it is required for other proteins such as monoclonal antibodies before they can be used in humans. Furthermore, biopharmaceutical manufacturers monitor HCPs to demonstrate reproducibility of their purification process, ensure HCP clearance and perform product lot release testing. The antibody deployed in the Cygnus C1 ELISA kit has been evaluated for over 1,000 HCPs that have appeared in C1-produced product, as determined by antibody affinity extraction and mass spectrometry methods. The availability of the test is an important tool for Dyadic collaborators and partners as it makes testing easier, faster and more accurate compared to other methods.

DYAI-100 Phase I Topline Results

Dyadic [announced](#) topline results from its Phase I DYAI-100 study evaluating a C1-derived antigen used in a vaccine to prevent COVID. Dyadic's partner Rubic One Health ran the study in South Africa which enrolled 30 healthy adults who were administered the vaccine at two dose levels. The C1 SARS-CoV-2 RBD single booster vaccine achieved its primary endpoint and demonstrated safety and reactogenicity of the DYAI-100 recombinant protein. Both dose levels were considered safe and well tolerated. The final clinical study report has since been completed for this first-in-human clinical trial which is the first incidence of a vaccine antigen produced using a filamentous fungal cell line. In the press release, the CEO of partner Rubic noted that the C1-produced product is particularly well suited to Africa due to its relatively low cost and ability to produce product that does not require ultra-cold storage and that can be distributed throughout remote areas of Africa.

DYAI-100 Program

Dyadic achieved a pivotal point in its maturation as a provider of therapeutic proteins as it and partner Rubic One Health completed patient dosing with DYAI-100, a COVID-19 recombinant protein receptor binding domain (RBD) booster vaccine candidate.

The Phase I was designed as a randomized, double blind, placebo-controlled clinical trial conducted in South Africa. It measured the clinical safety and antibody response of DYAI-100, a C1-SARS-CoV-2 recombinant protein RBD vaccine, produced using the C1 platform, administered as a booster vaccine at two single dose levels in healthy

volunteers. Patients aged 18 – 55 were randomized 4:1 for DYAI-100 and placebo, with 15 subjects per cohort. Following the screening period there were eight scheduled clinic visits. The first six visits occurred within the first 29 days following administration and two follow up visits will take place on Days 90 and 180. Safety data will be collected throughout the trial and immunogenicity assessments will be made. An interim analysis of the Day 29 data for both the low and high dose groups by the Data Safety Monitoring Board (DSMB) **determined** there were no major vaccine-related safety concerns.

On March 7th, 2023, an **update** informed stakeholders that dosing was complete and that no serious adverse events were reported. Initial safety and antibody response data was **reported** in late July that reiterated the absence of vaccine-related safety concerns and serious adverse events.

In September 2023, the last patient, last visit occurred and data lock was implemented on November 1, 2023. Top line is expected to be reported to stakeholders in December with a Phase I clinical study report (CSR) to follow.

A November 29th **press release**, discussed above, provided top-line results from the study.

Conference Attendance

Management has continued its busy schedule communicating with investors and leaders in the life sciences industry at a variety of investor events including JP Morgan in San Francisco and BIO CEO in New York. Below we summarize the latest events the team has attended. Management is available for 1:1 meetings with investors.

- NobleCon-19 – December 3-5, 2023
 - Boca Raton, Florida
 - Mark Emalfarb, CEO, presenting
- The Benchmark Company's Investor Conference – December 7, 2023
 - New York
 - Management team
- 7th Annual BFC Global Healthcare BD and Investment Conference – January 7th, 2024
 - San Francisco, California
 - Mark Emalfarb, CEO, presenting
- JP Morgan 42nd Annual Healthcare Conference – January 8-11, 2024
 - San Francisco, California
 - Mark Emalfarb, CEO, Joe Hazelton, CBO
- Discovery to Innovation in Animal Health – February 6-8, 2024
 - Belgium
- The Annual Meat Evolution Leaders Summit – February 7-8, 2024
 - Spain
- BIO CEO & Investor Conference – February 26-27, 2024
 - New York

Summary

Dyadic adds another global biopharma to its roster and is working on a co-development program with Cygnus Technologies to develop an ELISA test. The assay will make cGMP production of C1 produced proteins faster and more accurate. Management continues to interact with investors and scientific teams around the globe. Topline data was reported for DYAI-100 where the C1-derived COVID vaccine was found to be safe and produce an immune response in subjects. We maintain our valuation of \$9 per share.

Research Collaboration Summary

Exhibit I – Summary of Dyadic Collaborations¹

Collaborator	Deal	Ownership	Description	Date
Cygnus Technologies	Co-development		ELISA test	13-Feb-24
Unnamed Global Biopharma	Fully funded		4 recombinant proteins	6-Feb-24
Unnamed CDMO	Fully funded		Injected drug enzyme	8-Nov-23
Unnamed Multinational Pharma	Fully funded		mAbs for infectious disease	8-Nov-23
Unnamed Biopharma	Fully funded		mAbs for Ebola/Marburg	8-Nov-23
Vaccine & Immunotherapy Center	Antigen for infectious disease vaccine		Self Assembling Vaccine	5-Oct-23
bYoRNA SAS	Dev & commercial of mRNA production		mRNA vaccines/RNAi therapies	26-Sep-23
Inzymes	License agreement		Dairy enzymes/Food products	18-Sep-23
Animal Health Co.	Fully funded R&D collaboration		Livestock antigen	Jun-23
Fondazione Biotec di Siena	MoU for epidemic research		Vaccine & antibody develop	24-May-23
Uvax Bio	Research collaboration		Infectious disease vaccine	Jun-23
Fermbio Bio	Funded development & marketing		Animal free proteins	8-May-23
Top 5 Pharma	Research collaboration		Vaccine Antigen	2Q:23
Virovax	Collaboration		Vaccine Candidates	2021
Top tier pharma company	Funded R&D collab & license agmt		Companion animal	mid-2022
Leprino Foods	Funded R&D collab & license agmt		Animal free proteins	11-May-22
Phibro Animal Health	Exclusive License Agreement		Poultry vaccine-2 targets	10-Feb-22
Undisclosed academic collaborator	Fully funded R&D collaboration		Pharmaceutical / antibody	Nov '21
Rubic Consortium	Co-development research collaboration		COVID Vaccine Clin Trials	July'21
Syngene International	Co-development research collaboration		COVID Vaccine	May'21
IDBiologics, Inc	Expansion/Fully funded collaboration	0.4%	mAbs for infectious disease	April '21
Unnamed Collaborator	Fully funded R&D collaboration		Viral antigen	11-Mar-21
CR20	Fully funded R&D collaboration		COVID antibody	22-Apr-21
TurtleTree Scientific	Fully funded R&D collaboration		Recomb protein growth factor	2-Feb-21
Epygen Biotech	Non exclusive license agreement		Paper & pulp enzymes	12-Oct-20
Jiangsu Hengrui Medicine	Fully funded R&D collaboration		Biologic drug development	17-Sep-20
Animal Health Co.	Funded feasibility study		Top 4	8-Jul-20
WuXi Biologics	Nonexclusive research license		Vaccine, drug, biologics	30-Mar-20
University of Oslo	Feasibility Study		Influenza antigens	17-Mar-20
Leading Animal Health Co.	Research funding, full		3 Protein Types	28-Oct-19
Top Tier Pharma	Proof of Concept (PoC)		3 Protein Classes	13-Aug-19
Microbial division	Fermentation evaluation		Microbial division	3Q:19
Affiliate	Evaluate & experiment with C1		C1 commercialization goal	4Q:19
Sanofi Aventis	PoC, Research funding		Biologics & Vaccines	Sep-18
Pharma 1	PoC, Research funding		undisclosed proteins	Dec-18
Pharma 3	PoC, Research funding		undisclosed proteins	Apr-19
Pharma 5	PoC, Research funding		undisclosed protein	4Q:19
VTT/Internal	CRO		Metabolites/Nivolumab	2015

¹ Source: Zacks Research, Dyadic corporate filings and Dyadic Press Releases. Green highlight indicates animal health collaboration. Blue highlight indicates academic collaborator, orange indicates a follow-on project with a previous partner.

PROJECTED FINANCIALS

Dyadic International, Inc. - Income Statement

Dyadic International, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues	\$2.9	\$1.0	\$0.8	\$0.4	\$0.8	\$3.0	\$4.2	\$6.1
<i>YOY Growth</i>	22%	51%	27%	-55%	8%	3%	39%	45%
Cost of R&D Revenue	\$2.1	\$0.7	\$0.8	\$0.1	\$0.6	\$2.3	\$3.4	\$4.9
R&D	\$4.5	\$0.8	\$0.9	\$0.7	\$0.8	\$3.2	\$4.8	\$5.0
G&A	\$6.4	\$1.5	\$1.4	\$1.3	\$1.7	\$5.9	\$6.5	\$6.6
Foreign Currency Exchange	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Income from operations	(\$10.2)	(\$2.1)	(\$2.3)	(\$1.7)	(\$2.3)	(\$8.4)	(\$10.5)	(\$10.4)
<i>Operating Margin</i>	-347%	-210%	-274%	-433%	-293%	-280%	-249%	-170%
Interest Income	\$0.2	\$0.1	\$0.1	\$0.1	\$0.2	\$0.5	\$0.5	\$0.5
Other	\$0.3	\$1.0	\$0.0	\$0.0	\$0.0	\$1.0	\$0.0	\$0.0
Pre-Tax Income	(\$9.7)	(\$1.0)	(\$2.2)	(\$1.6)	(\$2.2)	(\$6.9)	(\$10.0)	(\$9.9)
Provision for Income Tax	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$3.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	200.0%	300.0%
Net Income	(\$9.7)	(\$1.0)	(\$2.2)	(\$1.6)	(\$2.2)	(\$6.9)	(\$10.0)	(\$12.9)
<i>Net Margin</i>	-332%	-98%	-257%	-407%	-273%	-231%	-237%	-211%
Reported EPS	(\$0.34)	(\$0.03)	(\$0.07)	(\$0.06)	(\$0.08)	(\$0.24)	(\$0.29)	(\$0.37)
Shares Outstanding	28.36	28.76	28.81	28.81	28.75	28.78	34.34	34.91

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Dyadic International, Inc. – Share Price Chart²



² Source: Courtesy of barchart.com

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