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August 11, 2023
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Dyadic International, Inc. (DYAI: NASDAQ)

DYAI: MoUs Highlight C1 Vaccine Potential

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 (8/10/2023)	$1.98
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 share repurchase and 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 began a Phase I trial evaluating the effectiveness of its COVID vaccine in 2022 in South Africa.

In the near term, we expect growing R&D revenue as additional partners are added with a material contribution from Janssen Biotech.

SUMMARY DATA

52-Week High	**3.02**
52-Week Low	**1.12**
One-Year Return (%)	**-26.1**
Beta	**0.6**
Average Daily Volume (sh)	**21,056**
Shares Outstanding (mil)	**28.8**
Market Capitalization ($mil)	**57.0**
Short Interest Ratio (days)	**7.6**
Institutional Ownership (%)	**16.1**
Insider Ownership (%)	**30.1**
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	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.6 A	$0.7 A	$0.9 A	$0.7 A	$2.9 A
2023	$1.0 A	$0.8 A	$0.8 E	$0.8 E	$3.4 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	-$0.07 E	-$0.08 E	-$0.25 E
2024					-$0.29 E
2025					-$0.37 E

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WHAT'S NEW

Second Quarter 2023 Operational & Financial Results

Dyadic International Inc. (NASDAQ: DYAI) provided 2Q:23 operational and financial results in a press release on August 9, 2023, filed its Form 10-Q with the SEC and held a conference call with investors.[1] Dyadic announced several new collaborations and expanded agreements since its first quarter report. It has also completed its first in-human trial where DYAI-100 was used as a booster vaccine. No serious adverse events were reported and a safety assessment was provided in June.

A few new collaborations were announced including Uvax Bio for an infectious disease vaccine, Fondazione Fondazione Biotecnopolo di Siena to develop epidemic related vaccines and antibodies and an unidentified animal health company in a fully funded livestock antigen program. A memorandum of understanding was signed with the Bangladesh state-owned pharmaceutical company which is seeking to develop a biopharmaceutical program to support improvement of public health. Work on the Janssen monoclonal antibody and bispecific continues.

Highlights for 2023 to date include:

- Sale of Alphazyme interest – January 2023
- Dosing initiated in DYAI-100 COVID trial – January 2023
- Dosing completed in DYAI-100 COVID trial – February 2023
- Participation in FDA Vaccine Workshop – April 2023
- Presentation at World Vaccine Congress – April 2023
- Patent Notice of Allowance awarded from USPTO – April 2023
- Fermbox Bio animal free protein collaboration – May 2023
- MoU with Bangladesh State-Owned Pharmaceutical Company – June 2023

Financial results for the quarter ending June 30, 2023, compared to the same prior year period:

- Revenues were $0.8 million, up 27% from $0.7 million and cost of revenues was $0.8 million vs. $0.4 million. The revenue and cost of research increase was attributable to activity related to the Janssen license agreements and other collaboration programs in the pipeline;
- Research and development expenses totaled $0.9 million, down 50% from $1.8 million. The decrease was attributable to the reduction in contract research organization activities and cost of pharmaceutical quality and regulatory consultants to manage and support the pre-clinical and clinical development. A decrease in current good manufacturing practice (cGMP) manufacturing costs also contributed to the change;
- General and administrative expenses were $1.4 million, down 18% over prior year period amounts. Lower incentives, insurance expenses, business development, investor relation and legal expenses contributed to the change;
- Interest income increased to $109,000 from $30,000 due to higher yields on securities held;
- Other income was $28,000 compared to $0 and reflected true-ups related to the Alphazyme sale;
- Net loss amounted to ($2.2) million compared to ($3.3) million. On a per share basis, net loss was ($0.07) vs. ($0.12).

As of June 30, 2023, cash, equivalents and short-term securities totaled $10.1 million compared to $12.6 million at the end of 2022. 2Q:23 cash burn was ($1.6) million compared with ($1.8) million in 2Q:22. Financing cash flows were zero. Dyadic holds no debt on its balance sheet. Cash burn guidance for 2023 is maintained at $6 to $7 million.

Bangladesh Memorandum of Understanding

Dyadic has entered into a Memorandum of Understanding (MoU) with Essential Drugs Company Limited (EDCL) the state-owned pharmaceutical company in Bangladesh. Details were provided in a June 21 press release. The

[1] A transcript is also available here.

purpose of the MoU is to help build the infrastructure to increase access and affordability of biomanufactured vaccines and drugs for underserved diseases. Dyadic hopes a collaboration will enable the acceleration of adoption of its microbial platform to manufacture vaccines and biologics faster. The government of Bangladesh seeks to expand collaborations with global partners in an effort to innovate critical therapies. The collaboration with Dyadic is intended to advance research, develop drugs and vaccines, facilitate current good manufacturing practices (cGMP) production and conduct clinical trials.

The relationship traces back to 2021, when Dyadic and Bangladesh began to work on a strategic plan to address the country's bio-security interests and to promote research training and dissemination of knowledge of health technology. This effort is particularly important as Bangladesh recently reported over 1,600 cases of dengue fever in a day and a 2023 total of almost 20,000 cases as of mid-July. More than 170 people have died. There is only one vaccine in the US for vaccine and it is recommended only for people who have had dengue in the past. The vaccine does not work in all types of the fever and new medicines are needed. For those with severe disease, hospitalization is required; however, there is no antiviral treatment for dengue. The prevalence of the mosquito-transmitted disease in Bangladesh highlights the need for internal development of vaccines and treatment.

Serum Albumin

Dyadic announced continued progress toward commercialization of animal-free recombinant serum albumin in an August 7th press release. The results of third-party clinical testing showed that C1 produced serum albumin is structurally equivalent to commercial animal derived product. C1 produced serum albumin has the additional advantage of providing more consistent product that does not include any animal-related contaminants and can be produced efficiently and at low-cost relative to the alternative now in use.

Dyadic is developing bovine and human animal-free serum albumin and has identified a market size of $5.7 billion in 2022 that is growing at a high single digit rate per annum. The product has both pharmaceutical and non-pharmaceutical applications. These include use of albumin to increase blood volume to treat various conditions such as surgical blood loss, hemorrhage, or trauma. Additionally, recombinant serum albumin is being used as an alternative to plasma-derived albumin in human therapeutics, cell culture media, diagnostic test kits and research & development. Serum albumin also has non-pharmaceutical applications as a component of cell culture media in the alternative protein segment. Bovine serum albumin is frequently used as a component of the cell culture media to grow animal cells for the production of cultivated meat.

Dyadic Presentation at FDA Vaccines Workshop

On April 27th, CEO Mark Emalfarb presented at the FDA Vaccines Workshop to present the C1 platform and discussed the expression system's relative speed, productivity, sustainability and affordability. The Phase I COVID study in South Africa was highlighted as was the expected vaccine trial in India. Mark discussed the background behind Dyadic's efforts to develop the vaccine and addressed concerns such as storage temperature, ability to address new COVID variants and production of sufficient antibodies in animal models using multiple forms of administration.

Exhibit I – C1 Expression System Comparison[2]

Characteristic	Pichia	Baculovirus	CHO	C1
Complex proteins	Difficult	Yes	Yes	Yes
Secreted	Yes	Yes	Yes	Yes
Endotoxins	No	No	Yes	No
Viral Clearing	No	Yes	Yes	No
High Yield (g/L)	Low/Med	Very Low	Low/Med	High
Production Speed	12-14d	17-20d	50-54d	12-14d
Multiple Cell Types	No	No	No	Yes
Human Trials	Yes	Yes	Yes	Yes

[2] Source: Dyadic April 27 Presentation at FDA Vaccine Workshop

Patent Notice of Allowance

On April 18th, 2023, Dyadic announced the receipt of a Notice of Allowance from the U.S. Patent and Trademark Office for patent application 16/640,483. The title of the patent is Production of flu vaccine in myceliophthora thermophila which is expected to be valid through 2038. The invention relates to the production of recombinant influenza virus surface proteins in C1. The recombinant proteins are for use in influenza vaccine compositions.

Collaboration with Fermbox Bio

Dyadic will be collaborating with Fermbox Bio Inc. to design, develop and commercialize innovative animal free alternative proteins and biomaterials. The arrangement is a fully funded, co-development collaboration that will employ the Dapibus filamentous fungal based microbial protein production platform and Fermbox's product development capabilities. The deal promises to offer near-term commercialization opportunities in bio-alternate development and microbial precision fermentation. This may produce product offerings for non-pharmaceutical alternative proteins applications, such as those in the food, nutrition, wellness and other bioproduct categories.

First Human Dosing of C1 Vaccine (Rubic)

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 as announced in a March 7th press release. This is an important milestone as first-in-human trials play a crucial role in the drug development process by evaluating the potential benefits and risks of a new treatment and its associated expression system. The work establishes the foundation for larger, more comprehensive trials and broader acceptance of the technology.

The Phase I was designed as a randomized, double blind, placebo-controlled clinical trial conducted in South Africa. It will measure 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 at the end of February and that no serious adverse events were reported. Initial safety and antibody response data was reported in late July the reiterated the absence of vaccine-related safety concerns and serious adverse events. At both dose levels, DYAI-100 produced an immune response and a Phase I clinical study report (CSR) is anticipated in 4Q:23.

C1 has demonstrated an ability to produce a broad variety of therapeutic proteins more quickly, at a lower production cost and with improved features as compared to the broadly used Chinese hamster ovary (CHO) cells. Demonstrating safety in humans could represent a similar breakthrough to the one made by CHO cells, which were first used to produce therapeutic proteins in the 1970s. CHO cells have since become one of the most widely used cell lines in biopharmaceutical production due to their ability to efficiently produce recombinant proteins and maintain proper folding and post-translational modifications. CHO cells produce a wide range of therapeutic proteins, including monoclonal antibodies, cytokines and hormones for use in the treatment of various diseases. Past is prologue for C1 as CHO cells provide a blueprint for what is achievable.

Dosing Background
In June 2022, Dyadic submitted a Clinical Trial Application (CTA) to the South African Health Products Regulatory Authority (SAHPRA) in order to gain approval to initiate a Phase I study. The trial will use C1-produced recombinant protein in the DYAI-100 COVID-19 study. SAHPRA provided clearance to start the trial in October to evaluate the safety and immunogenicity of the vaccine. The Phase I randomized, double blind, placebo-controlled trial is designed to demonstrate clinical safety and preliminary efficacy of DYAI-100, a COVID-19 recombinant protein receptor binding domain (RBD) booster vaccine candidate. Enrollment is targeted to be completed by 1Q:23 and we expect to see topline data available by 3Q:23.

Agreement Expansion
Based on the success of work completed so far, Dyadic and Rubic One Health will expand the licensing agreement to include vaccines and therapeutic proteins beyond COVID into other infectious diseases for both human and ani-

mal health as shared on the 1Q:23 conference call. The original 2021 agreement centered on establishing research, development and manufacturing of C1 produced vaccines. If the union is fruitful, Dyadic will receive marketing rights, milestones and royalty payments from Rubic. The goal of the collaboration is to develop a platform to produce high-quality, cost-effective human and animal vaccines and therapeutic proteins for African markets. Africa's profile requires low cost, temperature-amenable, rapidly producible biologic products to address the challenges it faces and C1 offers a mechanism to do so.

Upcoming Milestones

- DYAI-100 trial last patient, last visit – August 2023
- DYAI-100 trial clinical study report – 4Q:23
- Determine next steps for DYAI-100 – 1H:24

Summary

Dyadic wraps up the second quarter with several important updates and new collaborations. The DYAI-100 trial has provided an interim readout on safety for DYAI-100 as a COVID booster vaccine. No safety concerns were reported, the product was well-tolerated and the vaccine produced an immune response. Serum albumin moves a step closer to commercialization as third party testing shows the C1 produced protein is comparable to existing marketed products. New collaborations have been announced including a new animal health effort, a new program with Uvax Bio and two MoUs with Italian and Bangladeshi entities. Efforts continue with Janssen and the two proteins that the collaboration is developing. Dyadic is in discussions with peers at Janssen to potentially accelerate the pace of the program so that the platform may be embedded into Janssen sooner. We maintain our valuation of $9 per share.

Research Collaboration Summary

Exhibit II – Summary of Dyadic Collaborations[3]

Collaborator	Deal	Ownership	Description	Date
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
Fermbox Bio	Funded development & marketing		Animal free proteins	8-May-23
Top 5 Pharma	Research collaboration		Vaccine Antigen	2Q:23
Medium biotech	Research collaboration		Pharmaceutical enzyme	1Q:23
Small food biotech	Research collaboration		Food protein	Jan '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
Janssen	Funded R&D collab & license agmt		Therapeutic proteins/mAb	Dec '21
Undisclosed academic collaborator	Fully funded R&D collaboration		Pharmaceutical / antibody	Nov '21
Undisclosed industry collaborator	Fully funded R&D collaboration		Non-pharma protein	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
CR2O	Fully funded R&D collaboration		COVID antibody	22-Apr-21
TurtleTree Scientific	Fully funded R&D collaboration		Recomb protein growth factor	2-Feb-21
Top tier global pharma	Fully funded R&D collaboration		Express 2 molecules	12-Nov-20
Pharma 1 (same as below)	PoC, Research funding		Express new protein class	12-Nov-20
Epygen Biotech	Non exclusive license agreement		COVID vaccine-India	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
Animal Health Co.	Funded feasibility study		Two proteins	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
University of Iowa	Partner in-house research		Undisclosed protein	2Q:19
Structural Genomics/Oxford	Partner in-house research		Undisclosed proteins	3Q:18
Fraunhofer/Molecular Biotech	Partner in-house research		Undisclosed vaccines	4Q:18
VTT/Internal	CRO		Metabolites/Nivolumab	2015

[3] 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 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues	**$2.9**	**$1.0**	**$0.8**	**$0.8**	**$0.8**	**$3.4**	**$4.2**	**$6.1**
YOY Growth	*22%*	*51%*	*27%*	*-9%*	*8%*	*17%*	*23%*	*45%*
Cost of R&D Revenue	$2.1	$0.7	$0.8	$0.6	$0.6	$2.7	$3.4	$4.9
R&D	$4.5	$0.8	$0.9	$0.8	$0.8	$3.3	$4.8	$5.0
G&A	$6.4	$1.5	$1.4	$1.5	$1.7	$6.1	$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)	($2.1)	($2.3)	($8.7)	($10.5)	($10.4)
Operating Margin	*-347%*	*-210%*	*-274%*	*-268%*	*-293%*	*-254%*	*-249%*	*-170%*
Interest Income	$0.2	$0.1	$0.1	$0.2	$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)	($2.0)	($2.2)	($7.1)	($10.0)	($9.9)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*200.0%*	*300.0%*
Net Income	**($9.7)**	**($1.0)**	**($2.2)**	**($2.0)**	**($2.2)**	**($7.1)**	**($10.0)**	**($12.9)**
Net Margin	*-332%*	*-98%*	*-257%*	*-248%*	*-273%*	*-209%*	*-237%*	*-211%*
Reported EPS	**($0.34)**	**($0.03)**	**($0.07)**	**($0.07)**	**($0.08)**	**($0.25)**	**($0.29)**	**($0.37)**
Shares Outstanding	28.36	28.76	28.81	28.62	28.75	28.74	34.34	34.91

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

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HISTORICAL STOCK PRICE

Dyadic International, Inc. – Share Price Chart[4]



[4] Source: Courtesy of barchart.com

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