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Dyadic International, Inc. (DYAI: NASDAQ)

2022 Results

Based on our DCF model and a 15% discount rate, we value Dyadic International at approximately $9.00 per share. 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 (3/29/2023)	$1.49
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	**3.56**
52-Week Low	**1.12**
One-Year Return (%)	**-55.1**
Beta	**0.63**
Average Daily Volume (sh)	**27,201**
Shares Outstanding (mil)	**28.8**
Market Capitalization ($mil)	**42.9**
Short Interest Ratio (days)	**14.8**
Institutional Ownership (%)	**16.3**
Insider Ownership (%)	**30.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.5 A	$0.9 A	$0.7 A	$0.3 A	$2.4 A
2022	$0.6 A	$0.6 A	$0.9 A	$0.7 A	$2.9 A
2023					$3.3 E
2024					$2.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.12 A	-$0.14 A	-$0.06 A	-$0.15 A	-$0.47 A
2022	-$0.09 A	-$0.12 A	-$0.06 A	-$0.08 A	-$0.34 A
2023					-$0.42 E
2024					-$0.40 E

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WHAT'S NEW

2022 Operational & Financial Results

Dyadic International Inc. (NASDAQ: DYAI) provided 2022 operational and financial results in a press release on March 29, 2023, filed its Form 10-K with the SEC and held a conference call with investors. Dyadic has advanced to the next stage of a development company with C1 derived proteins evaluated in human subjects in the DYAI-100 study. Dosing of all patients in the trial has been completed and readouts are expected over the balance of the year. Management has continued to emphasize the orientation of its efforts towards three core verticals including Human Health, Animal Health and Alternative Proteins. The goal for each is to identify opportunities that can drive near-term revenues. Ongoing collaborations include strategic partnerships to produce animal free ingredients, opportunities for enzymes, growth factors and cell culture media in the food industry as well as production of metabolites and cannabinoids in the health and wellness space among other initiatives.

Dyadic highlights partner Virovax which is working with Dyadic on the next generation of vaccine candidates sharing its experience in vaccines and adjuvants in a variety of infectious diseases. Efforts are also advancing for a C1-produced bivalent COVID vaccine with Epygen. Other collaborations continue including those with Janssen, Phibro, university partners and others. We also note the sale of the Alphazyme interest provides $1.3 million in cash to the balance sheet in 1Q:23 while maintaining exposure to payments from C1 related Alphazyme sales.

Highlights for 2022 and to date include:

- Government funding granted for Epygen to advance C1 COVID vaccine in clinical trials – April 2022
- Toxicologic Pathology journal publication of DYAI-100 toxicology data – May 2022
- Collaboration agreement with cheese producing global foods company – May 2022
- Submission of Clinical Trial Application (CTA) to SAHPRA – June 2022
- Launch of Dapibus platform for non-pharmaceutical applications – 2Q:22
- Non-human primate study completed dosing for COVID antibody – mid-2022
- Expansion of license agreement with Phibro/Abic – July 2022
- DYAI-100 approval granted by SAHPRA to start Phase I – October 2022
- Publication of DYAI-100 COVID vaccine study in Vaccines – December 2022
- Sale of Alphazyme interest – January 2023
- Dosing initiated in DYAI-100 COVID trial – January 2023
- Dosing completed in DYAI-100 COVID trial – February 2023

Financial results for the year ending December 31, 2022, compared to the same prior year period:

- Revenues were $2.9 million, up 22% from $2.4 million and cost of revenues was $2.1 million vs. $1.9 million. The revenue and cost of research increase was attributable to activity related to the Phibro/Abic and Janssen license agreements;
- Research and development expenses totaled $4.5 million, down 46% from $8.4 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 $6.4 million, down 4% over prior year period amounts. Lower legal expenses were offset by higher incentive, insurance and business development and investor relations expenses;
- Net loss amounted to ($10.2) million compared to ($14.7) million. On a per share basis, net loss was ($0.34) vs. ($0.47).

As of December 31, 2022, cash, equivalents and short-term securities totaled $12.6 million compared to $20.3 million at the end of 2021. Annual cash burn was ($8.1) million compared with ($11.3) million in 2021. Financing cash flows were $0.5 million reflecting the exercise of options. Dyadic holds no debt on its balance sheet. Cash burn guidance for 2023 is $6 million.

First Human Dosing of C1 Vaccine

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. 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 clinical trial will be of a randomized, double blind, placebo-controlled design and 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 will be randomized 4:1 for DYAI-100 and placebo, with 15 subjects per cohort. Following the screening period there are eight scheduled clinic visits. The first six visits will occur 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.

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 is expected in 2Q:23 and a clinical study report (CSR) is anticipated in late 3Q:23 or early 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.

Alphazyme Interest Sale

Dyadic sold its interest in Alphazyme for approximately $1.27 million along with several other investors in an announcement made on January 19th. The agreement, which was originally signed in May 2019, was a sublicense to manufacture molecular enzymes using the C1 expression system. The original agreement included a ~2% equity stake which was sold to Maravai LifeSciences (NASDAQ: MRVI) along with other minority stake holders. The sale includes the option for future performance payments based on enzyme product revenues, subject to certain minimums.

Publication of Vaccine Study

"Thermophilic Filamentous Fungus C1-Cell-Cloned SARS-CoV-2-Spike-RBD-Subunit-Vaccine Adjuvanted with Aldydrogel85 Protects K18-hACE2 Mice against Lethal Virus Challenge" was published in the December edition of the journal Vaccines. The paper addresses the development of C1 produced vaccines for SARS-CoV-2 and addresses the importance of having a widely available, equitably distributed, inexpensive, and rapidly modifiable vaccine platform. The animal study produced results suggesting that DYAI-100 provides sustained immunogenic response against the receptor binding domain (RBD) and comparable efficacy and safety to existing approved recombinant RBD vaccines. No local or systemic toxicity was observed. The piece concluded that the C1 production platform is suitable for production of glycoprotein subunit vaccines and that it will be the subject of a Phase I clinical study. Other benefits of the vaccine are its ability to be stored at higher temperatures compared with mRNA vaccines and ease of rapid manufacture at low cost.

Upcoming Milestones

- DYAI-100 trial last patient, last visit – August 2023
- DYAI-100 trial clinical study report – Late 3Q:23/Early 4Q:23
- Determine next steps for DYAI-100 – 1H:24

Summary

The DYAI-100 trial has continued to progress and dosing has now been completed for all 15 subjects. Updates are expected throughout the year with the key clinical study report expected to be available in late 3Q:23 or early 4Q:23. On other fronts, management has reiterated its strategy shift towards three veritcals including human health, animal health and alternative proteins generated by the newly introduced Dapibus protein expression system. The goal in each segment is to identify and execute around programs that have a near term revenue opportunity.

The benefits of Dyadic's partnership efforts were apparent in the sale of its stake in Alphazyme which generated $1.27 million in cash. This will provide additional working capital to advance internal R&D programs and shows the benefit that can be gained with the many partnerships forged by Dyadic. Dyadic's preclinical R&D work was recognized with a journal publication in Vaccines. The C1 vaccine was able to protect mice against a lethal COVID challenge and demonstrate its flexible and low cost features. We maintain our valuation of $9 per share.

Research Collaboration Summary

Exhibit I – Summary of Dyadic Collaborations[1]

Collaborator	Deal	Ownership	Description	Date
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
Sorrento Therapeutics	Licensing agreement		COVID vaccine & therapeutics	Aug'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
Medytox	Vaccine co-development collaboration		C1 enabled COVID+variant vaccine	22-Mar-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
Top 5 Human Health	Fully funded R&D collaboration		Top 5 with 2 proteins	15-Jul-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

[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.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues	**$2.4**	**$0.6**	**$0.7**	**$0.9**	**$0.7**	**$2.9**	**$3.3**	**$2.8**
YOY Growth	*50%*	*41%*	*-30%*	*27%*	*137%*	*22%*	*13%*	*211%*
Cost of R&D Revenue	$1.9	$0.4	$0.4	$0.6	$0.7	$2.1	$2.6	$2.2
R&D	$8.4	$1.3	$1.8	$0.7	$0.6	$4.5	$5.5	$5.5
G&A	$6.7	$1.7	$1.7	$1.4	$1.7	$6.4	$6.8	$7.5
Foreign Currency Exchange	$0.1	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($14.7)	($2.7)	($3.3)	($1.9)	($2.2)	($10.2)	($11.6)	($12.4)
Operating Margin	*-613%*	*-423%*	*-504%*	*-212%*	*-301%*	*-347%*	*-353%*	*-443%*
Interest Income	$0.1	$0.3	$0.0	$0.1	($0.2)	$0.2	$0.5	$0.5
Other	$1.6	$0.0	$0.0	$0.0	$0.3	$0.3	$0.0	$0.0
Pre-Tax Income	($13.1)	($2.5)	($3.3)	($1.8)	($2.1)	($9.7)	($11.1)	($11.9)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$2.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*200.0%*
Net Income	**($13.1)**	**($2.5)**	**($3.3)**	**($1.8)**	**($2.1)**	**($9.7)**	**($12.1)**	**($13.9)**
Net Margin	*-544%*	*-384%*	*-499%*	*-206%*	*-289%*	*-332%*	*-368%*	*-496%*
Reported EPS	**($0.47)**	**($0.09)**	**($0.12)**	**($0.06)**	**($0.08)**	**($0.34)**	**($0.42)**	**($0.40)**
Shares Outstanding	27.84	28.25	28.26	28.39	28.55	28.36	28.62	34.34

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

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HISTORICAL STOCK PRICE

Dyadic International, Inc. – Share Price Chart[2]



[2] Source: Courtesy of barchart.com

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