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Dyadic International, Inc. (DYAI: NASDAQ)

DYAI-100 Phase I in the Spotlight

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 (11/10/2022)	$2.07
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 currently working with several biopharmaceutical companies and government organizations to validate the technology and has begun 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	**4.98**
52-Week Low	**1.58**
One-Year Return (%)	**-47.1**
Beta	**0.48**
Average Daily Volume (sh)	**31,985**
Shares Outstanding (mil)	**28.7**
Market Capitalization ($mil)	**59.1**
Short Interest Ratio (days)	**8.0**
Institutional Ownership (%)	**14.0**
Insider Ownership (%)	**29.4**
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	$0.9 E	$3.1 E
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	-$0.10 E	-$0.37 E
2023					-$0.43 E
2024					-$0.40 E

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WHAT'S NEW

Third Quarter 2022 Operational & Financial Results

Dyadic International Inc. (NASDAQ: DYAI) provided third quarter 2022 operational and financial results in a press release on November 10, 2022, filed its Form 10-Q with the SEC and hosted a conference call with investors. Dyadic is more explicitly orienting its efforts towards three core verticals including Human Health, Animal Health and Alternative Proteins. Its most important efforts center on the fully-owned C1 produced COVID vaccine that has been granted approval to start a Phase I trial and is expected to enroll patients before year end in South Africa. Efforts are also advancing for a C1 produced COVID vaccine with Epygen in India. Historically, C1 has dominated the company's product set, but earlier this year the Dapibus platform was introduced which is oriented towards non-pharmaceutical applications such as plant-based proteins and cultured meat.

Highlights for 2022 to date include:

- Presentations at multiple conferences – April 2022
- 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
- COVID-19 antibody safety, efficacy & productivity presented by Dr. Osterhaus – October 2022

Financial results for the quarter ending September 30, 2022, compared to the same prior year quarter:

- Revenues were $0.9 million, up 27% from $0.7 million and cost of revenues were $0.6 million vs. $0.4 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 $0.7 million, down 61% from $1.9 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 cGMP manufacturing costs also contributed to the change;
- General and administrative expenses were $1.4 million, down 18% over the prior year period. Lower legal, incentive, and insurance expenses were partially offset by a rise in business development and investor relations expense;
- Net loss amounted to ($1.8) million compared to ($1.7) million. On a per average share balance, net loss was ($0.06) for both periods.

As of September 30, 2022, cash, equivalents and short-term securities totaled $14.2 million compared to $20.3 million at the end of 2021. Quarterly cash burn was ($1.8) million compared with ($4.3) million in 3Q:21. Financing cash flows were $0.4 million reflecting the exercise of warrants. Dyadic holds no debt on its balance sheet.

Clinical Trial Application Submitted in South Africa

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 begin before year end and we expect to see topline data available by 3Q:23.

Other Initiatives

Dyadic has shared a full slate of new initiatives, offerings and movement toward clinical trials. The achievements range from its codified focus on three primary verticals in Human Health, Animal Health and Alternative Proteins to continued advancement towards Phase I studies for DYAI-100 in South Africa and India. The Dapibus platform was introduced mid-year and allows Dyadic to enter spaces that may have been protected by the DuPont license agreement. It is a new fungal expression system targeting the rapid development and large-scale manufacture of low-cost proteins, metabolites, and other biologic products for use in non-pharmaceutical applications such as food, nutrition, and wellness. It is being applied in the Leprino and cultured meat initiatives.

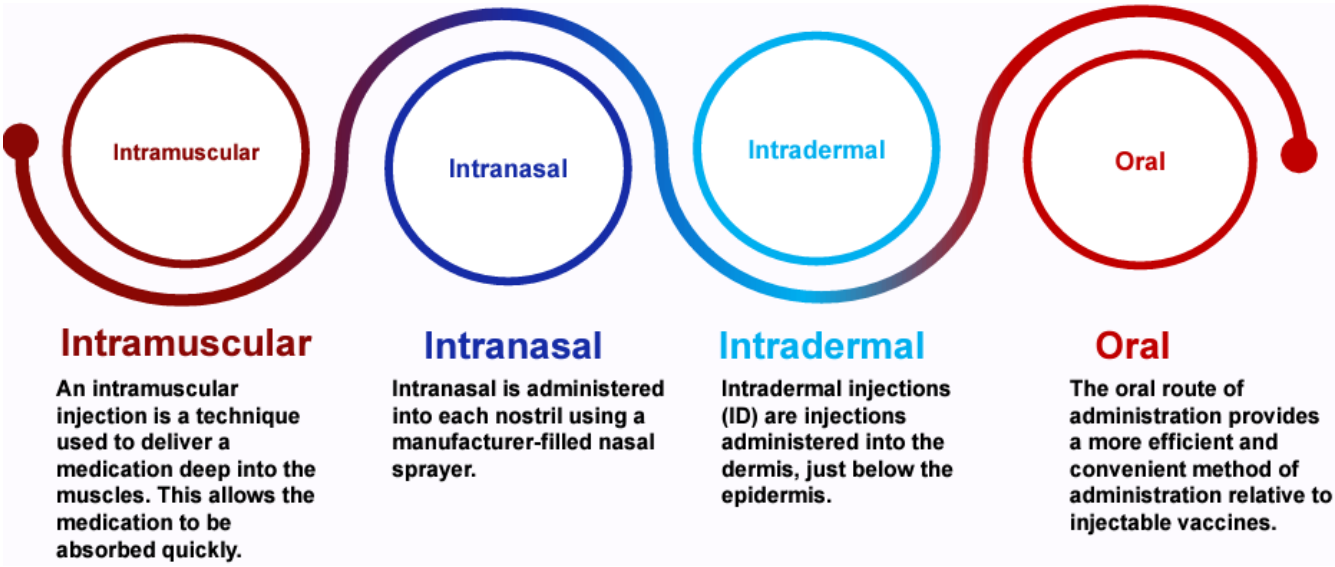
A new protein, neuraminidase (NA), was expressed by C1 which is a type of enzyme that is used to develop influenza vaccines. Neuraminidase appears on the surface of the flu virus and seeks to neutralize antibodies. As it is a feature of the flu virus, it is also an antigen that the immune system can recognize to build resistance. The neuraminidase antigen has been difficult to manufacture at efficient volumes and with an optimal profile, making it an attractive candidate for C1 and for pharmaceutical, biotechnology and government entities that are developing vaccines.

Biologically active NA has been expressed at 0.8 g/L in 7 days for potential use in combination with Hemagglutinin (HA) to play an important role in providing broader influenza vaccine-induced protection. Mice trials conducted by Oslo University for NA have generated high neutralizing antibody levels.

Advances have been made in animal health with expression of a recombinant livestock antigen reaching 10 g/L in seven days. Research projects have also expanded into livestock with work conducted on animal vaccines. In October, a new proof of concept project was initiated with a top animal health company, and two additional recombinant protein projects were launched to support vaccine research and development.

Dyadic is also has many collaborations that span multiple routes of administration, from intramuscular, to intranasal, intradermal and oral. These efforts rely on the delivery technology of partners who are using Dyadic's C1 to produce proteins, such as antigens and monoclonal antibodies for human health.

Exhibit I – Routes of Administration for C-1 Produced Proteins[1]



Recent Scientific Achievements

Dyadic updated investors on several recent achievements with its C1 protein production platform in the infectious disease space. C1 has produced many COVID variant vaccine antigens including Alfa, Beta, Gamma, Delta, and Omicron B.1.1.529 at 0.5-2.5 g/L levels, with Omicron BA.5 currently under development. Next generation pan-coronavirus candidates including Wuhan and Omicron Ferritin S gRBD nanoparticle antigens were expressed with the former at a level greater than 3 g/L over five days.

[1] Source: October 2022 Dyadic Corporate Presentation

World Vaccine Congress Europe

Dyadic collaborator Dr. Albert Osterhaus of the University of Veterinary Medicine, Hannover Germany presented C1 data at the World Vaccine Congress Europe in Barcelona, Catalonia on October 13, 2022. His work demonstrated that the safety and efficacy for C1-produced antigens and antibodies in animal studies are as effective as those produced by other reference production systems such as Chinese hamster ovary (CHO) cells. The SARS-CoV-2 challenge study using non-human primates showed that the C1 antibodies provided protection and preventative benefits.

Summary of Recent and Future Scientific and Investor Events

- H.C. Wainwright (Ping Rawson/Joe Hazelton) – September
- World Health Organization Panel Presentation (Mark Emalfarb) – September
- Vaccine Technology Summit (Mark Emalfarb) – September
- Bioprocess International (Mark Emalfarb) – September
- World Vaccine Congress (Mark Emalfarb/Dr. Albert Osterhaus) – October
- RAFT 14 Conference (Mark Emalfarb) – November
- BARDA Industry Day (Virtual) – November
- INV€$TIVAL Showcase (Mark Emalfarb) – November
- Jefferies London Healthcare Conference – November

Epygen Biotech COVID Funding

In mid-April, Dyadic announced that its partner Epygen Biotech, which had originally become a partner in October 2020, was granted government funding to support Phase I and II clinical trials of Epygen's COVID vaccine candidate. The Indian government's Department of Biotechnology has selected Epygen's vaccine, which uses Dyadic's C1 protein production platform, for funding to support clinical trials. The efforts are expected to develop vaccines that can address new COVID variants and produce 100 million doses per year at a cost of $2 per dose. Additional funding will be needed to support pivotal studies and Epygen is seeking to raise $26 million to support a Phase III trial. Next steps for Epygen on the road to Phase I are preparing the chemistry, manufacturing and control (CMC) package and scaling up the operations to produce clinical quantities of DYAI-100.

Research, License, and Collaboration Agreement with Janssen

On December 17, 2021, Dyadic released news that the company had entered into a research, license, and collaboration agreement with Janssen Biotech, Inc. one of the Janssen Pharmaceutical Companies of Johnson & Johnson (NYSE: JNJ). The agreement was facilitated by Johnson & Johnson Innovation. Details of the structure of the Janssen agreement are provided in filed Form 8-K; however, parameter specifics, including strategic targets and payment amounts, have been redacted. One of the therapeutic proteins that Dyadic is helping Janssen to produce is a monoclonal antibody. The antibody target(s) remain undisclosed, but the partnership is a testament to the abilities for Dyadic's C1, fungal-based technology, to produce complex therapeutic proteins. As of March 2022, the $500,000 upfront payment was received. While timelines are difficult to predict for large pharma, interim details from this project may be provided in early 2023. We provide additional detail on this arrangement in our prior report found here.

Summary

Dyadic released 3Q:22 operational and financial results on November 10, 2022. Highlights since our prior update in mid-August include increases in production capibility for many C1 produced proteins and expansion of antigen production into many new strains of coronavirus. The company signed a new fully funded R&D collaboration with a top tier pharmaceutical company in the companion animal space and will soon start its first in-human trial for the C1 produced COVID vaccine DYAI-100 in South Africa. Dyadic has also introduced a food-oriented expression system called Dapibus that opens the door to new markets. The relationship with Janssen remains on the horizon and could be very favorable to Dyadic if progress continues. Future catalysts include the addition of more collaborators, achieving output milestones with Janssen and launching the planned clinical trial. We maintain our valuation of $9 per share.

Research Collaboration Summary

Exhibit II – Summary of Dyadic Collaborations[2]

Collaborator	Deal	Ownership	Description	Date
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
Alphazyme	Sublicense, Milestone, Royalties	2.0%	Molecular Enzymes	5-May-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

[2] 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 E	2022 E	2023 E	2024 E
Total Revenues	**$2.4**	**$0.6**	**$0.7**	**$0.9**	**$0.9**	**$3.1**	**$3.3**	**$2.8**
YOY Growth	*50%*	*41%*	*-30%*	*27%*	*187%*	*28%*	*7%*	*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	$1.6	$5.5	$5.5	$5.5
G&A	$6.7	$1.7	$1.7	$1.4	$1.7	$6.5	$7.0	$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)	($3.1)	($11.0)	($11.9)	($12.4)
Operating Margin	*-613%*	*-423%*	*-504%*	*-212%*	*-344%*	*-357%*	*-360%*	*-443%*
Interest Income	$0.1	$0.3	$0.0	$0.1	$0.2	$0.5	$0.5	$0.5
Other	$1.6	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($13.1)	($2.5)	($3.3)	($1.8)	($2.9)	($10.5)	($11.4)	($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)**	**($2.9)**	**($10.5)**	**($12.4)**	**($13.9)**
Net Margin	*-544%*	*-384%*	*-499%*	*-206%*	*-322%*	*-340%*	*-375%*	*-496%*
Reported EPS	**($0.47)**	**($0.09)**	**($0.12)**	**($0.06)**	**($0.10)**	**($0.37)**	**($0.43)**	**($0.40)**
Shares Outstanding	27.84	28.25	28.26	28.39	28.45	28.34	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



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