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Dyadic International, Inc. (DYAI: NASDAQ)

DYAI: CEPI Grants Recognize C1

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 (3/26/2025)	$1.33
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 recombinant proteins, 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 and revenues related to albumin and DNAse-1 in 2025.

SUMMARY DATA

52-Week High	**2.67**
52-Week Low	**0.93**
One-Year Return (%)	**-15.8**
Beta	**1.0**
Average Daily Volume (sh)	**80,354**
Shares Outstanding (mil)	**30.1**
Market Capitalization ($mil)	**40.0**
Short Interest Ratio (days)	**2.5**
Institutional Ownership (%)	**17.3**
Insider Ownership (%)	**30.2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**16**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$1.0 A	$0.8 A	$0.4 A	$0.7 A	$2.9 A
2024	$0.3 A	$0.4 A	$2.0 A	$0.8 A	$3.5 A
2025					$6.1 E
2026					$5.5 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023	-$0.03 A	-$0.07 A	-$0.06 A	-$0.07 A	-$0.24 A
2024	-$0.07 A	-$0.07 A	-$0.01 A	-$0.05 A	-$0.20 A
2025					-$0.32 E
2026					-$0.32 E

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WHAT'S NEW

Dyadic International Inc. (NASDAQ: DYAI) announced 2024 results and listed a number of accomplishments that will bring both product and grant revenue in the next months. We are most excited about the partnership with Proliant Health. Dyadic signed a deal in June with Proliant which has so far generated multiple milestone payments while preparing for commercialization of animal-free recombinant albumin products manufactured using C1. We anticipate albumin product sales in 2Q:25. Later this year, product sales from non-animal dairy enzymes with partner Inzymes are forecast to flow through the door. Several grant awards have also been announced, including a Gates Foundation award and two Coalition for Epidemic Preparedness Innovation (CEPI) awards, which are also backed by the Gates Foundation.

2024 Operational & Financial Results

Dyadic released 2024 operational and financial results in a press release on March 26th, 2025, filed its Form 10-K with the SEC and held a conference call with investors. Since the last quarterly update, Dyadic participated in several industry events around the globe where it updated stakeholders on the progress achieved for the C1 and Dapibus microbial platforms and identified several recombinant proteins of interest.

2024 financial results for the period ending December 31st, 2024, compared to the prior year period:

- Revenues were $3.5 million, up 21% from $2.9 million. The increase is due to milestones from the Proliant and Inzymes relationships and contributions from 19 vs. 16 collaborations respectively;
- Research and development expenses totaled $3.2 million, down 39% from $5.3 million. The decrease was attributable to the absence of expenses related to the DYAI-100 clinical trial;
- General and administrative expenses were $6.1 million vs. $5.8 million, rising 5%. The change was attributable to higher professional services, share based compensation, business development and investor relations expenses offset by decreases in management incentives, legal expenses and insurance;
- Other expenses were $0.1 million vs. $1.4 million as increases in interest income were more than offset by expenses related to the convertible notes and the contributions in the prior year from the sale of Dyadic's interest in Alphazyme;
- Net loss amounted to ($5.8) million compared to ($6.8) million. On a per share basis, net loss was ($0.20) vs. ($0.24).

As of December 31st, 2024, cash, equivalents and short-term securities totaled $9.3 million compared to $7.3 million at the end of 2023. Cash burn for 2024 was ($4.0) million compared with ($6.7) million for 2023. Financing cash flows were $5.8 million reflecting the net proceeds from the $6.0 million convertible note issuance in the first quarter.

CEPI Awards

Fondazione Biotecnopolo di Siena
On March 20th, Dyadic announced that CEPI[1] granted $4.5 million to the non-profit Fondazione Biotecnopolo di Siena (FBS) to conduct proof of concept research that will examine the efficiency of producing antigens using C1 vs. mammalian cells. In the release, Dyadic highlights the potential efficiencies of C1 comparing the four-to-six-month duration of producing protein antigens using mammalian cells compared with a potential 35 days for C1. The goals of the program are to develop a system that can rapidly produce large quantities of therapeutic proteins in standard biomanufacturing facilities with an output that does not require extreme cold for transport and storage.

Specifically, the CEPI grant will support the production of a SARS-CoV-2 spike protein comparing output from C1 mammalian cell expression systems. Researchers will then compare the two to see if the antigen produced by the C1 fungus is comparable in structure and immunogenicity to those produced in mammalian cells. If successful, the next phase of the project will focus on selecting an antigen from a pathogen of interest to CEPI for development of a vaccine that can be rapidly deployed.

[1] The Coalition for Epidemic Preparedness Innovations (CEPI) is a global partnership established to accelerate the development of vaccines against emerging infectious diseases that could potentially cause epidemics or pandemics. CEPI was launched in January 2017 at the World Economic Forum in Davos, Switzerland, with initial funding from the Bill and Melinda Gates Foundation, the Wellcome Trust, and governments including Norway and India.

Uvax Bio

On March 23rd, CEPI announced a $2.6 million investment to advance Uvax Bio's Middle East Respiratory Syndrome (MERS). CEPI's funding will also support research to assess manufacturing the vaccine using C1. If successful, this could increase the speed of vaccine production and lower manufacturing costs to improve access to vaccine doses in the future.

$3 Million Gates Foundation Grant

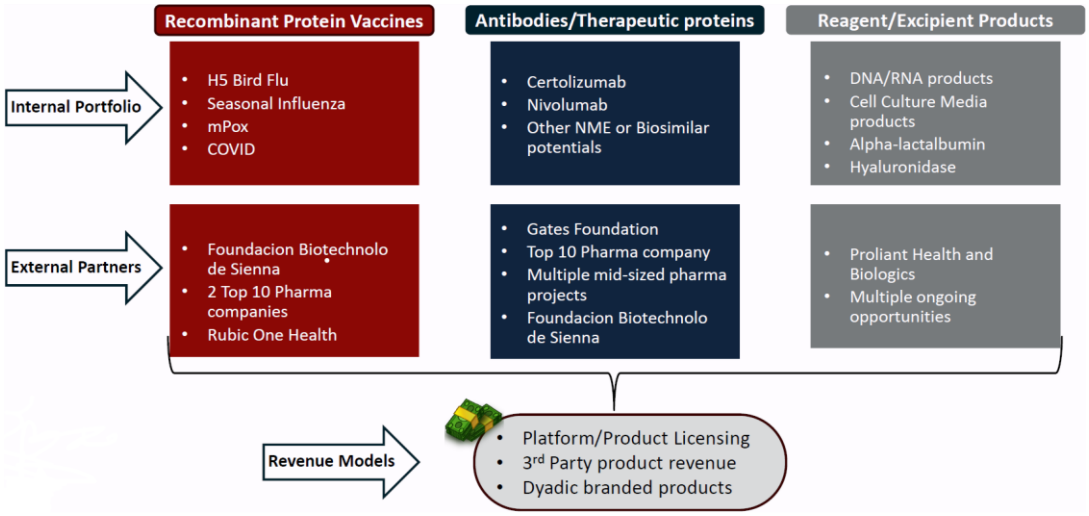
Dyadic's other work, especially that related to the $3 million grant from the Bill and Melinda Gates Foundation, provides other pathways to revenue. The Gates Foundation funding will allow Dyadic to validate its expression platform to manufacture monoclonal antibodies to address malaria and respiratory syncytial virus (RSV). The grant, announced last November, is seeking a way to make traditionally expensive biologics more cost effective so that they can be produced in developing countries such as Africa. If Dyadic successfully completes early-stage clinical trials, it may partner with South Africa's Rubic One Health or Fondazione Biotecnopolo di Siena to advance it towards commercialization in developing regions where cost constraints demand novel solutions.

Competitive Advantage of C1 Produced Proteins

Consumers prefer recombinant proteins because they are more consistent, avoid the impurities of animal-derived product and are more sustainable; however, the hurdle to use has been cost. With C1's efficient production ability, Dyadic asserts that recombinant bovine serum albumin can be manufactured at expense levels competitive with animal-based product. This has the potential of attracting market share from traditional sources as customers of these products recognize its value. In addition to the proteins that Dyadic has licensed to Proliant, there are other proteins[2] that have received a certificate of analysis[3] and are exposed to attractive markets.

Deoxyribonuclease I (DNAse1) is a critical and expensive input into manufacturing messenger RNA, producing proteins and enzymes, removing genomic DNA contamination and cell isolation procedures. In mRNA manufacturing, it helps ensure the purity and quality of the final mRNA product. Dyadic's C1 produced DNAse1 holds a certificate of analysis and the product is ready for non-GMP production and cGMP process development. Dyadic is seeking a partner to manufacture and commercialize DNAse1 or may employ the services of a contract development and manufacturing organization (CDMO) to produce it and sell into small markets itself. This is estimated to be a $300 to $500 million total addressable market. Other raw material inputs to the mRNA enzyme market include another $825 million in total addressable market such as TdT terminal transferase, T4 DNA ligase, RNase Inhibitor and T7 RNA polymerase. These markets are served by high-cost *e. coli* expression systems or natural sources, each of which has purity and cost considerations that are largely solved using the C1 expression system. Dyadic has enumerated many of the key products in human health where it can contribute significant benefits listed below.

Exhibit I – C1 Derived Products for Human Health



Source: Dyadic January 2025 Presentation

[2] As of the latest update, Dyadic has received a certificate of analysis for DNAse-1, bovine albumin, bovine transferrin and bovine alpha-lactalbumin

[3] A Certificate of Analysis is a document that verifies that a product meets specified quality and consistency standards. When ensuring that expressed proteins are equivalent to another product (such as a reference protein or biosimilar), the CoA typically includes analytical test results and key quality attributes.

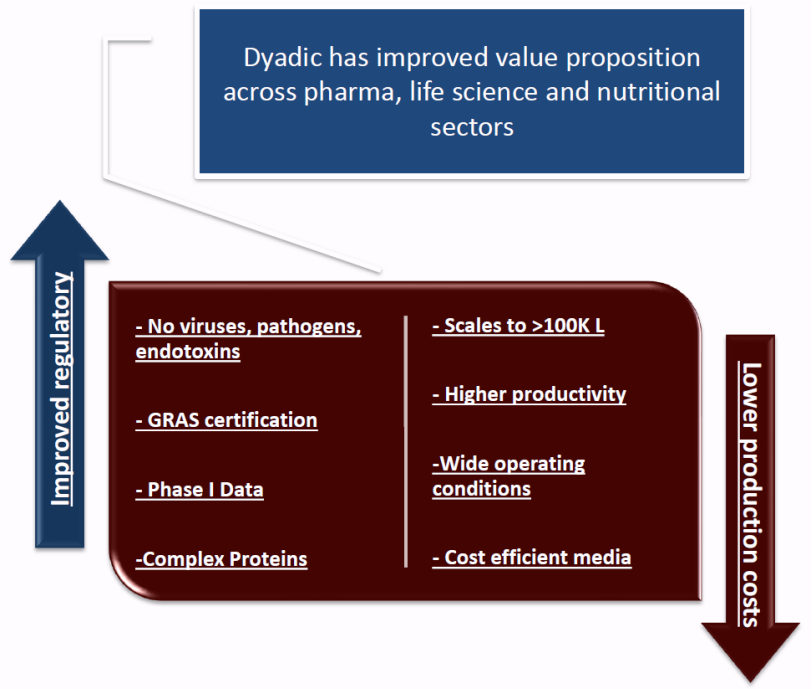
Proliant Health and Biologicals Partnership Background

Last June, Dyadic announced a development and commercialization partnership with Iowa-based Proliant Health and Biologicals to sell animal-free recombinant albumin products produced by C1. The deal included initial payments of $1.5 million which supported Dyadic's technology transfer, scale up and commercialization obligations. According to the data collection firm Global Market Research Matrix, the global albumin market size was $6.4 billion in 2023 growing at a mid-single digit rate. Proliant is a dominant player in the albumin market and has a facility in New Zealand to source bovine blood product. The initial focus of the partnership is upon the production and commercialization of recombinant human serum albumin with launch expected in 2Q:25. We expect terminal profitability to be achieved quickly as assets are already in place. Dyadic has received the entire $1.5 million from Proliant in upfront and pre-commercialization milestones.

Recombinant serum albumin has several important uses in medicine and biotechnology. Below we identify several of the key areas where it is used:

- Stabilizer and carrier for drugs, particularly biologics;
- Supplement to cell culture media providing nutrients and growth factors;
- Plasma expander for patients with severe blood loss;
- Stabilizer for vaccine formulations;
- Protein purification;
- Diagnostic tests;
- Cryopreservation;
- Medical device coatings for stents and tubing to improve biocompatibility.

Exhibit II – Benefits of Recombinant Proteins



Source: Dyadic December 2024 Corporate Presentation

In many cases, recombinant albumin is more attractive than animal-based alternatives because it has fewer contaminants and no animal-borne viruses that may be present in the naturally derived version. Supply of recombinant albumin is more reliable, avoids ethical issues related to animal use, is preferred by regulatory agencies and customers and is more sustainable than animal-derived product.

C1-produced recombinant albumin offers the additional advantage of being less expensive to produce compared to product generated by other expression systems. Based on our analysis and feedback from Dyadic, the cost of producing recombinant serum albumin using C1 versus other popular expression systems would be from 25% to 30% lower.

Management has indicated that first albumin sales should appear in 2Q:25. Dyadic and the Proliant team have completed the technology transfer and scale up activities and are now sampling product. The next milestone is commercialization. Proliant's marketing team is informing customers and prospects of animal-derived albumin about the benefits of recombinant albumin, in preparation for first sales.

The deal between the two companies will provide an undisclosed share of Proliant's profits to Dyadic. We estimate this could be from 10 – 15% of total C1 derived recombinant albumin revenues. While the arrangement is exclusive for recombinant human albumin, it does not prevent Dyadic from signing other deals in the albumin space from other animal hosts such as canine albumin.

Proliant Profile
Proliant Health & Biologicals is a private manufacturer of proteins that serves companies in the microbiological, life sciences, biopharmaceutical and veterinary sciences around the world. The company has two production plants that host its closed-loop manufacturing process with one located in Boone, Iowa and the other in Feilding, New Zealand. The facilities produce outputs according to FDA cGMP standards. The New Zealand facility provides bovine blood product for processing in Iowa and subsequent global distribution. Proliant provides goods in the Diagnostics, Cell Culture and Nutrition space. This includes bovine serum albumin, bovine gamma globulin, purified proteins, and digestive and gut health products. Proliant works with many leading health science companies including Veritas, Biophyll and J Sights Corporation.

Proliant has traditionally produced only animal-based albumin, but it recognizes the preference for human and especially recombinant human albumin that can be used across broader applications. Up until now, the more expensive classes and grades of albumin which include human and recombinant human albumin are not used due to cost constraints. C1 produced product is expected to have substantially lower costs compared with competitors due to its efficiency as a production system and reduced purification demands relative to alternatives that are necessary for Chinese hamster ovary (CHO) or *e. coli* production.

Milestones

- $3 million grant from Gates Foundation – November 2024
- Proliant customer outreach for bovine/human albumin – 4Q:24 & 1Q:25
- Proliant conducting scale up activities – 1Q:25
- Proliant takes orders for C-1 produced product – 1Q:25
- Proliant ships albumin orders – 2Q:25
- Fibroblast growth factors sampling – 2Q:25
- Proliant productivity milestone – 3Q:25
- Human lactoferrin research & pharmaceutical applications sampling – 2H:25
- Expanded enzymes (RNAse inhibitors/T7 RNA polymerase) development & optimization results – late 2025
- Launch of recombinant dairy enzyme – late 2025

Summary

Dyadic reports 2024 results on the cusp of product revenues from recombinant albumin sales. Dairy enzyme product revenues are expected before year end. Funding from grants is another important contributor to the business with three recent awards tied to the productivity and efficiency of the C1 expression system. The company has other initiatives that can also generate product revenues such as DNAse1, which is the subject of ongoing discussions and could be the third product to generate sales. Options abound for many of these proteins. Dyadic could either partner with a CDMO to sell the product itself or find a partner that would pay a royalty. We hope to see Dyadic continue this methodical approach to pick the low hanging fruit so it can evolve into a self-funding entity and pursue other recombinant markets in the animal health, food, and vaccine markets. In the meantime, Dyadic maintains a strong balance sheet, with minimal cash burn. Our main focus remains on Proliant, dairy enzymes and DNAse1. We maintain our valuation of $9 per share.

Research Collaboration Summary

Exhibit III – Summary of Dyadic Collaborations[4]

Collaborator	Deal	Description	Date
Gates Foundation	Grant for $3mm	RSV & Malaria mAbs	21Nov24
Fondazione Biotecnopolo di Siena	Grant funded partnership	Vaccine antigens & antibodies	3Q:24
Top 10 Global Dairy Company	Joint development agreement	non-animal alpha-lactalbumin	Aug '24
Proliant Health & Biologicals	Dev & commercial + profit share	Recomb human albumin	Jun '24
Biftek Inc	Co-promotion/Revenue share	Growth medium supplement	Mar '24
Top 10 Pharma	Fully Funded	Vaccine Antigen	3/25/24
Rabian BV	Fully Funded	Rabies vaccine	2/28/24
Israel Institute of Bio Research	Targeting commercialization	Emerging diseases & biothreats	Feb '24
Cygnus Technologies	Co-development	ELISA test	2/13/24
Unnamed Global Biopharma	Fully funded	4 recombinant proteins	2/6/24
Unnamed CDMO	Fully funded	Injected drug enzyme	11/8/23
Unnamed Multinational Pharma	Fully funded	mAbs for infectious disease	11/8/23
Unnamed Biopharma	Fully funded	mAbs for Ebola/Marburg	11/8/23
Vaccine & Immunotherapy Center	Antigen for infectious disease vaccine	Self Assembling Vaccine	10/5/23
bYoRNA SAS	Dev & commercial of mRNA production	mRNA vaccines/RNAi therapies	9/26/23
Inzymes	License agreement	Dairy enzymes/Food products	9/18/23
Animal Health Co.	Fully funded R&D collaboration	Livestock antigen	Jun-23
Fondazione Biotec di Siena	MoU for epidemic research	Vaccine & antibody develop	5/24/23
Uvax Bio	Research collaboration	Infectious disease vaccine	Jun-23
Fermbox Bio	Funded development & marketing	Animal free proteins	5/8/23
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	5/11/22
Phibro Animal Health	Exclusive License - expanded Mar '24	Poultry/livestock vaccine-2 targets	2/10/22
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	mAbs for infectious disease	April '21
Unnamed Collaborator	Fully funded R&D collaboration	Viral antigen	3/11/21
CR2O	Fully funded R&D collaboration	COVID antibody	4/22/21
TurtleTree Scientific	Fully funded R&D collaboration	Recomb protein growth factor	2/2/21
Epygen Biotech	Non exclusive license agreement	Paper & pulp enzymes	10/12/20
Jiangsu Hengrui Medicine	Fully funded R&D collaboration	Biologic drug development	9/17/20
Animal Health Co.	Funded feasibility study	Top 4	7/8/20
WuXi Biologics	Nonexclusive research license	Vaccine, drug, biologics	3/30/20
University of Oslo	Feasibility Study	Influenza antigens	3/17/20
Leading Animal Health Co.	Research funding, full	3 Protein Types	10/28/19
Top Tier Pharma	Proof of Concept (PoC)	3 Protein Classes	8/13/19
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	9/1/18
Pharma 1	PoC, Research funding	undisclosed proteins	12/1/18
Pharma 3	PoC, Research funding	undisclosed proteins	4/1/19
Pharma 5	PoC, Research funding	undisclosed protein	4Q:19
VTT/Internal	CRO	Metabolites/Nivolumab	7/7/05

[4] 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

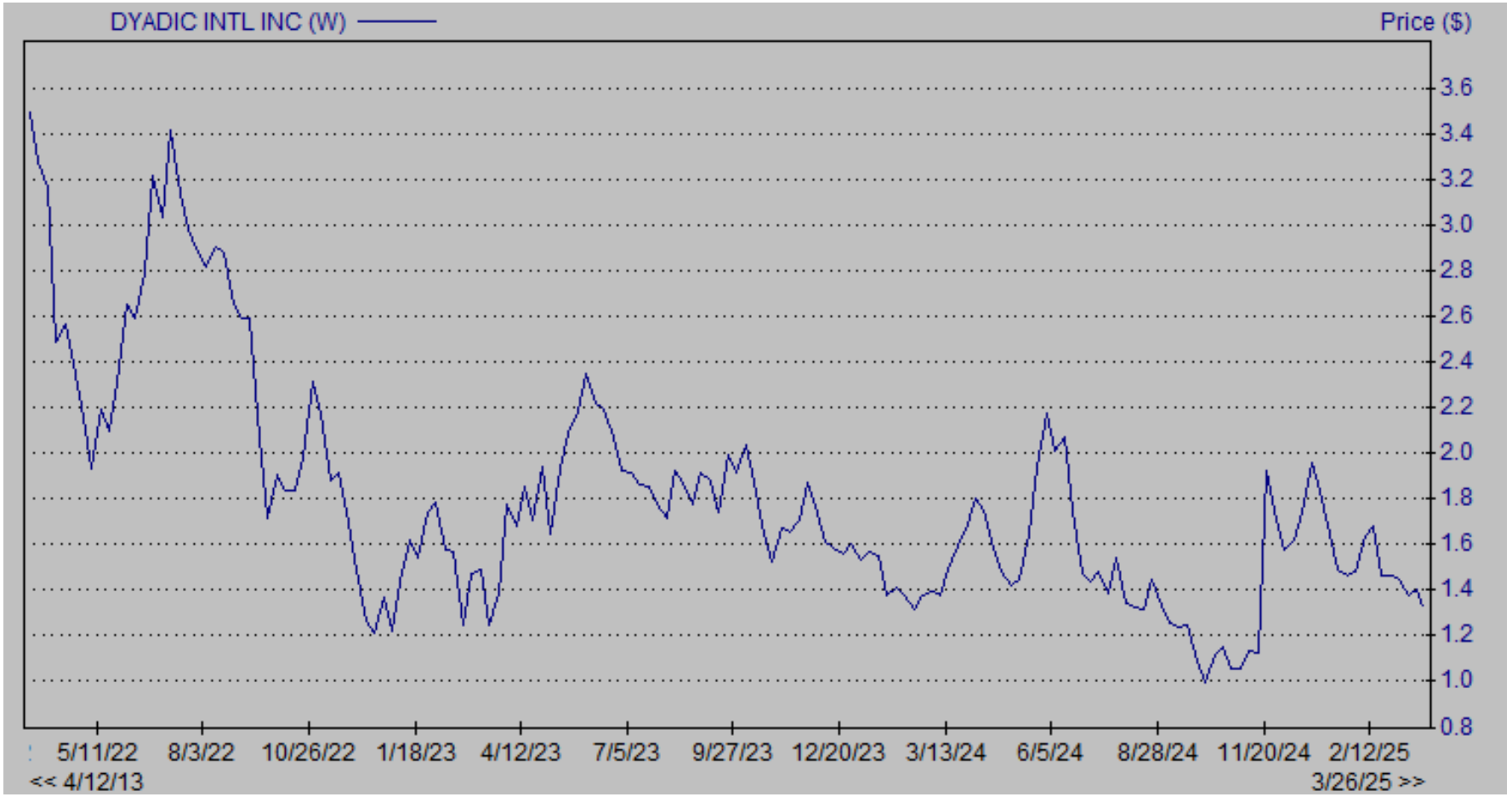
Dyadic International, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	2025 E	2026 E
Total Revenues	**$2.9**	**$0.3**	**$0.4**	**$2.0**	**$0.8**	**$3.5**	**$6.1**	**$5.5**
YOY Growth	*-1%*	*-66%*	*-54%*	*393%*	*19%*	*21%*	*75%*	*-10%*
Cost of R&D Revenue	$2.0	$0.1	$0.3	$0.4	$0.4	$1.2	$3.0	$2.8
R&D	$3.3	$0.5	$0.5	$0.5	$0.5	$2.0	$2.2	$2.5
G&A	$5.8	$1.8	$1.6	$1.3	$1.4	$6.1	$6.3	$4.8
Foreign Currency Exchange	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($8.2)	($2.1)	($2.0)	($0.2)	($1.5)	($5.9)	($5.4)	($4.6)
Operating Margin	*-284%*	*-635%*	*-529%*	*-10%*	*-187%*	*-169%*	*-89%*	*-84%*
Interest Income	$0.4	$0.1	($0.0)	($0.0)	$0.4	$0.5	$0.5	$0.5
Other	$1.0	$0.1	$0.0	$0.0	($0.4)	($0.4)	$0.0	$0.0
Pre-Tax Income	($6.8)	($2.0)	($2.0)	($0.2)	($1.6)	($5.8)	($4.9)	($4.1)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3.0	$4.0
Tax Rate	*100.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*200.0%*	*300.0%*	*400.0%*
Net Income	**($6.8)**	**($2.0)**	**($2.0)**	**($0.2)**	**($1.6)**	**($5.8)**	**($7.9)**	**($8.1)**
Net Margin	*-234%*	*-601%*	*-530%*	*-10%*	*-190%*	*-166%*	*-130%*	*-147%*
Reported EPS	**($0.24)**	**($0.07)**	**($0.07)**	**($0.01)**	**($0.05)**	**($0.20)**	**($0.23)**	**($0.23)**
Shares Outstanding	28.80	28.83	29.29	29.50	29.56	29.32	34.91	35.00

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

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HISTORICAL STOCK PRICE

Dyadic International, Inc. – Share Price Chart[5]



[5] Source: Courtesy of barchart.com

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