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Dyadic International, Inc. (DYAI - NASDAQ)

Six New Deals Since Q2

Based on our DCF model and a 15% discount rate, we value Dyadic International at approximately $10.00 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 (11/13/2020)	$6.42
Valuation	**$10.00**

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.

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

SUMMARY DATA

52-Week High	**10.98**
52-Week Low	**2.51**
One-Year Return (%)	**11.8**
Beta	**0.32**
Average Daily Volume (sh)	**104,575**
Shares Outstanding (mil)	**27.5**
Market Capitalization ($mil)	**176.4**
Short Interest Ratio (days)	**10.5**
Institutional Ownership (%)	**24.9**
Insider Ownership (%)	**30.0**
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 2020 Estimate	**N/A**
P/E using 2021 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)
2019	$0.4 A	$0.4 A	$0.5 A	$0.4 A	$1.7 A
2020	$0.3 A	$0.5 A	$0.4 A	$0.6 E	$1.9 E
2021					$3.0 E
2022					$3.1 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.08 A	-$0.10 A	-$0.06 A	-$0.06 A	-$0.31 A
2020	-$0.08 A	-$0.10 A	-$0.09 A	-$0.08 E	-$0.35 E
2021					-$0.31 E
2022					-$0.31 E

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WHAT'S NEW

Third Quarter Operational & Financial Results

Dyadic International Inc. (NASDAQ: DYAI) released third quarter operational and financial results on November 12, 2020 and filed its form 10-Q with the SEC. The company continued to add funded collaborations to its portfolio, aggregating several new partners since the beginning of July. These include two new animal health groups, a Chinese and Indian biotechnology firm, a large unidentified pharmaceutical company and a private biotech group developing human monoclonal antibodies. Other highlights include expanded animal efficacy data in the COVID-19 programs and further preclinical efforts by ZAPI for Schmallenberg Virus and Rift Valley Fever Virus.

Revenues of $0.4 million represented research and development proceeds from eight on-going research collaborations working to develop C1. Total expenses were $3.0 million and net loss was ($2.5) million after adding interest income. On a per-share basis, net loss was ($0.09).

Third quarter 2020 revenues fell 8% to $0.4 million despite an increase in active research collaborations. The decline in research collaboration revenues was attributable to the smaller dollar amount for each project. Total expenses during the three month period rose 26% to $3.0 million. In the research and development category,[1] the increase was due to expenditures on COVID-related and internal research and development projects partially offset by the completion of research projects with BDI. General and administrative expenditures were up 56% to $1.6 million on higher cash compensation expenses, legal and SEC registration expenses, accrued incentives and insurance premiums. Net loss was ($2.5) million for the period, lower than the ($1.7) million recorded in 3Q:19. On a per share basis, net loss was ($0.09) which compares to the ($0.06) recognized in the prior year period.

Cash burn was ($1.4) million in 3Q:20 compared to ($1.5) million in 3Q:19. Cash and equivalents were $31.8 million on June 30, 2020, down from $34.2 million at the end of 2019. Cash balances at the end of the quarter were equivalent to ~$1.11 per share.

Animal Health

Dyadic has relationships with all of the top four animal health companies. Two additional animal health companies were added to the partner list and were announced on July 8th. While management has not explicitly disclosed the partners' identities, we know that the top four companies are Zoetis, Merck Animal Health, Boehringer Ingelheim and Elanco. This brings the total number of animal health collaborations to eight, two of which include a partial ownership in successful commercialization of successful products. Dyadic expects that at least one of these partners will move into animal health studies in 2021.

Cost pressures are acute in animal health and development and manufacturing of pharmaceutical products requires efficiencies that can economically address large populations of livestock and pets. In a competitive landscape where cost is key, C1 is a leading technology that can provide this needed characteristic. We discussed these arrangements in an article found here.[2]

The work with ZAPI is providing exposure of C1's capabilities not only to the European public-private partnership that serves to respond to new infectious disease threats but also to the other partners involved in the effort. Other partners include large pharmaceutical firms such as AstraZeneca, Boehringer Ingelheim and the academic community in the veterinary and infectious disease spaces. ZAPI continues its work on antigens for the Schmallenberg (SBV) and Rift Valley Fever (RVFV) viruses. Additional challenge studies will be conducted to determine the effectiveness of the vaccines.

[1] Total R&D includes Cost of R&D Revenue, R&D and R&D Related Party amounts.
[2] https://scr.zacks.com/News/Press-Releases/Press-Release-Details/2020/DYAI-Dyadic-Animal-Health-Partners-Summary/default.aspx

Research Collaborations

Since the second quarter report, Dyadic has announced several new collaborations and an expansion of an existing relationship. The newest projects include a fully funded collaboration with a large global pharmaceutical company that will focus on two molecules and a follow-on project with an existing partner which will evaluate C1's ability to express a new class of protein. Dyadic has also set its sights on the two most populous countries, signing an agreement with Epygen Biotech in India and Jiangsu Hengrui Medicine in China. Epygen focuses on development of therapeutic proteins in oncology, cardiovascular disease, immune disorders and vaccines, with an emphasis on affordability. It will use C1 to develop a vaccine for clinical trials in India. Hengrui is a leader in cancer drugs, surgical medicines and owns a drug engineering technology research center. Hengrui is expected to focus on a new drug, but one that may be in an existing class that has seen success.

Exhibit I – Summary of Dyadic Collaborations[3]

Collaborator	Deal	Ownership	Description	Date
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
Small Unidentified Biotech	Fully funded R&D collaboration		COVID vaccine	10-Aug-20
Top 5 Human Health	Fully funded R&D collaboration		Top 5 with 2 proteins	15-Jul-20
IDBiologics, Inc	Feasibility Study funded w/ equity	0.4%	mAbs for infectious disease	8-Jul-20
Animal Health Co.	Funded feasibility study		Top 4	8-Jul-20
Animal Health Co.	Funded feasibility study		Global	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
Small Unidentified	Funded feasibility study		No detail	30-Mar-20
EU Consortium	Feasibility Study		Corona vaccine	17-Mar-20
Ufovax/Scripps Research	Feasibility Study		HIV and Corona vaccine	17-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
Serum Institute of India	PoC, Royalty, Milestone		8 antibodies & 4 vaccines	7-May-19
Alphazyme	Sublicense, Milestone, Royalties	7.5%	Molecular Enzymes	5-May-19
Luina Bio/Novovet	Sublicense, Milestone, Royalties	20.0%	Animal Health	26-Apr-19
Sanofi Aventis	PoC, Research funding		Biologics & Vaccines	Sep-18
Mitsubishi Tanabe	PoC, Research funding		Difficult to express proteins	Mar-18
Pharma 1	PoC, Research funding		undisclosed proteins	Dec-18
Pharma 2	PoC, Research funding		undisclosed protein	Feb-19
Pharma 3	PoC, Research funding		undisclosed proteins	Apr-19
Pharma 4	PoC, Research funding		Primary metabolite	Feb-18
Pharma 5	PoC, Research funding		undisclosed protein	4Q:19
Israel Institute of Bio Research	Partner in-house research/Expanded		Antigen,Enzyme,Corona&proteins	1Q:18
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
ZAPI	Research funding/Expanded		Epidemic Vaccines	2015
VTT/Internal	CRO		Metabolites/Nivolumab	2015
VLPbio	CRO	16.1%	Virus Like Particles	2017
BDI	CRO	16.1%	Certolizumab/AAV	2017

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

Dyadic is willing to partner in all shapes and forms, either with contribution of funds or an ownership stake in the research group. On July 8th, the company signed an agreement with IDBiologics, Inc. to develop human monoclonal antibodies for the treatment of infectious diseases including SARS-CoV-2 and Zika. In return for participating in the feasibility study, Dyadic received 129,611 shares of IDBiologics' common stock which represents 0.37% of shares outstanding. The shares will vest as milestones are achieved. This brings the total to five partnerships that include an equity ownership stake in the partners' success.

Management indicated that we should expect additional collaborations to be announced before year end. Dyadic continues to engage additional prospects and to sign non-disclosure agreements with them. One of the most important collaborations is with Sanofi where Dyadic was able to express all seven of the therapeutic and vaccine proteins that were identified in the project. More than 50% of the proteins were expressed above target levels and now Dyadic is in conversations with Sanofi to determine next steps. A decision whether or not to move forward remains underway. We are optimistic on the other research collaborations with large pharmaceutical companies as they allow potential acquirers of this technology to evaluate C1 and retain a stake in its success. With numerous interested parties invested in developing the technology we anticipate that if a bidding war begins, substantial value will accrue to Dyadic shareholders.

COVID-19

Dyadic is working with nine groups on various COVID-19 projects that will be launching trials in a variety of animal models, including challenge studies. It engineered several C1 strains that express the full spike protein and the receptor binding domain (RBD) antigen for SARS-CoV-2. We discussed some of the details of this work in a recent article located here. Since Dyadic's previous update, management noted that the RBD antibody has demonstrated favorable immunogenicity and neutralization as well as a T cell response in a follow on mouse trial. Productivity has also increased from an initial output of 1 gram per liter to more than 3 grams per liter over a four day period.

The COVID-19 collaborations have been forged with Infrastructure Innovation for Biological Research (IIBR), EU Scientists, UfoVax, Frederick National Laboratory, a small undisclosed biotech and Zoonoses Anticipation and Preparedness Initiative (ZAPI) among others. The IIBR effort has expressed a number of high producing C1 cell lines that possess the RBD of the coronavirus spike protein. These lines are being used for both IIBR and the EU programs. IIBR has entered animal studies, which have produced high neutralizing antibody titers and will soon be followed by hamster studies. The EU program is about to start animal studies and is awaiting regulatory approval to begin. The UfoVax effort is producing several COVID-19 vaccines that will be used by the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. Dyadic is providing samples of C1-expressed SARS-CoV-2 RBD to the Frederick National Laboratory for evaluation. The latest addition to the COVID-19 portfolio is a small research collaboration with a regional biotech company whose identity was undisclosed. Up to ten animal trials are expected to be completed by or shortly after year end 2020 that will focus on the RBD.

Other Projects

Dyadic's internal projects include four publicized efforts: two monoclonal antibodies and two others in non-traditional areas. With respect to biosimilars, BDI and VTT are synthesizing certolizumab and nivolumab respectively. Certolizumab was a good first choice as it has a relatively simple antigen binding fragment (Fab) that Dyadic was able to produce with biological activity comparable with Cimzia. The other biosimilar, nivolumab, is more complex. This biologic presents a glycosylated structure which has also been successfully expressed by C1. Currently, glyco-engineering efforts are underway to potentially make Dyadic's copy a biobetter as compared to Opdivo.

Adeno-associated viruses (AAVs), which are used to deliver gene therapy, are another area of investigation for Dyadic. BDI is developing AAVs to meet increasing demand for this product that is in short supply. The fourth pursuit targets secondary metabolites that are important for digestion of nutrients, functional health of cells and also used in cosmetic applications. Dyadic aims to demonstrate that C1 can produce these metabolites and may either fund the project internally through continued efforts with VTT or partner with others.

Glycosylation

In February, Dyadic announced that it had achieved G2 human-like glycosylation with its partner VTT. C1 was able to produce a G2 glycan level of over 76% using host cell proteins, following the achievement of G0 in November 2019. Dyadic can additionally produce high concentrations of Man_{3-9} and Man_3 which, along with G0 and G2, allows C1 to produce vaccines, monoclonal antibodies and other biologics that are either immunogenic or recognized as self by the immune system. Dyadic expanded its contract with VTT in the first quarter and is now merging the low protease strain with the glycoengineered modification and reconstituting the productivity. This new flexibility is expected to elicit additional interest from partners.

Summary

Dyadic has steadily added new collaborations during 2020 signing several agreements and expansions with both large and small partners in animal and human health. Agreements have even extended into developing markets with the Epygen and Hengrui collaborations. Internal programs are advancing for certolizumab and nivolumab, secondary metabolites and AAVs. Progress is also being made with protease deletions and complex glycosylation forms. Dyadic anticipates that at least one of the animal health partners will move into animal studies in 2021 in a move that will bring sales based revenues closer. We are eager to see Dyadic take the next step and enter an agreement that provides upfronts, milestones and royalties based on a successful candidate in animal health, human health or as a vaccine for SARS-CoV-2.

The pandemic may catalyze the pathway forward for C1 to be used as an expression system for producing vaccines and treatments. Using a C1 expressed protein in human trials would be a tremendous achievement and this may first occur with the COVID-19 efforts. C1 may be able to provide much higher output with improved characteristics compared to current approaches which addresses one of the primary bottlenecks when manufacturing sufficient quantities of vaccine for global populations.

There is substantial value in Dyadic's broad portfolio of options and in their exciting technology that can revolutionize the protein expression industry. Future favorable catalysts include the addition of more collaborators, achieving output milestones and entering into clinical trials. We maintain our target price to $10.00 per share.

PROJECTED FINANCIALS

Dyadic International, Inc. - Income Statement

Dyadic International, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$1.7**	**$0.3**	**$0.5**	**$0.4**	**$0.6**	**$1.9**	**$3.0**	**$3.1**
YOY Growth	*30%*	*-22%*	*34%*	*-8%*	*39%*	*10%*	*62%*	*3%*
Cost of R&D Revenue	$1.5	$0.3	$0.6	$0.3	$0.5	$1.6	$2.4	$2.48
R&D	$3.1	$0.8	$1.1	$1.0	$0.8	$3.7	$3.5	$3.7
R&D Related Party	$0.9	$0.0	$0.0	$0.0	$0.4	$0.4	$2.0	$2.0
G&A	$5.5	$1.7	$1.5	$1.6	$1.2	$6.0	$4.8	$4.8
Foreign Currency Exchange	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0
Income from operations	($9.3)	($2.4)	($2.8)	($2.6)	($2.3)	($10.1)	($9.7)	($9.9)
Operating Margin	*-552%*	*-755%*	*-534%*	*-619%*	*-387%*	*-543%*	*-323%*	*-319%*
Interest Income	$1.0	$0.2	$0.1	$0.1	$0.2	$0.6	$0.5	$0.5
Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($8.3)	($2.2)	($2.7)	($2.5)	($2.2)	($9.5)	($9.2)	($9.4)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($8.3)**	**($2.2)**	**($2.7)**	**($2.5)**	**($2.2)**	**($9.5)**	**($9.2)**	**($9.4)**
Net Margin	*-494%*	*-702%*	*-506%*	*-600%*	*-360%*	*-513%*	*-307%*	*-303%*
Reported EPS	**($0.31)**	**($0.08)**	**($0.10)**	**($0.09)**	**($0.08)**	**($0.35)**	**($0.31)**	**($0.31)**
Shares Outstanding	27.00	27.45	27.47	27.48	27.50	27.48	29.50	30.00

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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