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Dyadic International, Inc. (DYAI - NASDAQ)

Adding Another COVID Collaborator

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 (8/13/2020)	$8.89
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. By 2020, we anticipate first sales-related revenues from C1 represented by licensing fees, upfront payments, milestones and royalties.

SUMMARY DATA

52-Week High	**10.98**
52-Week Low	**2.51**
One-Year Return (%)	**45.7**
Beta	**0.48**
Average Daily Volume (sh)	**237,929**
Shares Outstanding (mil)	**27.5**
Market Capitalization ($mil)	**244.3**
Short Interest Ratio (days)	**9.3**
Institutional Ownership (%)	**16.3**
Insider Ownership (%)	**30.2**
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	$0.6 E	$0.6 E	$2.0 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	-$0.07 E	-$0.07 E	-$0.32 E
2021					-$0.31 E
2022					-$0.31 E

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WHAT'S NEW

Second Quarter Financial & Operational Results

Dyadic International Inc. (NASDAQ: DYAI) released second quarter financial and operational results on August 13, 2020. Revenues were $0.5 million and represented research and development proceeds from partners working to develop C1. Total expenses were $3.3 million and net loss was ($2.7) million after adding interest income. On a per-share basis, net loss was ($0.10). Total cash and investments were $31.8 million as of June 30, 2020, equivalent to ~$1.16 per share.

Since the start of the second quarter, four additional collaborations were signed, including two with leading animal health firms, one with a top five human health company and a small deal to develop a coronavirus vaccine. We count ten new relationships year to date. Opportunities for product development in infectious disease have emerged and the relationships have expanded with the Israeli Institute of Biological Research (IIBR) and Zoonoses Anticipation and Preparedness Initiative (ZAPI). Other work by partners to develop a treatment or vaccine against the coronavirus using C1 has also emerged. This includes efforts by a consortium of academics from Erasmus Medical Center, Utrecht University, University of Veterinary Medicine Hannover, Ufovax and Frederick National Laboratory. Recognizing its increasing importance in the biotechnology space, Dyadic was added to the Russell 2000 and Russell 3000 indices. Dyadic filed a shelf registration, Form S-3, simultaneously with the earnings release to enable future offerings of up to $50 million which may be offered under an at-the-market (ATM) arrangement with Jefferies LLC.

Second quarter 2020 revenues rose 34% to $0.5 million reflecting additional collaborations compared to the prior year period. Total expenses during the three month period declined less than 1% to $3.3 million. Research and development[1] was up 18% to $1.7 million due to additional research projects. General and administrative expenses fell 21% to $1.5 million on account of lower executive compensation costs, NASDAQ uplisting expenses and noncash share-based compensation expenses partially offset by higher insurance premiums, business development and investor relations costs. Net loss was ($2.7) million for the period, essentially flat with the comparable quarter in 2019. On a per share basis, net loss was ($0.10) also matching the per share loss in the same period last year.

Cash burn was ($1.9) million in 2Q:20 compared to ($1.4) million in 2Q:19. Cash and equivalents were $31.8 million on June 30, 2020 down from $34.2 million at the end of 2019.

Animal Health

Dyadic now has relationships with all of the top four animal health companies. Since the previous quarter's update, 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.

Cost pressures are acute in animal health and require efficiencies that can effectively address large populations of livestock and pets. In a competitive landscape where cost is key, C1 is a leading technology that can provide needed efficiency. 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.

[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 beginning of 2020, Dyadic has entered into ten new agreements to explore the use and potential of C1 to express proteins and other biological materials. Since our previous update, there has been one more addition in human health with a top five global pharmaceutical company and a small partnership with a biotech developing a coronavirus vaccine. The global pharmaceutical agreement will express two different types of therapeutic compounds.

Exhibit I – Summary of Dyadic Collaborations[3]

Collaborator	Deal	Ownership	Description	Date
Small Unidentified Biotech	Fully funded R&D collaboration	0.0%	COVID vaccine	10-Aug-20
Top 5 Human Health	Fully funded R&D collaboration	0.0%	Top 5 with 2 proteins	15-Jul-20
Animal Health Co.	Funded feasibility study	0.0%	Top 4	8-Jul-20
Animal Health Co.	Funded feasibility study	0.0%	Global	8-Jul-20
WuXi Biologics	Nonexclusive research license	0.0%	Vaccine, drug, biologics	30-Mar-20
Animal Health Co.	Funded feasibility study	0.0%	Two proteins	30-Mar-20
Small Unidentified	Funded feasibility study	0.0%	No detail	30-Mar-20
EU Consortium	Feasibility Study	0.0%	Corona vaccine	17-Mar-20
Ufovax/Scripps Research	Feasibility Study	0.0%	HIV and Corona vaccine	17-Mar-20
University of Oslo	Feasibility Study	0.0%	Influenza antigens	17-Mar-20
Leading Animal Health Co.	Research funding, full	0.0%	3 Protein Types	28-Oct-19
Top Tier Pharma	Proof of Concept (PoC)	0.0%	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	0.0%	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	0.0%	Biologics & Vaccines	Sep-18
Mitsubishi Tanabe	PoC, Research funding	0.0%	Difficult to express proteins	Mar-18
Pharma 1	PoC, Research funding	0.0%	undisclosed proteins	Dec-18
Pharma 2	PoC, Research funding	0.0%	undisclosed protein	Feb-19
Pharma 3	PoC, Research funding	0.0%	undisclosed proteins	Apr-19
Pharma 4	PoC, Research funding	0.0%	Primary metabolite	Feb-18
Pharma 5	PoC, Research funding	0.0%	undisclosed protein	4Q:19
Israel Institute of Bio Research	Partner in-house research/Expanded	0.0%	Antigen,Enzyme,Corona&proteins	1Q:18
University of Iowa	Partner in-house research	0.0%	Undisclosed protein	2Q:19
Structural Genomics/Oxford	Partner in-house research	0.0%	Undisclosed proteins	3Q:18
Fraunhofer/Molecular Biotech	Partner in-house research	0.0%	Undisclosed vaccines	4Q:18
ZAPI	Research funding/Expanded	0.0%	Epidemic Vaccines	2015
VTT/Internal	CRO	0.0%	Metabolites/Nivolumab	2015
VLPbio	CRO	16.1%	Virus Like Particles	2017
BDI	CRO	16.1%	Certolizumab/AAV	2017

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 is expected on whether or not to move forward either late 3Q or early 4Q:20. 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.

[3] Source: Zacks Research and Dyadic corporate filings. Green highlight indicates animal health collaboration. Blue highlight indicates academic collaborator.

COVID-19

Dyadic is involved in five different COVID-19 projects. These include collaborations with IIBR, EU Scientists, UfoVax, Frederick National Laboratory and a new arrangement with a small undisclosed biotech. The IIBR effort has expressed a number of high producing C1 cell lines that possess the receptor binding domain (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 which 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. Additional discussions are underway for further partnerships in this space.

Other Projects

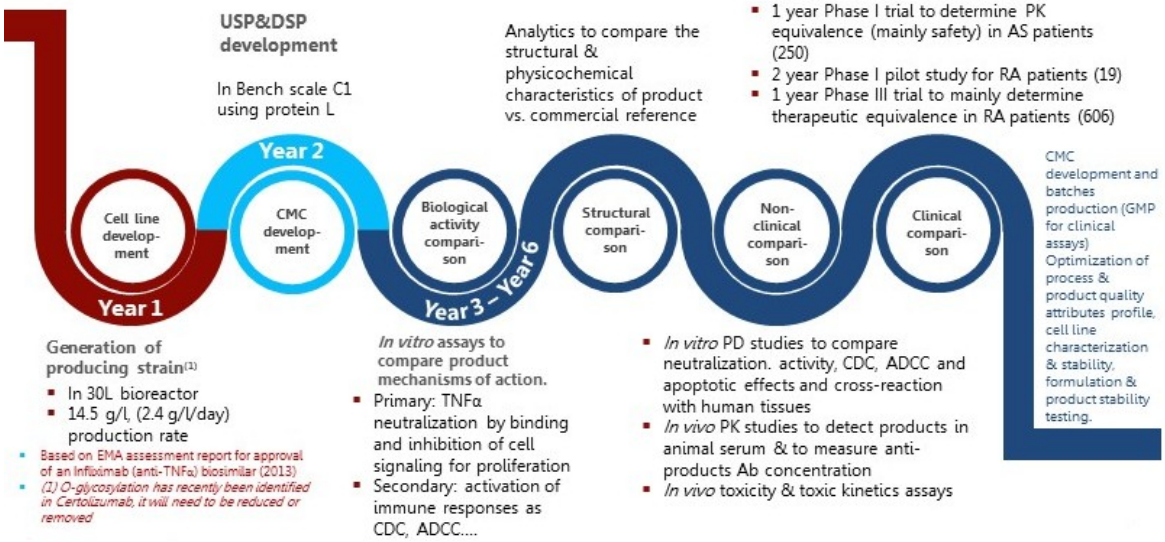
Dyadic's internal projects include four publicized efforts: two in the monoclonal antibody space (mAbs) and two others in non-traditional areas. With respect to biosimilars, BDI and VTT are synthesizing certolizumab and nivolumab respectively. Certolizumab was a good first choice as it has a relatively 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, mAb 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 paying an additional €700,000 over a 19 months period to accelerate development. We expect to hear updates on these glycoforms in the coming months.

Exhibit II – Certolizumab Development Pathway[4]



[4] Source: Dyadic Corporate Presentation, October 29, 2019.

Milestones

Dyadic has performed well since we initiated coverage adding numerous new collaborations. We include below recently achieved milestones and others we expect in the near term:

- Additional detail on glycosylation progress including G0F & G2F – 1H:20
- 14x deletion protease with 1/50 protease activity of 4x deletion protease – 1H:20
- Update on Sanofi arrangement – Fall 2020
- Potential cash inflow from licensing or development arrangement – 2020/2021

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. Internal programs are also advancing for certolizumab and nivolumab, secondary metabolites and AAVs. Progress is also being made with protease deletions and achieving additional glycosylation forms. These all contribute to the "shots on goal" which we believe will lead to a billion dollar opportunity.

We anticipate that there will be additional arrangements signed in 2020, some of which may include upfront cash flows. The pandemic may catalyze the pathway forward for C1 to be used as an expression system for producing vaccines and treatments. Entering human trials would be a tremendous achievement. C1 may be able to provide much higher output with improved characteristics compared to current approaches which addresses one of the primary bottlenecks during a pandemic.

We see opportunities for additional equity interest in fast growing partnerships, upfronts, milestones and royalties from larger partnerships and potentially a buyout. 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 the clinical trial process. 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 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$1.7**	**$0.3**	**$0.5**	**$0.6**	**$0.6**	**$2.0**	**$3.0**	**$3.1**
YOY Growth	*30%*	*-22%*	*34%*	*32%*	*39%*	*21%*	*47%*	*3%*
Cost of R&D Revenue	$1.5	$0.3	$0.6	$0.5	$0.5	$1.9	$2.4	$2.48
R&D	$3.1	$0.8	$1.1	$0.8	$0.8	$3.5	$3.5	$3.7
R&D Related Party	$0.9	$0.0	$0.0	$0.4	$0.4	$0.9	$2.0	$2.0
G&A	$5.5	$1.7	$1.5	$1.2	$1.2	$5.5	$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)	($2.3)	($2.3)	($9.8)	($9.7)	($9.9)
Operating Margin	*-552%*	*-755%*	*-534%*	*-387%*	*-387%*	*-482%*	*-323%*	*-319%*
Interest Income	$1.0	$0.2	$0.1	$0.2	$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)	($2.2)	($2.2)	($9.2)	($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)**	**($2.2)**	**($2.2)**	**($9.2)**	**($9.2)**	**($9.4)**
Net Margin	*-494%*	*-702%*	*-506%*	*-360%*	*-360%*	*-450%*	*-307%*	*-303%*
Reported EPS	**($0.31)**	**($0.08)**	**($0.10)**	**($0.07)**	**($0.07)**	**($0.32)**	**($0.31)**	**($0.31)**
Shares Outstanding	27.00	27.45	27.47	29.00	29.30	28.30	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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