Dyadic Announces Third Quarter 2020 Financial Results and Highlights Recent Company Progress

- ***Six new and expanded animal and human health collaborations since Q2 2020***
- ***Expanded presence in the Asia Pacific Region***
- ***Important progress and expanded animal efficacy data in COVID-19 vaccine and antibody programs***
- ***ZAPI to conduct additional animal studies for Schmallenberg Virus (SBV) and initiate animal studies for Rift Valley Fever Virus (RVFV)***
- ***Continued strong financial position at end of third quarter***

JUPITER, FL / ACCESSWIRE / November 12, 2020 / Dyadic International, Inc. ("Dyadic") (NASDAQ:DYAI), a global biotechnology company focused on further improving and applying its proprietary C1 gene expression platform to accelerate development, lower production costs and improve the performance of biologic vaccines and drugs at flexible commercial scales, today announced its financial results for the quarter ended September 30, 2020, and recent developments.

"We continued to advance our proprietary C1 gene expression platform into a safe and efficient expression system, with improved properties and impressive scientific results," stated Mark Emalfarb, Dyadic's Chief Executive Officer. "Our business development pipeline continues to grow with additional interest from both new and previously engaged collaborators, which we believe will accelerate the adoption of our C1 gene expression platform toward the goal of commercialization. In addition to our COVID-19 initiatives, we signed six new and expanded collaborations with human and animal health companies. Additionally, we are expanding our presence in the Asia Pacific region with the signing of a research collaboration agreement with Jiangsu Hengrui Medicine, the largest pharmaceutical company in China (by market capitalization), and our previously announced, non-exclusive, research collaboration with WuXi Biologics, a leading global CDMO."

"With respect to our COVID-19 programs, we are currently working with nine groups, including the Israel Institute for Biological Research ("IIBR"), the European ZAPI scientists, scientists from Oxford University among others, and we anticipate that up to ten animal trials will be completed by, or shortly after, year-end. This is in addition to the Frederick National Laboratory project that we announced in June, which is ongoing and showing encouraging expression data. Importantly, there will be trials with mice, hamsters and ACE2 transgenic mice, including challenge studies. We anticipate the additional animal data generated will help us to evaluate the best path forward towards a potential clinical trial in humans."

"The results from our animal health programs have been very promising and ZAPI continues to work on antigens for both the Schmallenberg (SBV) and Rift Valley Fever (RVFV) viruses. ZAPI reported that they will conduct additional challenge studies on animals which are

expected to start before the end of the year, with expected readouts in 2021. On the human health side, we signed four new and expanded collaborations with global pharmaceutical companies during the quarter. In some of these cases, we have moved beyond the proof-of-concept stage and our collaborators have identified specific proteins for which they believe our C1 technology could be very beneficial to their efforts."

"We continue to successfully advance our strategy through fully funded collaborations with leading pharma and biotech companies complemented by our solid cash position of $30.5 million. Overall, we remain disciplined and opportunistic regarding capital allocation. The at-the-money (ATM) program we put in place adds to our financial flexibility should we want to accelerate existing programs or pursue additional opportunities that leverage the broad and growing potential applications of C1. To date, we have not sold, and we are not obligated to sell, any shares under the ATM program and we have no immediate plans to sell any securities under this program to fund our near-term business plan," concluded Mr. Emalfarb.

RECENT COMPANY PROGRESS

- On November 12th, the Company entered into a fully funded collaboration with a top-tier global pharmaceutical company to express two (2) molecules of commercial interest.

- On November 12th, the Company expanded its collaboration with one of the top-ten global drug manufacturers we are collaborating with, who is funding the research to evaluate C1's ability to express a new class of proteins in our ongoing research collaboration.

- In October, Dyadic entered into a non-exclusive technology agreement with Epygen Biotech of India, who after obtaining required funding, expects to produce cGMP clinical trial material at their facility and conduct trials in India, using Dyadic's C1 expressed RBD antigen of the SARS-CoV-2 Spike Protein. This agreement demonstrates how potential collaborators globally can develop and manufacture vaccines and drugs on a regional basis that are affordable, safe, and effective.

- On September 17th, Dyadic announced a fully funded collaboration with Jiangsu Hengrui Medicine Co., Ltd. ("Hengrui") to apply Dyadic's C1 technology to the development of selected Hengrui biologic drugs. This agreement highlights C1's potential value proposition to address demand for more efficient biomanufacturing processes of biologic drugs and vaccines.

- On July 15th, Dyadic signed a fully funded R&D collaboration with one of the top five global pharmaceutical companies for human health. Under this agreement, Dyadic will be expressing two different types of therapeutic compounds.

- On July 8th, Dyadic announced the signing of two new fully funded collaborations with

two of the leading global animal health companies to demonstrate the C1 technology platform for expression and production of therapeutic proteins for companion and farm animal diseases. The Company has rapidly expanded into the animal health market and has signed fully funded agreements with all four leading animal health companies, as well as a fifth global animal health company to evaluate C1. The first two projects have been expanded into the second phase and the Company has received additional funding. We anticipate that one or both product candidates will enter animal trials in 2021.

- The Company continues to make progress in terms of stability and productivity in its glycoengineering and non-glycoengineering of its C1 cell lines to broaden the potential application of the C1 gene expression platform for its use in developing and manufacturing vaccines, monoclonal antibodies and other therapeutic proteins.

- Currently, Dyadic's COVID-19 initiatives are as follows:
    - Dyadic, in conjunction with VTT, has successfully engineered several C1 strains that express the Full Spike protein and the Receptor Binding Domain (RBD) antigen of the SARS-CoV-2 spike protein. C1 RBD is being expressed in multiple forms at high levels, which can be used to produce very large quantities of several potential COVID-19 vaccine candidates at flexible commercial scales, at low cost. The proprietary C1 expressed RBD antigen is being used in animal trials by nine different research groups, governmental agencies, and biopharma companies, including the Israel Institute for Biologic Research (IIBR) and in collaboration with scientists from Oxford University, Utrecht University, Erasmus Medical Center and University of Veterinary Medicine Hannover, DE (TiHo) and others who are testing the C1 expressed RBD vaccine candidate(s) in animal trials on a stand-alone basis as well as testing the C1 RBD with nanoparticles and adjuvants. The animal studies are currently scheduled to include challenge studies with transgenic mice that express the Human Ace-2 and Hamsters as well as additional mice studies.
    - In June, Dyadic was selected by the Frederick National Laboratory to engineer its patented and proprietary C1 cell lines to produce several COVID-19 vaccine candidates which will be utilized by the Vaccine Research Center part of the National Institute of Allergy and Infectious Diseases at the National Institute of Health. This collaboration is ongoing and C1 has shown to be able to express one or more of their SARS-CoV-2 vaccine candidates. We expect to send samples to them later this month for them to analyse and characterize.
    - Dyadic provided one of its C1 RBD SARS-CoV-2 vaccine strains, along with samples of the C1 expressed RBD vaccine candidate, to the IIBR for their use in developing a potential COVID-19 vaccine. A recently concluded IIBR mice study showed that the C1 expressed SARS-CoV-2 RBD has the potential to generate excellent immunogenicity responses with very high titers and neutralizing antibodies against the Covid-19 virus. The successful mice study has encouraged

them to perform a new challenge study in which transgenic mice expressing the Human Ace2 will be infected with the SARS-CoV-2 virus. This study is expected to start soon.

- Interim results from a recent additional mouse study further supports that the C1 expressed SARS-CoV-2 RBD, in addition to generating excellent immunogenicity responses with very high titers and neutralizing antibodies against the Covid-19 virus, also has the potential to stimulate the memory cellular immune response induced in human cells by the SARS-CoV-2 virus.
- Dyadic has expressed a SARS-CoV-2 monoclonal antibody (mAb) in collaboration with IDBiologics, Inc., who licensed this mAb from the Vanderbilt Vaccine Center ("VVC"). A sample of this potential C1 expressed COVID-19 antibody has been delivered to the VVC and is currently being compared to the same mAb expressed from CHO. Initial neutralization results are encouraging and are supported by prior non-SARS-CoV-2 monoclonal antibody neutralization results reported in one our ongoing pharmaceutical collaborations.
- Dyadic continues to provide samples of its proprietary C1 expressed RBD SARS-CoV-2 antigens to additional parties who are evaluating the RBD antigen for potential use in SARS-CoV-2 vaccine and diagnostic applications.

FINANCIAL RESULTS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2020

On September 30, 2020, cash and cash equivalents were approximately $21.9 million compared to $4.8 million on December 31, 2019. The carrying value of short-term and long-term investment grade securities, including accrued interest on September 30, 2020, was approximately $8.7 million compared to $31.2 million on December 31, 2019.

Research and development revenue for the quarter ended September 30, 2020, was approximately $416,000 compared to $455,000 for the quarter ended September 30, 2019. Cost of research and development revenue for the quarter ended September 30, 2020 decreased to approximately $267,000 compared to $385,000 for the quarter ended September 30, 2019. The slight decrease in revenue and cost of research and development revenue for the three months ended September 30, 2020 reflected smaller dollar amounts for the eight on-going research collaborations compared to five collaborations a year ago. The increase in provision for contract losses reflected the activities of one biopharmaceutical collaboration research project.

Research and development expenses for the three months ended September 30, 2020 increased to approximately $986,000 compared to $841,000 for the same period a year ago. The increase primarily reflected the costs of COVID-19 projects as well as additional internal research projects.

There were no research and development expenses – related party, for the three months ended September 30, 2020 compared to approximately $102,000 for the same period a year ago. The decrease was due to the completion of the Research Service Agreement with BDI in June 2019.

General and administrative expenses for the three months ended September 30, 2020, increased 55.6% to approximately $1,643,000 compared to $1,056,000 for the same period a year ago. The increase principally reflected increase in noncash share-based compensation expenses of $236,000, legal and SEC registration expenses of $217,000, accrued incentives of $54,000, insurance premium of $46,000, and other increases of $34,000.

Interest income for the three months ended September 30, 2020 was approximately $77,000 compared to $245,000 for the same period a year ago. The decrease was primarily due to the lower interest rate and yield on the Company's investment grade securities, which are classified as held-to-maturity.

Net loss for the three months ended September 30, 2020 was approximately $2,499,000, or $(0.09) per share, compared to $1,698,000, or $(0.06) per share for the same period a year ago.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020

Research and development revenue for the nine months ended September 30, 2020, increased to approximately $1,256,000 compared to $1,248,00 for the nine months ended September 30, 2019. The increase in revenue and cost of research and development revenue for the nine months ended September 30, 2020 reflected twelve on-going research collaborations compared to eight collaborations for the same period a year ago. The increase in provision for contract losses reflected the activities of one biopharmaceutical collaboration research project.

Research and development expenses for the nine months ended September 30, 2020 increased to approximately $2,858,000 compared to $2,352,000 for the same period a year ago. The increase primarily reflected the additional costs of COVID-19 related projects and other internal research projects.

There were no research and development expenses – related party, for the nine months ended September 30, 2020 compared to approximately $828,000 for the same period a year ago. The decrease was due to the completion of the Research Service Agreement with BDI in June 2019.

General and administrative expenses for the nine months ended September 30, 2020, increased 9.6% to approximately $4,772,000 compared to $4,355,000 for the same period a year ago. The increase principally reflected increases in insurance premium of $186,000,

noncash share-based compensation expenses of $167,000, legal and SEC registration expenses of $99,000, business development and investor relations costs of $65,000 and other increases of $66,000, offset by reductions in executive compensation costs and accrued incentives of $166,000.

Interest income for the nine months ended September 30, 2020 was approximately $392,000 compared to $778,000 for the same period a year ago. The decrease was primarily due to the lower interest rate and yield on the Company's investment grade securities, which are classified as held-to-maturity.

Net loss for the nine months ended September 30, 2020 was approximately $7,365,000, or $(0.27) per share, compared to $6,569,000, or $(0.24) per share for the same period a year ago.

CONFERENCE CALL INFORMATION

Dyadic management will host a conference call today, Thursday, November 12, 2020, at 5:00 PM ET to discuss the financial results for the quarter ended September 30, 2020. To participate in the conference call, please dial (877) 407-8033 for U.S./Canada callers and +(201) 689-8033 for International callers or use webcast link: https://www.webcaster4.com/Webcast/Page/2031/38362

An archive of the webcast will be available approximately three hours after completion of the live event and will be accessible on the "Investors" section of the Company's website at www.dyadic.com. To access the replay of the webcast, please follow the Webcast link above. A dial-in replay of the call will also be available to those interested. To access the replay, please dial 1 (877) 481-4010 (U.S. or Canada) or 1 (919) 882-2331 (International) and enter replay pass code: 38362.

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company which is developing what it believes will be a potentially significant biopharmaceutical gene expression platform based on the fungus *Thermothelomyces heterothallica (formerly Myceliophthora thermophila)*, named C1. The C1 microorganism, which enables the development and large-scale manufacture of low-cost proteins, has the potential to be further developed into a safe and efficient expression system that may help speed up the development, lower production costs and improve the performance of biologic vaccines and drugs at flexible commercial scales. Dyadic is using the C1 technology and other technologies to conduct research, development and commercial activities for the development and manufacturing of human and animal vaccines and drugs, such as virus like particles (VLPs) and antigens, monoclonal antibodies, Fab antibody fragments, Fc-Fusion proteins, biosimilars and/or biobetters, and other therapeutic proteins. Certain other research activities are ongoing which include the

exploration of using C1 to develop and produce certain metabolites and other biologic products. Dyadic pursues research and development collaborations, licensing arrangements and other commercial opportunities with its partners and collaborators to leverage the value and benefits of these technologies in development and manufacture of biopharmaceuticals. As the aging population grows in developed and undeveloped countries, Dyadic believes the C1 technology may help bring biologic vaccines, drugs, and other biologic products to market faster, in greater volumes, at lower cost, and with new properties to drug developers and manufacturers, and improve access and cost to patients and the healthcare system, but most importantly save lives.

Please visit Dyadic's website at http://www.dyadic.com for additional information, including details regarding Dyadic's plans for its biopharmaceutical business.

Safe Harbor Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including those regarding Dyadic International's expectations, intentions, strategies, and beliefs pertaining to future events or future financial performance. Actual events or results may differ materially from those in the forward-looking statements because of various important factors, including those described in the Company's most recent filings with the SEC. Dyadic assumes no obligation to update publicly any such forward-looking statements, whether because of new information, future events or otherwise. For a more complete description of the risks that could cause our actual results to differ from our current expectations, please see the section entitled "Risk Factors" in Dyadic's annual reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, as such factors may be updated from time to time in Dyadic's periodic filings with the SEC, which are accessible on the SEC's website and at http://www.dyadic.com.

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DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Research and development revenue	$416,361	$454,507	$1,256,004	$1,247,908
Costs and expenses:				
Costs of research and development revenue	266,929	384,803	1,169,351	1,034,934
Provision for contract losses	112,433	–	187,388	–
Research and development	986,054	841,343	2,857,670	2,351,953
Research and development – related party	–	101,849	–	827,632
General and administrative	1,643,493	1,056,196	4,772,117	4,354,941
Foreign currency exchange loss (gain), net	(16,240)	13,727	26,317	24,693
Total costs and expenses	2,992,669	2,397,918	9,012,843	8,594,153
Loss from operations	(2,576,308)	(1,943,411)	(7,756,839)	(7,346,245)
Interest income	76,809	245,027	391,779	777,711
Loss before income taxes	(2,499,499)	(1,698,384)	(7,365,060)	(6,568,534)
Provision for income taxes	–	–	–	900
Net loss	$(2,499,499)	$(1,698,384)	$(7,365,060)	$(6,569,434)
Basic and diluted net loss per common share	$(0.09)	$(0.06)	$(0.27)	$(0.24)
Basic and diluted weighted-average common shares outstanding	27,482,157	27,181,003	27,467,051	26,909,205

See Notes to Condensed Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with Securities and Exchange Commission on November 12, 2020.

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2020 (Unaudited)	**December 31, 2019** (Audited)
Assets		
Current assets:		
Cash and cash equivalents	$21,862,581	$4,823,544
Short-term investment securities	8,544,815	29,399,146
Interest receivable	106,405	329,711
Accounts receivable	806,847	558,530

Income tax receivable	–	250,308
Prepaid expenses and other current assets	419,498	277,999
Total current assets	31,740,146	35,639,238
Non-current assets:		
Long-term investment securities	–	1,511,636
Long-term income tax receivable	–	250,308
Other assets	5,558	51,314
Total assets	$31,745,704	$37,452,496
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$976,762	$943,378
Accrued expenses	620,633	566,003
Deferred research and development obligations	153,855	78,644
Total current liabilities	1,751,250	1,588,025
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $.0001 par value:		
Authorized shares – 5,000,000; none issued and outstanding	–	–
Common stock, $.001 par value:		
Authorized shares – 100,000,000; issued shares – 39,735,659 and 39,612,659, outstanding shares – 27,482,157 and 27,359,157 as of September 30, 2020 and December 31, 2019, respectively	39,736	39,613
Additional paid-in capital	97,600,771	96,105,851
Treasury stock, shares held at cost – 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(48,716,138)	(41,351,078)
Total stockholders' equity	29,994,454	35,864,471
Total liabilities and stockholders' equity	$31,745,704	$37,452,496

See Notes to Condensed Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with Securities and Exchange Commission on November 12, 2020.

SOURCE: Dyadic International, Inc.

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