Dyadic Reports Third Quarter 2022 Financial Results and Highlights Recent Company Developments

- *Received regulatory approval from South African Health Products Regulatory Authority (SAHPRA) to initiate a Phase 1 clinical trial to demonstrate clinical safety and antibody response in humans for DYAI-100 COVID-19 recombinant protein RBD booster vaccine candidate*
- *Presented safety, efficacy, and productivity data at World Vaccine Congress Europe*
- *New and expanded collaborations with top animal health companies to develop vaccines and treatments for companion and livestock animal diseases*
- *Initiated multiple product candidates to support the newly launched Dapibus™ platform, a fungal-based microbial platform for use in non-pharmaceutical applications such as food, nutrition, health, and wellness*
- *Cash and investment grade securities of $14.2 million as of September 30, 2022*
- *Financial results and business update conference call scheduled for 5:00 pm EST today*

JUPITER, Fla., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Dyadic International, Inc. ("Dyadic", "we", "us", "our", or the "Company") (NASDAQ: DYAI), a global biotechnology company focused on building innovative microbial platforms to address the growing demand for global protein production and unmet clinical needs for effective and affordable biopharmaceutical products for human and animal health, today announced its financial results for the third quarter of 2022, and highlighted recent company developments.

"The approval of our first-in-human clinical trial application with the South African Health Products Regulatory Authority (SAHPRA) to initiate a Phase 1 clinical trial is a significant milestone for Dyadic which further supports the C1-cell protein production platform as a potentially transformational technology for use in developing and manufacturing biopharmaceuticals," said Mark Emalfarb, President and Chief Executive Officer of Dyadic. "In addition to establishing a safety record with regulatory agencies for proteins produced from C1-cells we continually strive to improve productivity and quality and, in some cases efficacy, of those proteins. These efforts led to several scientific breakthroughs this quarter, including increased protein expression levels through the application of our new genetic approaches in engineering C1- cells.

"In our Alternative Proteins vertical, our *Dapibus*™ microbial cell line continues to gain traction in several areas, including the cultured meat industry where we have initiated efforts in the production of media components to support scale up and commercialization in this rapidly growing market. We signed new and expanded animal health collaborations this quarter with top animal health companies. We are accelerating our efforts in the Animal Health vertical based upon recent positive data we received with a livestock antigen in the vaccine market as well as our success in demonstrating the ability for C1-cells to express ferritin nanoparticle antigens. In the Human Health vertical, we are focusing on the initiation of the Phase 1 clinical trial for DYAI-100 and continued progress on programs with our pharmaceutical partners," Mr. Emalfarb concluded.

Recent Company Developments

- DYAI-100, C1-SARS-CoV-2 RBD (Receptor Binding Domain) Booster Vaccine Candidate
  - On October 27, 2022, the Company announced receipt of regulatory approval of its Clinical Trial Application (CTA) from the South African Health Products Regulatory Authority (SAHPRA) to initiate a Phase 1 clinical trial of the DYAI-100 COVID-19 Receptor Binding Domain (RBD) booster vaccine.
  - The Phase 1 randomized, double blind, placebo-controlled trial is designed to demonstrate clinical safety and preliminary efficacy of the DYAI-100, COVID- 19 recombinant protein RBD booster vaccine candidate. Preparations are now underway to initiate the Phase 1 clinical trial to evaluate the safety and immunogenicity of the vaccine, with a plan to commence enrollment of subjects later this year in South Africa.
- Multiple Ongoing Research Projects:
  - **Third Party C1 Produced COVID-19 Antibody** - A non-human primate challenge study completed dosing of

a C1 produced COVID-19 monoclonal antibody (mAb) that had previously demonstrated broad neutralization and protection against Omicron (BA.1 and BA.2) and the other earlier variants of concern in hamsters.
    - Preliminary results obtained from a challenge study with the SARS-CoV-2 Delta virus on non-human primates demonstrated potential high protection.
    - No SARS-CoV-2 RNA in throat and nasal swab samples were obtained in animals pre-treated with the C1 produced neutralizing monoclonal antibody (mAb), demonstrating potential for preventative effects.
    - Pre-clinical safety and efficacy data from animal studies, including hamsters and non-human primates, demonstrates C1 produced antigens and antibodies are as effective as those produced by reference platforms.
        - At the World Vaccine Congress Europe, Dr. Albert Osterhaus (University of Veterinary Medicine Hannover Germany), who has been collaborating with Dyadic for over 5 years, presented pre-clinical safety and efficacy data from animal studies, including hamsters and non- human primates, demonstrating C1 produced antigens and antibodies are as effective as those produced by reference platforms. Dr. Osterhaus's video presentation can be found on Dyadic's website under Media Center, Video Gallery.
        - CEO Mark Emalfarb presented data that demonstrated, in addition to C1-cells producing even higher levels of productivity to date across different classes and types of proteins for both animal and human health, innovative approaches and designs to C1 produced proteins which generated higher neutralizing antibody activity in pre-clinical animal studies with the potential to improve vaccines for influenza, COVID-19 and other disease areas.
  - **Influenza and COVID-19 Vaccines** - Additional preclinical studies are ongoing with C1 produced antigens for potential seasonal and/or pandemic influenza and/or an influenza / SARS-CoV-2 combined vaccine.
  - **Mono and Multi-Valent RBD-based Blended Vaccine** - Based on the RBD antigen cell lines that we have constructed to express Wuhan, Alpha, Beta, Gamma, Delta, and Omicron BA.1 and BA.5 CoV-2 variants, additional animal data is being generated through several preclinical trials using mono and multi-valent blends of C1 produced SARS-CoV-2 RBD variants of concern. Research is ongoing with various collaborators who are conducting animal trials on mono and multi-valent RBD-based blended COVID-19 vaccines for potential next generation pan-coronavirus vaccine candidates that may provide broader protection and longer lasting prevention against a wide variety of corona viruses than what is presently available in the market.
- **Influenza Neuraminidase (NA) Protein** - Dyadic developed a C1-cell line capable of achieving high titers of neuraminidase ("NA"). NA in combination with Hemagglutinin ("HA") is expected to play an important role in providing broader influenza vaccine-induced protection. Mice trials conducted by Oslo university for NA, like the previously reported HA produced from C1-cells, generated high neutralizing antibody levels. Additional animal trials are ongoing.
- **Scientific Updates**
  - Dyadic recently developed innovative cell engineering approaches which have resulted in the achievement of higher titers across different classes and types of proteins.
    - We have successfully expressed the following variants: Alpha, Beta, Gamma, Delta, and Omicron B.1.1.529 and BA.5 at 0.5-2.5 g/L levels, in addition to DYAI-100.
    - A nine-fold (9x) improvement in the expression yield for Nivolumab, a potential monoclonal antibody for oncology expressed from a C1-cell at 22.3 g/l in a seven-day fermentation.
    - A biologically active neuraminidase (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, like the previously reported HA produced from C1-cells, generate high neutralizing antibody levels.
    - A non-human primate study completed dosing of a C1 produced COVID-19 monoclonal antibody (mAb) that has demonstrated broad neutralization and protection against Omicron (BA.1 & BA.2) and other earlier variants of concern in hamsters. Full data readout is anticipated later this year.

        - Potential next generation pan coronavirus vaccine candidates:
            - Successful production of Wuhan and Omicron Ferritin gRBD nanoparticle antigens.
            - The Wuhan S gRBD nanoparticle has been expressed at greater than 3 g/L in five days.
    - The new data presented by Dr. Albert Osterhaus came from three pre-clinical studies which demonstrated the potential positive preventative effects of two C1-cell produced proteins being as effective as those produced by reference platforms, including CHO (Chinese Hamster Ovary) cells.
- **Third Party Collaborations** - Several on-going fully funded research collaborations are on track as we continue to optimize our C1-cell protein production platform and increase productivity, including collaborations with Janssen, NIIMBL, Jiangsu Hengrui, Epygen Biotech, and other partners.
- **Animal Health**
    - The Company has successfully expressed a recombinant livestock antigen at titers up to 10 g/L in 7 days.
    - The Company expanded its research projects in animal health for the development of animal vaccines for livestock.
    - In October, the Company commenced a new proof of concept project with a top animal health company for the treatment of a targeted disease.
    - The Company has initiated two (2) additional recombinant protein projects to support vaccine research and development.
- **Alternative Proteins**
    - Dyadic has launched its *Dapibus*™ platform, a filamentous fungal based microbial gene expression and protein production platform, which is further designed and customized to enable the rapid development and large-scale manufacture of low-cost enzymes, proteins, metabolites, and other biologic products for use in non-pharmaceutical applications such as food, nutrition, and wellness.
    - The Company initiated an animal free recombinant serum albumin and other projects related to cell culture media to support the *Dapibus*™ platform, which is being developed, among other applications, to meet the growing demand and unmet needs of alternative proteins in emerging market such as cultured meat.

Third Quarter 2022 Financial Results

Cash Position: As of September 30, 2022, cash, cash equivalents, and the carrying value of investment grade securities, including accrued interest were approximately $14.2 million compared to $20.4 million as of December 31, 2021. Based on current plans, the Company expects that its existing cash, cash equivalents, and investment securities will be sufficient to enable it to fund Phase 1 clinical trials of DYAI-100 and its operating expenses into 2024.

Revenue: Research and development revenue and license revenue for the quarter ended September 30, 2022, increased to approximately $880,000 compared to $693,000 for the same period a year ago. Research and development revenue and license revenue for the nine months ended September 30, 2022, increased to approximately $2,187,000 compared to $2,091,000 for the same period a year ago.

Cost of Revenue: Cost of research and development revenue for the quarter ended September 30, 2022, increased to approximately $603,000 compared to $393,000 for the same period a year ago. Cost of research and development revenue for the nine months ended September 30, 2022, decreased to approximately $1,419,000 compared to $1,613,000 for the same period a year ago.

R&D Expenses: Research and development expenses for the quarter ended September 30, 2022, decreased to approximately $744,000 compared to $1,902,000 for the same period a year ago. Research and development expenses for the nine months ended September 30, 2022, decreased to approximately $3,917,000 compared to $5,919,000 for the same period a year ago.

The decrease in research and development expenses was due to the winding down of activities of contract research organization and pharmaceutical quality and regulatory consultants to manage and support the pre-clinical and clinical

development as well as a decrease in cGMP manufacturing costs as the Company moves towards its anticipated Phase 1 clinical trial of its DYAI-100 RBD COVID-19 booster vaccine candidate.

G&A Expenses: General and administrative expenses for the quarter ended September 30, 2022, decreased to approximately $1,383,000 compared to $1,693,000 for the same period a year ago. General and administrative expenses for the nine months ended September 30, 2022, decreased to approximately $4,753,000 compared to $4,994,000 for the same period a year ago.

Net Loss: Net loss for the quarter ended September 30, 2022, was approximately $1,809,000 or $(0.06) per share compared to $1,715,000 or $(0.06) per share for the same period a year ago. Net loss for the nine months ended September 30, 2022, was approximately $7,589,000 or $(0.27) per share compared to $8,856,000 or $(0.32) per share for the same period a year ago.

Conference Call Information

Date: Thursday, November 10, 2022
Time: 5:00 p.m. Eastern Time
Dial-in numbers: Toll Free 1-877-407-0784 International 1-202-689-8560
Conference ID: 13731917
Webcast Link: https://viavid.webcasts.com/starthere.jsp?ei=1561607&tp_key=84d3d19ead

An archive of the webcast will be available within 24 hours after completion of the live event and will be accessible on the Investor Relations section of the Company's website at www.dyadic.com. To access the replay of the webcast, please follow the webcast link above.

About DYAI-100

DYAI-100, also known as C1-SARS-CoV-2 RBD vaccine, is a novel receptor-binding domain (RBD) recombinant booster vaccine candidate, highly expressed in Dyadic's proprietary C1-cell protein production platform for the prevention of COVID-19. The C1-SARS-CoV-2 RBD vaccine drug product consists of the SARS-CoV-2 RBD-C-tag adjuvanted with alum Alhydrogel 85® 2%. DYAI-100 is expected to start a Phase 1 clinical trial in South Africa in late 2022 to assess the safety, reactogenicity, and immunogenicity of the C1-SARS-CoV-2 RBD vaccine, administered as a booster, in healthy volunteers.

About C1-cell Protein Production Platform

C1-cell protein production platform is Dyadic's platform technology, which is based on an industrially proven microorganism (named C1). The C1-cell protein production platform is a robust and versatile thermophilic filamentous fungal expression system for the development and production of biologic products, including enzymes, antigens, antibodies, and other therapeutic proteins. The C1 technology is currently used to speed development, lower production costs, and improve performance of biologic vaccines and drugs at flexible commercial scales for the human and animal health markets.

About Dapibus™ Protein Production Platform

Dapibus™ is Dyadic's newly developed filamentous fungal based microbial gene expression and protein production platform, which is being further designed and customized to enable the rapid development and large-scale manufacture of low-cost enzymes, proteins, metabolites, and other biologic products for use in non- pharmaceutical applications, such as food, nutrition, and wellness.

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company committed to building disruptive microbial platforms to

address the growing demand for global protein bioproduction and unmet clinical needs for effective, affordable, and accessible biopharmaceutical products for human and animal health.

Dyadic's lead technology, its C1-cell gene expression and protein production platform, C1 gene expression and protein production platform is based on the highly productive and scalable industrially proven fungus *Thermothelomyces heterothallica* (*formerly Myceliophthora thermophila).* is currently used to speed development, lower production costs, and improve performance of biologic vaccines and drugs at flexible commercial scales for the human and animal health markets.

Dyadic is also developing the Dapibus™ filamentous fungal based microbial protein production platform to enable 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.

With a passion to enable our partners and collaborators to develop effective preventative and therapeutic treatments in both developed and emerging countries, Dyadic is building an active pipeline by advancing its proprietary microbial platform technologies, including our lead product DYAI-100 COVID-19 vaccine candidate, as well as other biologic vaccines, antibodies, and other biological products.

To learn more about Dyadic and our commitment to helping bring vaccines and other biologic products to market faster, in greater volumes and at lower cost, please visit www.dyadic.com.

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, such as the success of our clinical trial our research projects and third-party collaborations, as well as the availability of necessary funding. 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 www.dyadic.com.

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DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Research and development revenue	$835,480	$692,929	$1,983,636	$2,090,541
License revenue	44,117	-	202,941	-
Total revenue	879,597	692,929	2,186,577	2,090,541
Costs and expenses:				
Costs of research and development revenue	602,847	392,544	1,418,702	1,612,810
Research and development	743,585	1,901,548	3,917,245	5,918,888
General and administrative	1,383,433	1,692,837	4,753,162	4,994,458
Foreign currency exchange loss, net	13,205	30,002	23,578	76,080
Total costs and expenses	2,743,070	4,016,931	10,112,687	12,602,236
Loss from operations	(1,863,473)	(3,324,002)	(7,926,110)	(10,511,695)
Other income:				
Interest income	54,300	3,202	87,277	49,772
Other income	-	1,605,532	250,000	1,605,532
Total other income	54,300	1,608,734	337,277	1,655,304
Net loss	$(1,809,173)	$(1,715,268)	$(7,588,833)	$(8,856,391)
Basic and diluted net loss per common share	$(0.06)	$(0.06)	$(0.27)	$(0.32)
Basic and diluted weighted-average common shares outstanding	28,391,894	28,079,157	28,302,332	27,754,597

See Notes to Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2022.

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2022	December 31, 2021
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	$6,739,117	$15,748,480
Short-term investment securities	7,461,884	4,511,780
Interest receivable	43,873	94,375
Accounts receivable	235,368	277,831
Prepaid expenses and other current assets	448,208	375,830
Total current assets	14,928,450	21,008,296
Non-current assets:		
Investment in Alphazyme	284,709	284,709
Other assets	6,003	6,117
Total assets	$15,219,162	$21,299,122
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$777,238	$1,547,953
Accrued expenses	987,891	709,560
Deferred research and development obligations	445,044	151,147
Deferred license revenue, current portion	176,471	147,059
Total current liabilities	2,386,644	2,555,719
Deferred license revenue, net of current portion	220,588	352,941
Total liabilities	2,607,232	2,908,660
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 - 40,716,602 and 40,482,659, outstanding shares - 28,463,100 and 28,229,157 as of September 30, 2022, and December 31, 2021, respectively	40,717	40,483
Additional paid-in capital	102,836,563	101,026,496
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(71,335,435)	(63,746,602)
Total stockholders' equity	12,611,930	18,390,462
Total liabilities and stockholders' equity	$15,219,162	$21,299,122

See Notes to Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 2022.

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