SECURITIES & EXCHANGE COMMISSION EDGAR FILING

DYADIC INTERNATIONAL INC

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (date of earliest event reported) : October 12, 2020

Dyadic International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-55264**	**45-0486747**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification Number)

140 Intracoastal Pointe Drive, Suite 404
Jupiter, FL 33477

(Address of principal executive offices and zip code)

(561) 743-8333

(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	DYAI	The NASDAQ Stock Market LLC

Item 8.01 Other Events

On October 12, 2020, Dyadic International, Inc. issued a press release with an update on the progress made in certain of its coronavirus (COVID-19) programs globally.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

The following exhibit is being furnished herein:

Exhibit Number	Description
99.1	Press Release dated as of October 12, 2020

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 12, 2020

Dyadic International, Inc.

By: /s/ Mark A. Emalfarb
Name: Mark A. Emalfarb
Title: Chief Executive Officer

Dyadic Updates Market on COVID-19 Initiatives

- **C1 Expression of SARS-CoV-2 Monoclonal Antibody Achieved**
- **Ten On-going Animal Trials of C1 Expressed SARS-CoV-2 Receptor Binding Domain (RBD) Antigen by Seven Different Collaborators**
- **Record Expression Level of C1 SARS-CoV-2 RBD Antigen (3 g/l in 5 days)**
- **Non-Exclusive Technology Usage Agreement with Epygen Biotech of India**

JUPITER, FL / **ACCESSWIRE** / **October 12, 2020** Dyadic International, Inc. (“Dyadic” or the "Company") (NASDAQ: DYAI), a global biotechnology company focused on further 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 is updating the market on the progress made in certain of its coronavirus (COVID-19) programs globally.

Dyadic’s C1 Rapid Recombinant Protein Manufacturing Platform has demonstrated that it can manufacture monoclonal antibodies (mAbs) more efficiently and faster than currently existing CHO mAb technology, potentially broadening access to this therapeutic treatment. Dyadic has expressed a SARS-CoV-2 monoclonal antibody in collaboration with a biotech company that is developing antibody cocktails to treat COVID-19 patients.

“The recent successful use of monoclonal antibody cocktails for the treatment of COVID-19 has also highlighted important production and supply constraints. Our C1 platform has the potential to generate 3x to 4x greater quantities of monoclonal antibodies in the same timeframe when compared to the current production methods using CHO cells. While that is still not yet enough to meet anticipated global demand, it certainly is a significant step in potentially helping to ensure greater access to patients, and at a lower cost,” said Dyadic CEO, Mark Emalfarb.

Dyadic has developed a COVID-19 vaccine antigen from its proprietary and patented C1 cell line that can be produced at three grams per liter (3 g/l) in only five days. The proprietary C1 expressed receptor binding domain (RBD) of the SARS-CoV-2 spike protein is being used in animal trials by seven different research groups, governmental agencies and biopharma companies (including the Israel Institute for Biological Research (IIBR) and a collaboration of European Union scientists that participated with Dyadic in the ZAPI program). These parties 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 Company currently expects up to ten animal trials to be completed by the end of 2020. These programs are in addition to the previously announced activities with the Frederick National Laboratory, Jiangsu Hengrui Medicine and other third-party collaborations which are working with Dyadic’s C1 expression platform to express their own COVID-19 and other vaccine and antibody candidates for a number of animal and human health applications.

Data generated by a number of these third parties confirmed that the C1 expressed RBD has the correct structure resulting in high binding and neutralizing capacity. Additionally, the recently concluded IIBR mice study shows that the C1 RBD has the potential to generate excellent immunogenicity responses with very high titers and neutralizing antibodies against the SARS-CoV-2 coronavirus.

“The initial mice trial, as reported to us by the IIBR, was very successful, and we expect to have additional data to disclose after a number of these animal trials are completed and their data is analyzed further. Going forward, we expect there will be follow-on animal studies which will include challenge studies with hamsters and human Ace2 transgenic mice, as well as additional studies including a toxicology study,” continued Mr. Emalfarb. “Further, our C1 technology can express high levels of proteins more rapidly at flexible commercial scales more affordably using single use or stainless-steel bioreactors. We believe that our C1 platform, developed initially for high-volume low-cost industrial use, easily enables affordable,

regional production of vaccines, antibodies and other therapeutic proteins, which has driven a heightened interest in our C1 technology."

Dyadic has recently entered into a non-exclusive technology usage agreement with Epygen Biotech of India, who after obtaining required funding, expects to produce cGMP clinical trial material at their facility and conduct clinical trials in India using Dyadic's C1 expressed RBD antigen of the SARS-CoV-2 Spike Protein.

"The Epygen agreement demonstrates how potential collaborators globally can develop and eventually manufacture vaccines and drugs on a regional basis that are affordable, safe and effective. Debayan Ghosh, President and Founder of Epygen, is intimately familiar with our technology from his work at Biocon as a biotechnologist, his time spent working for Dyadic in the late 90's and, most recently, as a result of Epygen's interest in the manufacturing of cGMP clinical grade C1 expressed RBD antigens. It is especially gratifying for us to be working with someone who understands, firsthand, C1's success in industrial biotech and appreciates how the technology can be broadly applied to biopharmaceuticals," concluded Mr. Emalfarb.

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. In particular, 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 as a result 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 as a result 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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