SECURITIES & EXCHANGE COMMISSION EDGAR FILING

DYADIC INTERNATIONAL INC

Form: 8-K

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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):May 13, 2021

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 2.02. Results of Operations and Financial Condition

On May 13, 2021, Dyadic International, Inc. ("Dyadic") issued a press release announcing its results for the quarter ended March 31, 2021. 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.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit is being furnished herein:

Exhibit Number	Description
99.1	Dyadic International Press Release Dated May 13, 2021
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

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: May 13, 2021

Dyadic International, Inc.

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

Exhibit 99.1

DYADIC REPORTS 2021 FIRST QUARTER END RESULTS AND HIGHLIGHTS RECENT COMPANY PROGRESS

- ***Advancing Dyadic's proprietary COVID-19 vaccine candidate, DYAI-100, towards a first-in-human Phase 1 clinical trial***
  - ***Goal of validating that C1 produced proteins are safe in humans and to accelerate adoption and use of C1 technology platform for the development and manufacture of vaccines and therapeutics***
  - ***Goal of bringing larger quantities of lower cost COVID-19 vaccines that can be used as a prime and booster to existing vaccines***
  - ***Engaged CR2O to manage and support further preclinical and clinical development***
  - ***Initiated toxicology study***
  - ***cGMP manufacturing run in progress***
- ***Collaborating on next-generation COVID-19 variant vaccines and/or boosters through Korea and Southeast Asia vaccine development partnership with Medytox (086900) (KOSDAQ)***
- ***In parallel with DYAI-100, additional proprietary and third-party COVID-19 variant vaccine candidates are under development***
- ***Developing other infectious disease vaccines and antibodies internally and in conjunction with others***
- ***Continued scientific progress on animal and human health vaccines and antibodies in fully funded collaborations***
- ***Cash and investment grade securities of $27.4 million as of March 31, 2021***

JUPITER, FL / May 13, 2021 Dyadic International, Inc. ("Dyadic", "we", "us", "our", or the "Company") (NASDAQ: DYAI), a global biotechnology company focused on further improving, applying and deploying its proprietary C1-cell protein production platform to accelerate development, lower production costs and improve the performance of biologic vaccines and therapeutics today announced its financial results for the first quarter of 2021 and highlighted recent Company progress.

"We continued to advance our science as well as make progress in a number of our animal and human health initiatives and third party R&D collaborations during the first quarter," stated Mark Emalfarb, Dyadic's Founder and Chief Executive Officer. "We filed two patent applications so far this year and anticipate filing one or more provisional patent applications during the balance of the year. We are excited to be advancing our proprietary COVID-19 vaccine candidate, DYAI-100, towards a first-in-human Phase 1 clinical trial, which remains on track to initiate by year-end. This will be a major milestone for both the company and our C1 technology platform. Potentially demonstrating both safety and preliminary efficacy using a protein manufactured from our proprietary and patented C1 cell line will de-risk and accelerate the adoption and use of our C1 technology platform for the development and production of vaccines and therapeutics globally. Additionally, a successful Phase 1 clinical trial with DYAI-100 will bring us a step closer to another one of our goals, which is to bring a more efficient vaccine and drug manufacturing process to help combat the COVID-19 pandemic. Through the use of C1, Dyadic is well-positioned to

generate and deliver larger quantities of lower cost COVID-19 vaccines to the world's population that continues to suffer due to the lack of access and affordability to safe and effective COVID-19 vaccines and therapeutics."

Mr. Emalfarb continued, "In addition to advancing our own proprietary DYAI-100 vaccine candidate and our previously disclosed partnership with Medytox to develop next-generation COVID-19 variant vaccines, we have been engineering additional C1 cell lines to produce SARS-CoV-2 variant antigens for monovalent and multivalent vaccine candidates. The C1 produced antigen is also being evaluated by other parties, and there are a number of ongoing discussions with leading scientists, governmental agencies, pharmaceutical and biotechnology companies who are interested in using our C1 technology to develop and manufacture their COVID-19 vaccine candidates.

The potential of C1 to help meet global health challenges, such as COVID-19, was highlighted in a recent KOL fireside chat hosted by Dyadic. Regarding C1, Joris Vandeputte, D.V.M., President of IABS (International Alliance for Biological Standardization), stated, "Results show already today that C1 is able to produce large amounts of the receptor-binding domain of SARS-CoV-2 or even the complete spike, for different variants. It also glycosylates very well, which is a very time-saving element comparing to previous classical production times." He continued that "the versatility of the system is really very appropriate to adapt the vaccines quickly to variants in case of need. And again, in our experience, C1 fits to almost any steel bioreactor, single-use bags, anywhere in the world where there is fermentation experience. Even in the case of nano-particles, the system allows high flexibility. …I would say that the C1 production system is not only a potential game changer in the global access to much needed vaccines, but also a must, we have to focus on."

"The transformative potential of our C1 technology platform goes well beyond the COVID-19 pandemic, and in parallel to our COVID-19 initiatives, we remain focused on and are advancing C1 for several other human and animal health applications. During the first quarter, we entered four new funded collaborations with pharmaceutical and biotech companies, including our fully funded collaboration with TurtleTree Scientific to develop human growth factors. Importantly, as we continue to add new partners like TurtleTree, we are expanding the number of commercial opportunities for our C1 platform to address challenges in animal and human health globally. With such clear advantages for cost-effective and flexible scale commercial production, we believe, as do a growing number of partners, key opinion leaders and subject matter experts, that our C1 protein production platform presents a solution for more affordable and accessible therapeutics and vaccines worldwide," concluded Mr. Emalfarb.

Recent Company Progress

COVID-19 Initiatives:

- Advancing the Company's proprietary COVID-19 vaccine candidate (C1 produced SARS-CoV-2-S-RBD antigen), DYAI-100, towards a first-in-human Phase 1 clinical trial:
  - DYAI-100 is supported by a strategic collaboration with, among other parties, the IIBR and leading infectious disease scientists from Erasmus Medical Centre, University Utrecht, TiHo Hannover (scientists who were involved in the ZAPI program) to develop a temperature stable, safe and effective COVID-19 vaccine candidate that can be rapidly manufactured, in large quantities, at low cost, using standard microbial fermenters that are readily available globally.
  - In March 2021, the Company engaged CR2O, a contract research organization, to manage and support further preclinical and clinical development of DYAI-100. The animal GLP toxicology study began at the end of April 2021, the cGMP production of the C1 expressed SARS-CoV-2 RBD drug product has begun, and a first-in-human Phase 1 clinical trial is expected to begin by year-end.
  - There are a number of benefits the Company expects to come from the DYAI-100 Phase 1 clinical trial, including demonstrating that certain C1 produced proteins can be produced under cGMP conditions and are safe and tolerated in humans, which will be required by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Additionally, this will also serve as a proof of concept study for potential C1 manufactured next-generation monovalent and multivalent COVID-19 variant vaccine candidates that can be developed and manufactured rapidly, in large quantities, and more affordably.
- In parallel with advancing the DYAI-100 vaccine candidate towards a Phase 1 clinical trial, the Company has already started to engineer several C1 cell lines to produce several SARS-CoV-2 variant antigens, and has successfully expressed the South African, Brazilian, and UK variant antigens at high productivity and stability. The Company and its collaborators are working to produce RBD antigen and full spike proteins for additional COVID-19 variants.
- In March 2021, the Company expanded a vaccine development partnership with South Korea's Medytox Inc. to co-develop C1 enabled COVID-19 variant vaccines and/or boosters (e.g., tetravalent or quadrivalent COVID-19 vaccine candidates) to immunize people against two or more of the current and future COVID-19 variants in Korea and Southeast Asia.
- In April 2021, the Company signed a separate fully funded research collaboration with CR2O to develop a COVID-19 antibody.

Human Health (Non-COVID) Collaborations:

- In February 2021, the Company initiated a fully funded collaboration with TurtleTree Scientific to develop several recombinant protein growth factors, which have the potential to play a critical role in tissue development and healing, including regenerative therapies.
- In March 2021, the Company signed a research collaboration with a new research partner to develop an antigen.
- In April 2021, the Company expanded its collaboration with IDBiologics and started a new fully funded collaboration to develop a second antibody.
- Collaborating with Jiangsu Hengrui Medicine and two top pharmaceutical companies for proof of concept studies designed to improve the production of biologic drugs, including bispecific antibodies, of therapeutic interest. Interim results have demonstrated these biologic drugs were expressed from C1 and there are ongoing discussions for advancing some of these projects towards potential clinical development.
- Continued progress in several ongoing collaborations to develop potential therapeutic candidates of commercial potential, including expressing two new bispecific antibodies and advancing two other antibodies which are entering the second stages for applications in oncology and autoimmune disease.
- Conducting a feasibility study with the University of Oslo for a potential influenza vaccine. Interim results demonstrated that C1 can express hemagglutinin at a high level, and most importantly, that C1 hemagglutinin induced a high level response of neutralizing antibodies in a mice study.

Animal Health Collaborations:

- In collaboration with a top global animal health company, initial studies have demonstrated production of two different antigens for a potential vaccine for an acute respiratory disease of birds. Interim results demonstrated that the antigens were effective at generating high antibody titers. An animal challenge study designed to evaluate protection against the acute respiratory disease is expected to start in June 2021.
- ZAPI held its Final Stakeholders Virtual Web Meeting on February 4-5, 2021, where positive results were reported from animal studies in mice, sheep, and cattle which evaluated the safety, efficacy, and protection of the C1 produced Schmallenberg virus ("SBV") antigen. The C1 platform was selected by ZAPI to produce recombinant antigens after demonstrating far greater antigen productivity from C1-cells than insect (baculovirus) cells, the next leading expression platform, for both SBV and Rift Valley Fever Virus ("RVFV"). As previously disclosed, in the first quarter of 2021, ZAPI has provided the Company with additional funding to produce larger quantities of both the SBV and RVFV antigens to demonstrate commercial-scale viability of C1 produced SBV and RVFV antigens and to further optimize the use of C1 to produce recombinant protein subunit nanoparticle vaccines. Preliminary results have been very encouraging and continue to further support C1's potential for use in developing nanoparticle vaccines in larger quantities at lower cost. Several positive outcomes have already originated from the ZAPI results, including several fully funded animal health projects and several SARS-CoV-2 vaccine collaborations, including Dyadic's receptor-binding domain (RBD) antigen of the SARS-CoV-2 spike protein.

Corporate Highlights:

- The Company extended two non-exclusive research license agreements, including WuXi Biologics and an affiliate of a top pharma company, to continue their C1 research projects in a CDMO and manufacturing environment at their own facilities.
- Hosted KOL Fireside Chat: "The Potential of the Transformative Dyadic C1 Protein Technology in Helping Meet Global Health Challenges", which is available on the Investors section of the Company's website.
- To date, the Company participated in several scientific conferences, including the recently held World Vaccine Conference, Protein Engineering and Cell Therapy Conference (PEGS), and the ZAPI Final Stakeholders Virtual Conference. ZAPI Stakeholders Final Conference speaker slides and webinar replay are now available on the IABS website via the following link: https://zapi-stakeholders-final-conference.iabs.org/conference-information.php?parag=slides

Financial Highlights

Cash Position: At March 31, 2021, cash, cash equivalents, and the carrying value of investment grade securities, including accrued interest were approximately $27.4 million compared to $36.0 million at December 31, 2020.

Revenues: Research and development revenue for the quarter ended March 31, 2021, increased slightly to approximately $461,000 compared to $315,000 for the same period a year ago.

Cost of Revenues: Cost of research and development revenue for the quarter ended March 31, 2021, increased to approximately $391,000 compared to $278,000 for the same period a year ago.

The increase in revenue and cost of research and development revenue for the three months ended March 31, 2021, reflected the increased number of on-going research collaborations to eight, compared to five collaborations for the same period a year ago.

R&D Expenses: Research and development expenses for the three months ended March 31, 2021 increased to approximately $1,808,000 compared to $755,000 for the same period a year ago. The increase primarily reflected Phase 1 clinical trial cost of DAI-100, our COVID-19 vaccine in the amount of $882,000 and an additional cost of $159,000 related to our other internal research project.

G&A Expenses: General and administrative expenses for the three months ended March 31, 2021, decreased 6.0% to approximately $1,554,000 compared to $1,653,000 for the same period a year ago. The decrease principally reflected reductions in travel and rent expenses of $65,000, insurance and other outside services of $47,000, other decrease of $30,000, offset by increase in legal expenses of $43,000.

Interest Income: Interest income for the three months ended March 31, 2021 was approximately $26,000 compared to $168,000 for the same period a year ago. The decrease was primarily due to the lower balance of held-to-maturity and less reinvestment as a result of the decrease in interest rate.

Net Loss: Net loss for the three months ended March 31, 2021 was approximately $3.3 million or $(0.12) per share, compared to $2.2 million or $(0.08) per share, for the same period a year ago.

Exhibit 99.1

Conference Call Information

Date: Thursday, May 13, 2021
Time: 5:00 p.m. Eastern Time
Dial-in numbers: Toll Free: 877-407-8033 International: 201-689-8033
Webcast Link: https://www.webcaster4.com/Webcast/Page/2031/41076

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 for a limited time. 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 Toll Free: 877-481-4010 (U.S. or Canada) or International: 919-882-2331 (International) and enter replay pass code: 41076.

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.

Contact:

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Ping W. Rawson
Chief Financial Officer
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Email: prawson@dyadic.com

Exhibit 99.1

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Research and development revenue	$ 460,520	$ 315,372
Costs and expenses:		
Costs of research and development revenue	390,762	278,182
Research and development	1,808,098	755,453
General and administrative	1,554,007	1,653,392
Foreign currency exchange loss (gain), net	28,272	10,867
Total costs and expenses	3,781,139	2,697,894
Loss from operations	(3,320,619)	(2,382,522)
Interest income	25,670	168,383
Net loss	$ (3,294,949)	$ (2,214,139)
Basic and diluted net loss per common share	$ (0.12)	$ (0.08)
Basic and diluted weighted-average common shares outstanding	27,533,268	27,452,490

See Notes to Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with Securities and Exchange Commission on May 13, 2021.

Exhibit 99.1

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2021 (Unaudited)	December 31, 2020 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 13,055,558	$ 20,637,045
Short-term investment securities	14,177,441	8,457,452
Interest receivable	157,201	112,247
Accounts receivable	384,963	294,199
Prepaid expenses and other current assets	216,189	280,555
Total current assets	27,991,352	29,781,498
Non-current assets:		
Investment in Alphazyme	284,709	284,709
Other assets	6,151	6,225
Total assets	$ 28,282,212	$ 30,072,432
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,473,813	$ 1,013,099
Accrued expenses	277,668	489,756
Deferred research and development obligations	842,248	123,016
Total current liabilities	2,593,729	1,625,871
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 - 39,807,659 and 39,747,659, outstanding shares - 27,554,157 and 27,494,157 as of March 31, 2021 and December 31, 2020, respectively	39,808	39,748
Additional paid-in capital	98,549,890	98,013,079
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(53,971,300)	(50,676,351)
Total stockholders' equity	25,688,483	28,446,561
Total liabilities and stockholders' equity	$ 28,282,212	$ 30,072,432

See Notes to Consolidated Financial Statements in Item 1 of Dyadic's Quarterly Report on Form 10-Q filed with Securities and Exchange Commission on May 13, 2021.