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): May 14, 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 400
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 14, 2020, Dyadic International, Inc. (“Dyadic”) issued a press release announcing its results for the quarter ended March 31, 2020. 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 otherwise subject to the liabilities of that Section, nor shall it be deemed 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, Inc. Press Release Dated May 14, 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: May 14, 2020

Dyadic International, Inc.

By: /s/ Mark A. Emalfarb

Name: Mark A. Emalfarb

Title: Chief Executive Officer

DYADIC REPORTS 2020FIRST QUARTER RESULTS AND RECENT DEVELOPMENTS

- ***Two fully funded research projects with top four animal health companies.***
- ***Nonexclusive research license agreement with WuXi Biologics.***
- ***Feasibility study with the University of Oslo on influenza vaccine.***
- ***Engineered C1 cell lines to produce high levels of potential SARS-CoV-2 vaccines.***
- ***Strategic R&D relationships to assist in the development of potential COVID-19 vaccines and antibodies.***
- ***Cash and investment grade securities of $34 million at end of first quarter 2020.***

JUPITER, FL / ACCESSWIRE / May 14, 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 March 31, 2020, and recent developments.

"I am very pleased with the substantial progress we made in the first quarter, further executing on our growth strategy and with our efforts increasingly well-aligned to address many of the key global healthcare industry challenges. The data we are generating further highlights the robustness of our C1 gene expression platform and its broad and ever-growing potential applications. As a result, we continue to expand the potential range of commercial opportunities for Dyadic through our relationships with both existing and new partners who are well-established and top tier in their respective sectors. Our overall partnership efforts have been highly collaborative and well-coordinated," said Mark Emalfarb, Dyadic's Chief Executive Officer.

Mr. Emalfarb added "We currently have active programs with several of the top ten human pharma companies and three of the top four animal health companies which are generating encouraging data as well as ongoing discussions for new project opportunities. During the quarter, we moved into the second phase of two of our initial projects with one of our animal health collaborators. In addition, with regard to our self-funded glycoengineering efforts, we have developed a library of human-like C1 strains with higher yields, greater purity and better stability. As a result of these efforts, we are receiving increased levels of interest from the pharmaceutical industry.

With regard to the COVID-19 pandemic, we have formed collaborations both with existing partners such as the Israel Institute for Biologic Research, new collaborators such as Ufovax, a spin-off vaccine company of Scripps Research, as well as a consortium of European experts from our ZAPI project, resulting in proposals we have submitted to various funding agencies and other parties to develop potential SARS-CoV-2 vaccine candidates. Besides the tremendous potential benefit to society, these COVID-19 projects highlight the broad appeal of our C1 technology platform to potentially advance the process of vaccine and biopharma drug development in large and growing addressable markets."

Mr. Emalfarb concluded "With respect to the impact of COVID-19 on Dyadic, we have taken the necessary health and safety measures for our employees who have been primarily working remotely. The extent to which the COVID-19 pandemic will directly or indirectly impact our business will depend on future developments that are highly uncertain; however, our strong balance sheet and on-going R&D collaborations funded by our partners, and our active and diverse pipeline of potentially high return projects underpin our success and growth strategy during these difficult times."

RECENT DEVELOPMENTS

- Within the animal health market, Dyadic is actively working with three of the top four companies and in discussions with several others. Recently, the first two projects with one of these top three have been expanded with additional funding and have entered the second phase of development, and a new work proposal for a third project is under final review.

- Animal trial data reported by ZAPI related to the SBV antigen produced from C1 showed excellent safety and efficacy. As previously reported, the SBV antigen produced from C1 was more stable and was produced at 17 times the initial target level set by ZAPI and significantly higher levels than the SBV antigen produced from baculovirus which is a cell line currently used in influenza, COVID-19 and other vaccine programs.

- The Company has engaged with new and existing research partners globally to help expedite development, increase availability and lower the cost of manufacturing potential COVID-19 vaccine candidates, potential therapeutics and potential diagnostic candidates, as follows:

    - Dyadic has received certain gene sequences from the Israeli Institute for Biological Research ("IIBR") and has constructed C1 cell lines to express certain proteins that may help combat the COVID-19 pandemic as well as potentially be used for certain COVID-19 diagnostic tests. C1 cell lines expressing potential SARS-CoV-2 vaccine candidates have been sent to the IIBR for their use in developing and manufacturing potential COVID-19 vaccines.

    - Dyadic, in collaboration with Erasmus Medical Center, Utrecht University, and the University of Veterinary Medicine Hannover ("TiHo"), with whom Dyadic previously worked with on the EU ZAPI project, have developed a potential COVID-19 vaccine candidate which, based on preliminary results, has demonstrated successful engineering of C1 to express high levels of a potential SARS-CoV-2 vaccine candidate. This consortium has submitted proposals for program funding to pharmaceutical organizations and government agencies.

    - Ufovax, the Scripps Institute spinout, has provided Dyadic with their gene sequences, including potential SARS-CoV-2 and HIV vaccine candidates, to begin protein expression. UfoVax, in conjunction with Dyadic, has submitted proposals for funding the SARS-CoV-2 program to pharmaceutical organizations and government agencies.

- Dyadic entered into a feasibility study with a highly regarded group of flu experts at the University of Oslo regarding an influenza vaccine. The Company has begun expression of a targeted Influenza virus antigen protein provided by Oslo University.

- Dyadic entered into a non-exclusive research license with WuXi Biologics, one of the leading global Contract Development Manufacturing Organizations.

- Our collaboration with Sanofi has achieved or exceeded the targeted expression levels for a number of different types of biologic vaccines and drugs, and we are currently in discussions regarding next steps.

- In our collaboration with the Serum Institute of India, we have expressed 6 proteins and recently started a second phase of the research program with these proteins.

SCIENTIFIC ACHIEVEMENTS

- Successfully engineered several C1 cell lines to express and produce high levels of potential SARS-CoV-2 vaccine candidates. Preliminary results in microtiter plates indicate high productivity levels, and the Company expects to verify and quantify the expression level results in fermenters within the next few weeks.

- Dyadic continues to advance its self-funded glycoengineering program through the development of C1 cell lines that produce high proportions of human-like glycoforms while reducing the extra-cellular protease background in C1 cell lines. The Company is developing a diverse library of C1 strains that impart human-like glycosylation with greater purity and stability. We believe that through these advancements Dyadic may provide differentiated glycoengineered C1 cell lines for biopharmaceuticals, enabling more specific and refined classes and types of proteins and creating significant new opportunities for the Company and our collaborators.

- Data presented at the 15^{h} European Conference on Fungal Genetics ("ECFG15") demonstrated that Dyadic's C1 had been glyco-engineered to achieve a core human-like G2 glycan level over 76%. The data also showed a reduction in the extra-cellular protease background by 50 times in C1, making the cell line more efficient and stable, leading to higher expression levels and lower cost.

- Dyadic recently filed a provisional patent on the development of a C1 strain to produce a primary metabolite product. The next phase may include strain optimization to determine if the C1 strain could match the productivity and be cost effective versus current chemically synthesized products now on the market.

- Dyadic continues to self-fund a secondary metabolite project and is continuing to explore the market opportunity for certain secondary metabolite products that may be produced from C1 for a variety of applications.

RESULTS FOR THE QUARTER ENDED MARCH 31, 2020

At March 31, 2020, cash and cash equivalents were approximately $4.7 million compared to $4.8 million at December 31, 2019. The carrying value of short-term and long-term investment grade securities, including accrued interest at March 31, 2020 was approximately $29.3 million compared to $31.2 million at December 31, 2019.

Research and development revenue for the quarter ended March 31, 2020, decreased to approximately $315,000 compared to $403,000 for the quarter ended March 31, 2019.

Cost of research and development revenue for the quarter ended March 31, 2020 decreased to approximately $278,000 compared to $328,000 for the quarter ended March 31, 2019.

The decreases in revenue and cost of research and development revenue for the quarter ended March 31, 2020 reflects five on-going research collaborations compared to six research collaborations for the quarter ended March 31, 2019.

Interest income for the three months ended March 31, 2020, decreased 37.1% to approximately $168,000 compared to $267,000 for the for the same period a year ago. The decrease in interest income reflects the lower interest rate and yield on the Company's investment grade securities, which are classified as held-to-maturity.

Research and development expenses for the three months ended March 31, 2020 increased to approximately $755,000 compared to $692,000 for the same period a year ago. The increase primarily reflects the additional costs of accelerated glyco-engineering project conducted at VTT Technical Research Centre of Finland Ltd.

The Company did not have any research and development expenses - related party, for the three months ended March 31, 2020, compared to approximately $389,000 for the same period a year ago. The decrease was due to the completion of the Research Service Agreement with Biotechnology Developments for Industry in Pharmaceuticals, S.L.U. ("BDI") in June 2019.

General and administrative expenses for the three months ended March 31, 2020, increased 15.8% to approximately $1,653,000 compared to $1,428,000 for the same period a year ago. The increase principally reflects increases in insurance and other outside service costs of $101,000, noncash share-based compensation expenses of $97,000, business development and investor relations costs of $70,000, and other increases of $54,000, offset by reductions in executive compensation costs and accrued incentives of $74,000 and legal expenses of $23,000.

Net loss for the three months ended March 31, 2020 was approximately $2,214,000, or $(0.08) per share, compared to $2,175,000, or $(0.08) per share for the same period a year ago. The change was primarily due to an increase in G&A expenses, lower interest income, and fewer on-going research collaborations offset by the reduction in the total R&D expenses due to the completion of Research Service Agreement with BDI.

CONFERENCE CALL INFORMATION

Dyadic management will host a conference call today, Thursday, May 14, 2020, at 5:00 PM ET to discuss the financial results for the quarter ended March 31, 2020. In order 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/2031/34441.

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 which will expire May 28, 2020, dial 1 (877) 481-4010 (U.S. or Canada) or 1 (919) 882-2331 (International) and enter replay pass code: 34441.

About Dyadic International

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.

Contact:

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DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Revenues:		
Research and development revenue	$ 315,372	$ 402,527
Costs and expenses:		
Costs of research and development revenue	278,182	327,903
Research and development	755,453	692,370
Research and development - related party	—	389,473
General and administrative	1,653,392	1,428,067
Foreign currency exchange loss (gain), net	10,867	6,034
Total costs and expenses	2,697,894	2,843,847
Loss from operations	(2,382,522)	(2,441,320)
Interest income	168,383	266,962
Loss before income taxes	(2,214,139)	(2,174,358)
Provision for income taxes	—	900
Net loss	$ (2,214,139)	$ (2,175,258)
Basic and diluted net loss per common share	$ (0.08)	$ (0.08)
Basic and diluted weighted-average common shares outstanding	27,452,490	26,713,486

The accompanying notes are an integral part of these unaudited consolidated financial statements.

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2020	December 31, 2019
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 4,696,831	$ 4,823,544
Short-term investment securities	26,587,752	29,399,146
Interest receivable	227,146	329,711
Accounts receivable	518,601	558,530
Income tax receivable	500,616	250,308
Prepaid expenses and other current assets	288,495	277,999
Total current assets	32,819,441	35,639,238
Non-current assets:		
Long-term investment securities	2,518,160	1,511,636
Long-term income tax receivable	—	250,308
Other assets	50,489	51,314
Total assets	$ 35,388,090	$ 37,452,496
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 653,373	$ 943,378
Accrued expenses	240,003	566,003
Deferred research and development obligations	242,443	78,644
Total current liabilities	1,135,819	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 - 39,722,659 and 39,612,659, outstanding shares - 27,469,157 and 27,359,157 as of March 31, 2020 and December 31, 2019, respectively	39,713	39,613
Additional paid-in capital	96,707,690	96,105,851
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(43,565,217)	(41,351,078)
Total stockholders' equity	34,252,271	35,864,471
Total liabilities and stockholders' equity	$ 35,388,090	$ 37,452,496

The accompanying notes are an integral part of these unaudited consolidated financial statements.