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): March 30, 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 March 30, 2021, Dyadic International, Inc. ("Dyadic") issued a press release announcing its results for the quarter and year ended December 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 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 March 30, 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: March 30, 2021

Dyadic International, Inc.

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

Exhibit 99.1

DYADIC REPORTS 2020 YEAR END RESULTS AND RECENT COMPANY PROGRESS

- ***Advancing Dyadic's proprietary COVID-19 vaccine candidate, DYAI-100, towards a first-in-human Phase 1 clinical trial***
  - ***To validate C1 produced proteins are safe in humans and accelerate C1 adoption and commercialization***
  - ***To serve as proof of concept for next-generation multivalent COVID-19 vaccine candidates***
- ***Expanded Korea and Southeast Asia vaccine development partnership with Medytox 086900) (KOSDAQ) focused on next-generation COVID-19 variant vaccines and/or boosters***
- ***In parallel with DYAI-100, additional proprietary and third-party COVID-19 variant vaccine candidates are under development***
- ***Developing a number of other infectious disease vaccines and antibodies internally and in conjunction with others***
- ***Expanding commercial opportunities of C1 technology through eleven new and two expanded collaborations for human and animal health applications***
- ***C1 selected by ZAPI (Zoonosis Anticipation Preparedness Initiative) as a vaccine manufacturing platform for more efficient production of antigens that are safe, effective, and protective***
- ***Cash and investment grade securities of $29.2 million at year-end 2020***

JUPITER, FL / ACCESSWIRE / March 30, 2020 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, drugs and other commercial products at flexible commercial scales, today announced its financial results for 2020 and recent business highlights.

"We are very pleased with substantial progress made thus far in 2021 and over the course of 2020. With the ongoing challenges of the COVID-19 pandemic, we have been working tirelessly to identify ways to apply our C1 technology to help speed the development, increase availability, and lower the cost of COVID-19 vaccines and treatments to make them affordable and available worldwide. We and our collaborators worked conscientiously to introduce the C1 technology to the world to enable as many COVID-19 programs as possible and we are continuing to do so as COVID-19 variants continue to emerge. Due to our success in several animal studies where rapidly engineered C1-cells have achieved high levels of antigen productivity and were shown to be safe, effective, and protective, our C1 technology has gained the attention of a growing number of infectious disease and other scientists in industry and government. This momentum has begun to accelerate after our announcement that our proprietary COVID-19 vaccine candidate, DYAI-100, is advancing into a first-in-human Phase 1 clinical trial, which is expected to begin in the second half of 2021. As SARS-CoV-2 continues to mutate into different variants, we have already begun the engineering of

novel C1 cell lines to enable the development of next-generation multivalent COVID-19 vaccine candidates," stated Mark Emalfarb, Dyadic's Founder and Chief Executive Officer.

Mr. Emalfarb continued, "Additionally, we expanded our fully funded vaccine development partnership with Medytox to accelerate the development of multivalent COVID-19 vaccine candidates and/or boosters to immunize people against multiple existing or future SARS-CoV-2 variants. Dr. Gi-Hyeok Yang, Sr. Executive Vice President and Head of Research and Development at Medytox recently stated, "*Based on our experience and comparing the C1 technology platform against several other expression platforms, such as CHO and insect cells, we believe that the fungi-derived C1 expression system is the most realistic technology to develop and manufacture multi-valent (i.e., tri-valent, and tetra-valent) vaccines, rapidly and affordably, against COVID-19 mutant viruses, without the need for a large-scale bioreactor facility. Medytox has confidence that the C1 technology platform can play a critical role in helping combat COVID-19, which may continue to persist as a seasonal influenza and necessitate COVID-19 variant vaccine shots every year. We look forward to gaining additional experience with the C1 technology as it has potential for use in developing and producing a growing number of vaccines, drugs, and other biological products in addition to COVID-19.*"

"Beyond our COVID-19 initiatives, in 2020, we commenced five, new funded collaborations with top pharmaceutical companies to produce therapeutics of commercial interest for human health applications. Additionally, our fully funded collaboration with TurtleTree Scientific to develop human growth factors, enables us to enter a new and significant commercial opportunity that includes regenerative therapies. We believe these collaborations, as well as others currently in various stages of discussion, will help accelerate our C1 platform towards the commercialization of numerous products to improve animal and human health, globally. We look forward to evaluating new opportunities to maximize the value of our C1 technology and expand its commercial potential with the goal of driving further value for our shareholders." concluded Mr. Emalfarb.

Recent Company Progress

COVID-19 Initiatives:

- Advancing C1 produced SARS-CoV-2-S-RBD antigen, DYAI-100 vaccine candidate towards a first-in-human Phase 1 clinical trial:
  - The Company formed a strategic collaboration with leading infectious disease scientists from Erasmus Medical Centre, University Utrecht, TiHo Hannover (ZAPI scientists) to develop a COVID-19 vaccine that can be rapidly manufactured, in large quantities, at low cost, using standard microbial fermenters that are readily available.
  - The Company expanded its collaboration with the Israel Institute for Biological Research (IIBR), which supported the development of the DYAI-100 COVID-19 vaccine candidate and carried out preclinical and challenge studies in mice.
  - C1 produced SARS-CoV-2-S-RBD antigen has been evaluated in ten animal trials by academic, industrial, and governmental R&D groups globally.
  - The Company engaged CR2O, a contract research organization, to manage and support further preclinical and clinical development of DYAI-100 with a toxicology study expected to begin in the second quarter of 2021, and a first-in-human Phase 1 clinical trial expected to begin in the second half of 2021.
- In parallel with DYAI-100, the Company is developing additional proprietary and third-party monovalent and multivalent COVID-19 variant vaccine candidates by engineering a portfolio of C1 cell lines to produce several SARS-CoV-2 variant antigens, including the UK variant.
- 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.
- Frederick National Laboratory, ZAPI, and other third-party collaborators, are working on C1 produced SARS-CoV-2 and other antigens, to evaluate their properties and performance for possible use in the treatment of infectious diseases.
- On October 12, 2020, the Company announced it entered into a non-exclusive technology usage agreement with Epygen Biotech of India, who plans to conduct clinical trials in India using DYAI-100, or one or more of the COVID-19 variant vaccines, once funding becomes available.
- The Company engineered C1-cells to produce a COVID-19 monoclonal antibody in collaboration with IDBiologics, a biotechnology company that is co-developing antibodies with the Vanderbilt University Medical Center.

Human Health (Non-COVID) Collaborations:

- The Company is developing a number of other non-COVID infectious disease vaccine and antibody candidates internally and in conjunction with others.
- In February 2021, the Company entered into a potential new market with a fully funded collaboration with TurtleTree Scientific to develop a number of recombinant protein growth factors, which play a critical role in tissue development and healing, including regenerative therapies.
- In August 2020, the Company established a collaboration with Jiangsu Hengrui Medicine ("Hengrui"), the largest pharmaceutical company in China (by market capitalization) for the development of selected Hengrui biologic drug(s) using C1 technology.
- During 2020, the Company entered into a feasibility study with the University of Oslo for a potential influenza vaccine.
- During 2020, the Company established five new fully funded collaborations with top-tier global pharmaceutical and small biotech companies to express therapeutics of commercial interest using C1 technology.
- During 2020, the Company extended three existing collaborations to continue to investigate possible applications for its C1 technology.

Animal Health Collaborations:

- During 2020, the Company established three new fully funded collaborations with leading global animal health companies and expanded an existing collaboration to demonstrate the C1 technology platform for the expression and production of therapeutic proteins for animal diseases.
- ZAPI announced, at its Final Stakeholders Virtual Web Meeting on February 4-5, 2021, positive results from animal studies evaluating 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). Dyadic's C1 produced SBV antigen has also demonstrated strong protection of cattle, sheep and mice from SBV. In the first quarter of 2021, ZAPI expanded its program with Dyadic by providing additional funding to C1 research and development efforts as well as to conduct additional animal studies using the SBV and RVFV antigens produced from C1.

Research License:

- In March 2020, Dyadic entered into a non-exclusive research collaboration with WuXi Biologics, a leading contract development manufacturing organization. WuXi is providing funding to evaluate the C1 technology for possible commercial uses.

Financial Highlights

Cash Position: At December 31, 2020, cash, cash equivalents, and the carrying value of investment grade securities, including accrued interest were approximately $29.2 million compared to $36.0 million at December 31, 2019.

Revenues: Research and development revenue for the year ended December 31, 2020, decreased slightly to approximately $1,602,000 compared to $1,681,000 for the year ended December 31, 2019.

Cost of Revenues: Cost of research and development revenue for the year ended December 31, 2020, decreased slightly to approximately $1,425,000 compared to $1,460,000 for the year ended December 31, 2019. For the year ended December 31, 2020, the Company reported a provision for contract losses of approximately $187,000 from one research collaboration, compared to zero for the year ended December 31, 2019.

The slight decreases in revenue and cost of research and development revenue for the year ended December 31, 2020 reflected a growing number of research collaborations to fourteen, compared to ten research collaborations for the year ended December 31, 2019, however, with smaller dollar amounts for each project.

R&D Expenses: Research and development expenses for the year ended December 31, 2020 increased to approximately $3,868,000 compared to $3,088,000 for the year ended December 31, 2019. The increase primarily reflected the costs of COVID-19 projects and additional internal research projects.

Research and development expenses - related party, for the year ended December 31, 2020, were none compared to approximately $869,000 for the year ended December 31, 2019. The decrease was due to the completion of research service agreement with BDI in June 2019.

G&A Expenses: General and administrative expenses for the year ended December 31, 2020, increased by 10.2% to approximately $6,085,000 compared to $5,520,000 for the year ended December 31, 2019. The increase principally reflected increases in noncash share-based compensation expenses of $397,000, insurance premiums and other outside services of $216,000, legal and SEC registration expenses of $193,000, business development and investor relations costs of $191,000, offset by reductions in executive compensation costs and accrued incentives of $216,000, trade show and travel expenses of $143,000 and other decreases of $73,000.

Interest Income: Interest income for the year ended December 31, 2020, was approximately $447,000 compared to $985,000 for the year ended December 31, 2019. The decrease was primarily due to a decrease in interest rate and yield on the Company's investment grade securities, which are classified as held-to-maturity.

Other Non-Operating Items: For the year ended December 31, 2020, the Company recorded a gain related to its investment in Alphazyme resulting from a third-party capital contribution. As of December 31, 2020, the fair market value of the Company's investment in Alphazyme was approximately $285,000.

Net Loss: Net loss for the year ended December 31, 2020 was approximately $9.3 million, or $(0.34) per share, compared to a net loss of $8.3 million, or $(0.31) per share, for the year ended December 31, 2019. The change was primarily due to increases in general and administrative expenses of approximately $0.6 million, provision for contract losses of approximately $0.2 million, reduction in interest income of $0.5 million, offset by an unrealized gain from our investment in Alphazyme of approximately $0.3 million.

Conference Call Information

Date: Tuesday, March 30, 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/2031/40394

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: 40394.

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:

Dyadic International, Inc.
Ping W. Rawson
Chief Financial Officer
Phone: (561) 743-8333
Email: prawson@dyadic.com

Exhibit 99.1

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2020	**2019**
Revenues:		
Research and development revenue	$ 1,601,921	$ 1,681,076
Costs and expenses:		
Costs of research and development revenue	1,424,931	1,459,701
Provision for contract losses	187,388	—
Research and development	3,868,121	3,087,597
Research and development - related party	—	868,720
General and administrative	6,084,799	5,519,922
Foreign currency exchange loss (gain), net	62,345	27,725
Total costs and expenses	11,627,584	10,963,665
Loss from operations	(10,025,663)	(9,282,589)
Interest income	446,999	984,930
Unrealized gain from investment in Alphazyme	284,709	—
Loss before income taxes	(9,293,955)	(8,297,659)
Provision for (benefit from) income taxes	31,318	10,306
Net loss	$ (9,325,273)	$ (8,307,965)
Basic and diluted net loss per common share	$ (0.34)	$ (0.31)
Basic and diluted weighted-average common shares outstanding	27,471,587	27,003,695

See Notes to Consolidated Financial Statements in Part I of Dyadic's Annual Report on Form 10-K filed with Securities and Exchange Commission on March 30, 2021.

Exhibit 99.1

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 20,637,045	$ 4,823,544
Short-term investment securities	8,457,452	29,399,146
Interest receivable	112,247	329,711
Accounts receivable	294,199	558,530
Income tax receivable	—	250,308
Prepaid expenses and other current assets	280,555	277,999
Total current assets	29,781,498	35,639,238
Non-current assets:		
Long-term investment securities	—	1,511,636
Long-term income tax receivable	—	250,308
Investment in Alphazyme	284,709	—
Other assets	6,225	51,314
Total assets	$ 30,072,432	$ 37,452,496
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,013,099	$ 943,378
Accrued expenses	489,756	566,003
Deferred research and development obligations	123,016	78,644
Total current liabilities	1,625,871	1,588,025
Commitments and contingencies (Note 5)		
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 - 39,747,659 and 39,612,659, outstanding shares - 27,494,157 and 27,359,157 as of December 31, 2020 and 2019, respectively	39,748	39,613
Additional paid-in capital	98,013,079	96,105,851
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(50,676,351)	(41,351,078)
Total stockholders' equity	28,446,561	35,864,471
Total liabilities and stockholders' equity	$ 30,072,432	$ 37,452,496

See Notes to Consolidated Financial Statements in Part I of Dyadic's Annual Report on Form 10-K filed with Securities and Exchange Commission on March 30, 2021.