

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 9, 2019

Dyadic International, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or
organization)

000-55264

(Commission File Number)

45-0486747

(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 9, 2019, Dyadic International, Inc. ("Dyadic") issued a press release announcing its results for the quarter ended March 31, 2019. 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	<u>Dyadic International Press Release Dated May 9, 2019</u>

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 9, 2019.

Dyadic International, Inc.

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



DYADIC REPORTS FIRST QUARTER FINANCIAL RESULTS AND RECENT DEVELOPMENTS

- *Trading as DYAI on NASDAQ Capital Market as of April 17*
- *New fully-funded proof-of-concept research collaborations with two top twenty-five pharmaceutical companies*
- *Sub-licensing agreements with Luina Bio and Alphazyme*
- *Collaboration with Serum Institute of India to develop and manufacture up to twelve antibodies and vaccines*
- *Execution of multiple strategic research initiatives further reinforces strength of Dyadic's C1 gene expression platform, including exploring the use of C1 to produce Adeno-Associated Virus (AAV) Vectors*

JUPITER, FL / ACCESSWIRE / May 9, 2019 Dyadic International, Inc. ("Dyadic") (NASDAQ: DYAI), a global biotechnology company focused on further improving and applying its proprietary C1 gene expression platform to speed up the development, lower production costs and improve the performance of biologic vaccines, drugs, and other biologic products, at flexible commercial scales, today announced its financial results for the quarter ended March 31, 2019, and recent developments.

"2019 is off to a terrific start for Dyadic with many significant milestones achieved as we further ramp the potential adoption of C1, reinforcing the strength and multiple potential applications of our platform," said Mark Emalfarb, Dyadic's Chief Executive Officer. "In the first quarter of 2019, we signed new fully-funded research collaboration agreements with two top twenty-five pharmaceutical companies. On the scientific front, we have initiated several internal research programs, including a research project to explore the potential of C1 to produce Adeno-Associated Viral (AAV) vectors, which are in high demand despite being costly and in short supply. And, we strengthened our IP portfolio for C1 with the publication of a PCT patent application entitled, "Production of Flu Vaccine Produced from Myceliophthora Thermophila."

"Our momentum has continued into the second quarter as we entered into two new sub-licensing agreements and a new research collaboration. Our first sub-licensing agreement is with Luina Bio, an Australian-based drug development and contract manufacturing organization that will work with our C1 platform to develop and commercialize products to prevent and treat ailments for companion animals. The other agreement is with Alphazyme, a biotech company focused on producing molecular biology enzymes at industrial scale. Under this sub-license, Alphazyme will seek to commercialize certain pharmaceutical products that are used as reagents to catalyze a chemical reaction to detect, measure, or be used in the production of a nucleic acid as a therapeutic or diagnostic agent.

Additionally, we are excited to announce a collaboration with the Serum Institute of India Pvt, Ltd, one of the world's largest vaccine manufacturers, to develop and manufacture up to twelve antibodies and vaccines using Dyadic's C1 gene expression platform. This important collaboration is focused on making biologic vaccines and drugs accessible and more affordable to patients worldwide while lowering the financial burden on the global healthcare system" said Mark Emalfarb, Dyadic's CEO.

"Our pipeline continues to be very active and we are exploring numerous potential development and licensing opportunities. We believe that our C1 technology is extremely robust and are encouraged by the progress we are making. With a strong cash position on our balance sheet, we have the financial flexibility to partner with both large and small pharmaceutical and biotechnology companies," concluded Mr. Emalfarb.

RECENT DEVELOPMENTS

- On April 26, 2019, the Company entered into a sub-licensing agreement with Luina Bio, an Australian -based drug development and contract manufacturing organization with more than 20 years of contract manufacturing experience. Luina Bio will be working with Dyadic's C1 platform to develop and commercialize a number of targeted products for use in the prevention and treatment of various ailments for companion animals.

As part of this sub-licensing agreement, Dyadic will receive a 20% equity ownership stake in a new joint venture company, Novovet Pty Ltd ., in addition to earning a percentage of royalties on net sales and non-sales revenue which incorporate Dyadic's proprietary C1 gene expression platform.

- On May 5, 2019, the Company entered into a sub-licensing agreement with Alphazyme LLC., for the purpose of commercializing certain pharmaceutical products that are used as reagents to catalyze a chemical reaction to detect, measure, or be used as a process intermediate to produce a nucleic acid as a therapeutic or diagnostic agent. Upon the successful transfer of the C1 technology, Dyadic will receive a 7.5% ownership interest in Alphazyme, future milestone payments and a percentage of royalties on net sales.
- On May 7, 2019, the Company entered into a collaboration agreement with Serum Institute of India Pvt, Ltd. Under the terms of this collaboration, Serum anticipates applying Dyadic's C1 technology to express up to twelve proteins - 8 Mabs and 4 rVaccines and will undertake commercially best efforts to fully develop and commercialize the proteins expressed from Dyadic's C1 technology, provided the C1 modified strains pass all the requisite criteria as required by Serum. Dyadic has agreed to grant Serum the option to obtain an exclusive commercial sub-license for each of the twelve (12) proteins in return for certain research funding, milestone payments and royalties for 15 years from the date of the first commercial sale.

C1 PLATFORM AND COLLABORATION UPDATE

- Have achieved or exceeded the targeted expression levels for a number of the different types of biologic vaccines and drugs being expressed within our Sanofi collaboration.
- Under our Mitsubishi collaboration, we have expressed one of the target proteins using C1. A sample of this protein has been sent to them to conduct the functional analyses and characterization of this C1 expressed protein.
- Initiated additional internal research programs to further reinforce and strengthen the C1 gene expression platform and to develop potential C1 products, including a project to explore the potential of C1 to produce Adeno-Associated Virus (AAV) vectors which are widely used in gene therapy and are in high demand and short supply.

FINANCIAL RESULTS

Research and development revenue for the three months ended March 31, 2019 , increased to approximately \$403,000 compared to \$184,000 for the same period a year ago.

Cost of research and development revenue for the three months ended March 31, 2019 , increased to approximately \$328,000 compared to \$147,000 for the same period a year ago.

The increase in revenue and cost of research and development revenue reflect six on-going research collaborations in 2019 compared to two collaborations in 2018.

Research and development expenses for the three months ended March 31, 2019 , increased to approximately \$692,000 compared to \$577,000 for the same period a year ago. The increase reflects the costs of additional internal research activities with third-party contract research organizations.

Research and development expenses - related party, for the three months ended March 31, 2019 , decreased to approximately \$389,000 compared to \$393,000 for the same period a year ago. These expenses reflect the research and development costs related to the Company's R&D agreements with BDI, which started in July 2017.

General and administrative expenses for the three months ended March 31, 2019 , increased 10.4% to approximately \$1,428,000 compared to \$1,293,000 for the same period a year ago. The increase primarily reflects increases in share-based compensation expenses related to stock options granted in 2019 as well as various other expenses including those associated with the April uplisting to the NASDAQ.

Interest income for the three months ended March 31, 2019 , increased 43.5% to approximately \$267,000 compared to \$186,000 for the same period a year ago. The increase in interest income reflects higher yield on the Company's investment grade securities, which are classified as held-to-maturity.

Net loss for the three months ended March 31, 2019 , was approximately \$2.2 million, or \$0.08 per share, compared to a net loss of \$2.0 million, or \$0.07 per share, for the same period a year ago.

BALANCE SHEET

At March 31, 2019, cash and cash equivalents were approximately \$4.0 million compared to \$2.4 million at December 31, 2018. The carrying value of investment grade securities, including accrued interest at March 31, 2019, was \$36.1 million compared to \$39.1 million at December 31, 2018.

CONFERENCE CALL INFORMATION

Dyadic management will host a conference call today, Thursday, May 9, 2019, at 5:00 PM ET to discuss the financial results for the quarter ended March 31, 2019. In order to participate in the conference call, please dial (877) 407-8033 for U.S./Canada callers or +(201) 689-8033 for International callers (no pass code is needed), or use webcast link: <https://www.investornetwork.com/event/presentation/47550>.

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 for a limited time. To access the replay of the webcast, please use the webcast link above. A dial-in replay of the call will also be available to those interested until May 16, 2019. To access the teleconference replay, please dial (877) 481-4010 (U.S. or Canada) or +(919) 882-2331 (International) #47550.

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 *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. Additionally, and more recently, Dyadic is also beginning to explore the use of its C1 technology and other technologies to conduct research, development and commercial activities for the development and manufacturing of Adeno-associated viral (AAV) vectors, 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, hopefully, 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. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. These forward-looking statements involve risks, uncertainties and other factors that could cause Dyadic's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Investors are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on such forward-looking statements. Dyadic expressly disclaims any intent or obligation to update or revise any forward-looking statements to reflect actual results, any changes in expectations or any change in events. Factors that could cause results to differ materially include, but are not limited to: (1) general economic, political and market conditions; (2) our ability to generate the required productivity, stability, purity, performance, cost, safety and other data necessary to carry out and implement our biopharmaceutical research

and business plans and strategic initiatives; (3) our ability to retain and attract employees, consultants, directors and advisors; (4) our ability to implement and successfully carry out Dyadic's and third parties research and development efforts; (5) our ability to obtain new license and research agreements; (6) our ability to maintain our existing access to, and/or expand access to third party contract research organizations in order to carry out our research projects for ourselves and third parties; (7) competitive pressures and reliance on key customers and collaborators; (8) the pharmaceutical and biotech industry, governmental regulatory and other agencies' willingness to adopt, utilize and approve the use of the C1 gene expression platform; (9) speculative nature and illiquidity of equity securities received as consideration from sub-licensees; and (10) other factors discussed in Dyadic's publicly available filings, including information set forth under the caption "Risk Factors" in our March 31, 2019 Quarterly Report filed with the SEC on May 9, 2019 and our December 31, 2018 Annual Report filed with the SEC on the Form 10-K on March 27, 2019. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect us.

Contact:

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DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Research and development revenue	\$ 402,527	\$ 184,330
Costs and expenses:		
Costs of research and development revenue	327,903	146,809
Research and development	692,370	576,884
Research and development - related party	389,473	392,549
General and administrative	1,428,067	1,292,997
Foreign currency exchange loss, net	6,034	4,840
Total costs and expenses	2,843,847	2,414,079
Loss from operations	(2,441,320)	(2,229,749)
Interest income	266,962	186,457
Loss before income taxes	(2,174,358)	(2,043,292)
Provision for income taxes	900	—
Net loss	\$ (2,175,258)	\$ (2,043,292)
Basic and diluted net loss per common share	\$ (0.08)	\$ (0.07)
Basic and diluted weighted-average common shares outstanding	26,713,486	28,159,244

Consolidated balance sheet information:

	March 31, 2019	December 31, 2018*
	(Unaudited)	(Audited)
Cash and cash equivalents	\$ 3,975,761	\$ 2,386,314
Investment securities, short-term, long-term and interest receivable	36,068,352	39,110,681
Prepaid research and development (current and non-current)	170,334	253,446
Total assets	41,859,526	43,300,807
Accumulated deficit	(35,218,371)	(33,043,113)
Stockholders' equity	\$ 40,585,474	\$ 42,451,169

*Condensed from consolidated audited financial statements