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 7, 2019

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 1.01 Entry into a Material Definitive Agreement

On May 7, 2019, Dyadic International, Inc. (“Dyadic” or the “Company”) entered into a research and commercialization collaboration with Serum Institute of India Pvt., Ltd (“Serum”).

Under the terms of this collaboration, Serum anticipates applying Dyadic’s C1 technology to express up to twelve (12) antibodies and vaccines and will undertake commercially best efforts to fully develop and commercialize the proteins expressed from Dyadic’s C1 technology. 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.

The foregoing description of the research and commercialization collaboration is qualified in its entirety by reference to the complete terms and conditions of the agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 8.01 Other Events

On May 8, 2019, Dyadic issued a press release announcing the entry into a research and commercialization collaboration in Item 1.01 on this Current Report on Form 8-K. A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Exhibit Description
10.1	Research and Commercialization Collaboration Agreement with Serum Institute of India Pvt.. Ltd., dated May 7, 2019 . Specific items in this exhibit have been redacted, as marked by three asterisks [***].
99.1	Press Release issued by Dyadic International, Inc. Announcing a Research and Commercialization Collaboration with Serum

SIGNATURES

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

Dyadic International, Inc.

Date: May 8, 2019

By: /s/ Mark A. Emalfarb

Name: Mark A. Emalfarb

Title: Chief Executive Officer

Portions of this Exhibit have been redacted because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

Research and Commercialization Work Plan

EXECUTION COPY

The Development and Commercialization of Recombinant Vaccines and Therapeutic Proteins Using Dyadic's C1 Fungal Expression System as the Commercial Production Platform

1. Introduction

- Serum Institute of India Private Limited, a Company incorporated under the Laws of India and having its registered address at 212/2 Off Soli Poonawalla Road, Pune 411028 (Serum) and Dyadic have agreed to enter into a commercial collaboration for 12 product candidates to be expressed using Dyadic's C1 Technology through the definitive Collaboration Agreement for the development and commercialization of recombinant vaccines and therapeutic proteins using dyadic's C1 fungal expression system as the commercial production platform. Serum will undertake commercially best efforts to fully develop and commercialize the proteins expressed from Dyadic's C1 technology. [***]. Initially, through Phases I & II below Dyadic will [***] costs incurred by Dyadic from its third party research collaborator "The VTT Technical Research Center of Finland".
- The purpose of the Dyadic/Serum Collaboration is to apply Dyadic's C1 technology to express up to twelve proteins - 8 MABs and 4 rVaccines. In addition, Serum is also interested in developing [***]. Inclusion [***] in the Serum-Dyadic collaboration portfolio will be communicated and dealt separately. Serum will provide the gene sequences to Dyadic/VTT, which the Parties will need to agree upon in writing prior to the start of the project, which will be used for the expression and production of the Serum therapeutic and vaccine proteins using the C1 production platform.
- The specific goals of the collaboration are:

  ❑ For Dyadic to further develop/modify initial C1 strains to express up to twelve Serum proteins using the C1 gene expression platform of Dyadic.

  ❑ For Serum to bear the full cost of the development and commercialization of all twelve (12) of the proteins expressed from C1 in this collaboration and to conduct the necessary and required preclinical research and clinical trials and to file the required applications with the Indian FDA to begin with and other regulatory authorities including US FDA to allow the commercialization and marketing of the twelve (12) vaccines or drugs produced from Dyadic's C1 gene expression platform. It is further agreed that the new strains developed by Dyadic will be exclusively licensed to Serum and Dyadic cannot license, transfer, dispose off them to any third party including Danisco.

  In order to fulfill this goal:

- § Serum agrees to conduct all the necessary and required protein analysis and characterization in order to evaluate the quality of each of the expressed proteins. Serum also agrees to use its best efforts to develop and commercialize all twelve (12) of the proteins expressed from C1 in this project and to take all twelve (12) of these proteins through all the necessary and required preclinical research and clinical trials to prove that each of the chosen vaccines and/or drugs are safe and effective in treating a condition(s), and to file the required applications with the Indian FDA to begin with and other regulatory authorities including US FDA to allow the marketing of the twelve (12)) vaccines and/or drugs produced from Dyadic's C1 gene expression platform.

- § Provided both parties fulfill their respective obligations including that the C1 modified strains pass all the requisite criteria as required by Serum, then Dyadic shall grant Serum the option to obtain an exclusive commercial sublicense(s) to all twelve (12) of the specific developed/modified C1 strains expressing the selected Serum proteins from this collaboration. Each of the twelve (12) commercial sublicense(s) will be exclusive and shall be negotiated in good faith between Serum and Dyadic based on the projected commercial market for each of the selected proteins , provided that the financial obligations of Serum shall not exceed the terms and conditions of royalties & project costs as prescribed in this Research and Commercialization Work Plan. It is further agreed that Dyadic cannot transfer or dispose of the developed/modified C1 strains expressing the selected Serum proteins to any third party, including Danisco.

- § Each sublicense will provide for royalties of [***] upon commercial sale of each of the products for a period of 15 years from the date of first commercial sale. The Parties agree that such other terms & conditions (other than the royalty rates) will be on reasonable commercial terms and conditions and will be subject to each of the Party's other restrictions from third parties, if any. The terms and conditions of said sublicense(s) shall be negotiated in good faith by both Parties. Each commercial sublicense(s) option may be exercised by Serum by giving written notice to Dyadic following the conclusion of Phase I of the research below and such option shall be valid for a period of twelve months. Furthermore, Serum agrees to pay Dyadic a Milestone of [***] on 2nd anniversary of MA and an additional Milestone of [***] on 5th anniversary of MA.

- § [***]

- Dyadic/VTT will conduct the initial work to carry out Phase I and Phase II below at the VTT Technical Research Center of Finland.

- In order to carry out the Phase I and Phase II Research Serum will provide Dyadic/VTT (i) information about the proteins (ii) the amino acid sequences of the target proteins (iii) a minimum of 2 mg of each protein to be used as a standard and (iv) purification methods, suggested by Serum that can be applicable by Dyadic/VTT, in case Protein A purification method cannot be applied.

2. Dyadic/VTT Work Plan

- The R&D work will be done in two phases as follows:

2.1 Phase I – First expression and production of Serum's proteins at 1L scale

1) *Step 1 - Studying protease activity against the target proteins*

    a. [***]

2) *Step 2 -Design and constructing the expression vectors*

    a. [***]

3) *Step 3 - First set of proteins expression*

    a. [***]

4) *Step 4 - Laboratory scale fermentations*

    a. [***]

    b. Purified samples of the target proteins, if successful, will be delivered to Serum for further analysis and characterization.

2.2 Phase II – Second expression and production of Serum's proteins at 1L scale

5) *Step 5 - Second set protein expression*

    a. [***]

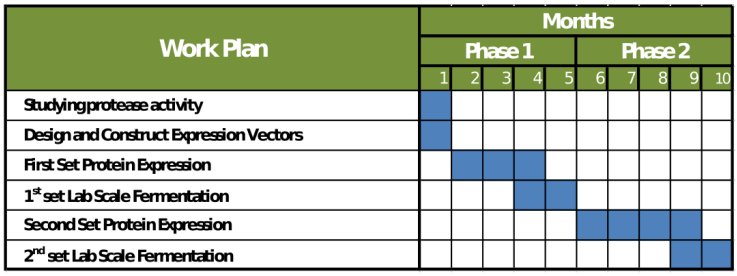
6) *Step 6 - Second set laboratory scale fermentation*

    a. [***]

    b. Samples of the target proteins will be delivered to Serum for further analysis and characterization.

3. Project timeline

The total duration of the project is 10 months excluding the time needed for gene synthesis by a gene synthesis company. Although these are projected timelines, Dyadic will try to deliver the proteins from Phase I at the earliest.



4. Progress/Interim Meetings and Final Report:

a. **Frequency of teleconferences and/or face-to-face meetings:** Throughout the project timeline monthly teleconferences or face to face meetings at VTT will be held between the project teams.

b. **Reports to be provided to Serum Project Manager:** At the end of the project timeline, Dyadic will provide a written summary of the findings in the form of a Serum slide deck summarizing key outcomes (in PowerPoint format).

5. Final Materials Deliverables

At the end of the development project if successful Dyadic will provide Serum with small samples of available proteins for further analysis

6. Project resources

a. Dyadic will provide all scientific and technical support as is required for this successful collaboration.

b. Project cost:

[***]

c. Payments:

- For phase I, serum will pay to Dyadic 50% on signing of this Research and Commercialization Work Plan and 50% at the completion of Phase I.
- For Phase II, Serum will pay to Dyadic 50% on the starting date of phase II and 50% at the completion of phase II.
- Serum shall make the payments subject to deduction of with-holding taxes, if any as may be applicable from time to time. Dyadic shall provide necessary document such as IRS Tax Residency Certificate in Form 6166, 'No permanent establishment' letter and Form 10F on letterhead that may be reasonably necessary in order for Serum to support concessional or No withholding taxes as per the Double Taxation Avoidance Agreement between India and US. If the relevant supporting documentation is not provided by Dyadic within a reasonable timeframe following Serum's request, the Serum shall deduct withholding tax at the applicable rate under tax legislations in India and shall provide a certificate of such deductions to Dyadic to claim credit of taxes in US.

Dyadic R&D Point of Contact:

Ronen Tchelet

Dyadic International (USA), Inc.

140 Intracoastal Pointe Drive

Suite # 404

Jupiter, Florida 33477 USA

Tel: + 36 30 864 6060

Email: rtchelet@dyadic.com

Copy: mjones@dyadic.com

Serum point of contact:

[***]

212/2 Off Soli Poonawalla Road

Hadapsar, Pune 411028

INDIA.

Tel : [***]

Email: [***]

IN WITNESS WHEREOF, duly-authorized representatives of the parties have signed as of the Effective Date.

DYADIC INTERNATIONAL (USA), INC. (DYADIC)	**SERUM INSTITUTE OF INDIA PVT. LTD. (SERUM)**
By: /s/ Mark A Emalfarb	By: /s/Adar C. Poonawalla
Printed Name: Mark A. Emalfarb	Printed Name: Adar C. Poonawalla
Title: **Chief Executive Officer**	Title: **Chief Executive Officer**
Date: 5-7-2019	Date: 6th May 2019

Dyadic and Serum Institute of India to Develop and Manufacture Globally Affordable and Accessible Antibody Products and Vaccines

PUNE, INDIA / **JUPITER, FLORIDA** / **ACCESSWIRE** / **May 8, 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, is pleased to announce a research and commercialization collaboration with Serum Institute of India Pvt., Ltd ("Serum"), 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 & drugs accessible and more affordable to patients worldwide while lowering the financial burden on the global healthcare system.

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. Dyadic has agreed to grant Serum the option to obtain an exclusive commercial sublicense 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.

"We are very excited to collaborate with Serum as our philosophies are directly aligned. Our goal is to offer our C1 gene expression platform to biotech and pharmaceutical companies as well as renowned institutes and governmental agencies that are committed to reducing the cost of healthcare and saving lives. Serum is a Worldwide leading vaccine and drug development institution and we are excited by the science and results we believe we can achieve together", said Mark Emalfarb, Dyadic's CEO.

"Serum has a proven track record of more than 50 years of developing and delivering affordable vaccines and drugs globally and we are eager to incorporate Dyadic's industrially proven C1 gene expression platform into our antibody and vaccine development and manufacturing programs" said Adar Poonawalla, CEO, Serum Institute of India. He further stated that "In recent years, monoclonal antibodies have emerged as preferred therapeutic candidates for the treatment of a multitude of disorders and diseases. These include a broad range of cancers, auto-immune diseases, microbial infections. Traditionally, antibody treatment is extremely costly and not widely affordable in the developed and developing worlds. We at Serum are committed to finding ways to speed the development, lower the cost and improve the performance of high quality, affordable antibodies and vaccines which have the potential to treat and prevent various diseases in India and across the globe. Dyadic's C1 gene expression platform has the potential to help us deliver on our commitment to bring down the cost of biologics in order to make them more accessible and affordable to patients globally."

"This collaboration will further demonstrate the potential of C1 to become a platform of choice for manufacturing protein-based biologics and vaccines because of its speed of development and low cost of goods." said Matthew Jones, Dyadic's CCO.

About Serum Institute

Serum Institute of India Pvt. Ltd. is the world's largest vaccine manufacturer by number of doses produced and sold globally (more than 1.3 billion doses) which includes Polio vaccine as well as Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps and Rubella vaccines. It is estimated that about 65% of the children in the world receive at least one vaccine manufactured by Serum Institute. Vaccines manufactured by Serum are accredited by the World Health Organization, Geneva and are being used in approximately 170 countries across the globe in their national immunization programs, saving millions of lives.

Serum is ranked as India's No.1 biotechnology company, manufacturing highly specialized lifesaving biologics like vaccines using cutting edge genetic and cell-based technologies, antisera and other medical specialties.

Serum was founded in 1966 by Dr. Cyrus Poonawalla with a mission of manufacturing life-saving immuno-biologics, which were in short supply in India and were being imported at extremely high prices. Thereafter, several life-saving biologics were manufactured by Serum with the result that the country became self-sufficient for Tetanus Anti-toxin and Anti-snake Venom serum, followed by the DTP (Diphtheria, Tetanus and Pertussis) group of Vaccines and then later with the MMR (Measles, Mumps and Rubella) group of vaccines.

The philanthropic philosophy of Serum continues with its work on newer vaccines such as Rotavirus vaccine, Meningitis A vaccine and other combination vaccines.

Learn more about Serum Institute of India at https://www.seruminstitute.com/

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 vectors (AAV), 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 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; and (9) other factors discussed in Dyadic's publicly available filings, including information set forth under the caption "Risk Factors" in 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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