

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): August 13, 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



DYADIC REPORTS SECOND QUARTER 2019 RESULTS AND RECENT DEVELOPMENTS

- **New Fully Funded Research Collaboration with a Top Tier Pharmaceutical Company**
- **Expanded Technology Platform Through Multiple Collaborations and Sublicensing Agreements**
- **Robust Scientific Data Reported**
- **Up-listed to the Nasdaq Capital Market and Joined Russell Microcap® Index**

JUPITER, FL / ACCESSWIRE / August 13, 2019 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, drugs, and other biologic products, at flexible commercial scales, today announced its financial results for the quarter ended June 30, 2019, and recent developments.

“I am pleased to report that we maintained our momentum in the second quarter by signing several agreements with highly experienced, value-added partners, including the Serum Institute of India (“Serum”). Serum is one of the world's largest vaccine manufacturers and our collaboration provides for the development and manufacture up to twelve antibodies and vaccines using Dyadic’s C1 gene expression platform. We expect these relationships, along with those we signed in the first quarter and the recent agreement we signed earlier this week with a top tier pharmaceutical company, will further the development of our C1 technology platform and expand the breadth of potential commercial opportunities for human and animal health applications,” said Mark Emalfarb, Dyadic’s Chief Executive Officer.

Mr. Emalfarb also commented, “We achieved several milestones in the quarter, including up-listing to the Nasdaq and joining the Russell Microcap Index® reinforcing the continued growth of our Company. As a result, we are well positioned to enhance our visibility in the investment community, broaden our shareholder base and further build long-term shareholder value. In the fall, our management team will continue to be very active at both investor and industry conferences. Our management team is lean but highly experienced and energized, supported by best in-class scientific partners. Finally, our balance sheet remains a source of strength with approximately \$38.8 million in cash and investment grade securities, no debt and complemented by partner funded on-going R&D collaborations.”

“We continue to make progress executing on our vision of creating more efficient and commercially cost-effective healthcare solutions for society globally. Based on the number of additional non-disclosure agreements we have signed year to date and our ongoing discussions with several pharma and biotech companies, we look forward to sharing additional new developments as the second half of the year unfolds,” concluded Mr. Emalfarb.

RECENT DEVELOPMENTS

- On August 12, 2019, Dyadic signed a fully funded research collaboration with a top tier pharmaceutical company to express three different types and classes of proteins.
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- On July 1, 2019, Dyadic was added to the Russell Microcap® Index, which is often used by investors for passive funds and investment products, and referenced as benchmarks for active investment strategies.
- On June 28, 2019, Dyadic extended its research and development contract through June 2022 with VTT Technical Research Centre of Finland Ltd (“VTT”). Data generated through our collaborative scientific research efforts has exceeded our initial expectations and produced record levels of productivity for several different types of proteins. This was demonstrated recently by the very high expression level reached of a full-length monoclonal antibody (mAb) of approximately 22 grams per liter in seven days or approximately 3 grams per liter per day, above the current industry average.
- On June 17, 2019, Dyadic rang the closing bell at the NASDAQ Stock Market in celebration of our April listing on the NASDAQ Stock Exchange.
- On May 7, 2019, Dyadic signed a research and commercialization collaboration with Serum Institute of India PVT., Ltd (“Serum”), a world-class developer and manufacturer of low-cost vaccines and drugs globally, to apply Dyadic’s C1 technology to express up to twelve proteins. Dyadic and Serum are working together to utilize cutting-edge drug development technologies to achieve their shared vision of making biologic vaccines and drugs more accessible and affordable to patients worldwide.
- On May 5, 2019, Dyadic entered into a sub-licensing agreement with Alphazyme, LLC (“Alphazyme”), whereby Alphazyme will use Dyadic’s C1 technology as a manufacturing platform for developing low-cost, high-volume molecular enzymes. Under the terms of this agreement, Dyadic will receive 7.5% equity stake in Alphazyme upon the successful transfer of the C1 technology, and additional milestone payments and royalties will be payable to Dyadic upon successful commercialization of C1 expressed products.
- On April 26, 2019, Dyadic entered into a global sub-licensing agreement of its C1 gene expression platform with Luina Bio Pty Ltd (“Luina Bio”), an Australia-based drug developer and contract manufacturing organization, for the development and commercialization of certain targeted antigen and biological products used for the prevention and treatment of various ailments of companion animals. Under the terms of this agreement, Dyadic will receive 20% equity stake in a new joint venture company, Novovet Pty Ltd, plus royalties on future sales.
- On April 5, 2019, Dyadic entered into an amendment to expand a research collaboration with one of the top twenty-five pharmaceutical companies previously reported.
- Demonstrated further success with fermentation results of the ZAPI antigen against the Schmallenberg virus with a yield of 1,780 mg/l (time point 121h) or 17 times the initially targeted expression level. Animal trials with the C1 produced ZAPI antigen are expected to begin this year.

FINANCIAL RESULTS

For The Three Months Ended June 30, 2019

Research and development revenue for the three months ended June 30, 2019, increased to approximately \$391,000 compared to \$161,000 for the same period a year ago. Cost of research and development revenue for the three months ended June 30, 2019, increased to approximately \$322,000 compared to \$129,000 for the same period a year ago. The increase in revenue and cost of research and development revenue reflect

four on-going research collaborations for the three months ended June 30, 2019 compared to two collaborations in 2018 for the same period.

Research and development expenses for the three months ended June 30, 2019, increased to approximately \$818,000 compared to \$601,000 for the same period a year ago. This 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 June 30, 2019, was approximately \$336,000 compared to \$341,000 for the same period a year ago. These expenses reflect the research and development costs related to the Research Services Agreement and the Service Framework Agreement ("R&D Agreements") between Dyadic and Biotechnology Developments for Industry in Pharmaceuticals, S.L.U. ("BDI"), which started in July 2017.

General and administrative expenses for the three months ended June 30, 2019, increased 102.9% to approximately \$1,871,000 compared to \$922,000 for the same period a year ago. The increase principally includes increases in noncash share-based compensation expenses of \$501,000 related to stock options granted in 2019 and options vested upon the April 2019 up-listing to the NASDAQ, the Securities and Exchange Commission (the "SEC") registration and up-listing expenses of \$176,000, accrued annual bonuses and incentives for employees of \$149,000 and business development and investor relations costs of \$86,000.

Interest income for the three months ended June 30, 2019, increased 20.9% to approximately \$266,000 compared to \$220,000 for the same period a year ago. The increase in interest income reflects higher yield on Dyadic's investments in held-to-maturity, investment grade securities.

Net loss for the three months ended June 30, 2019, was approximately \$2.7 million, or \$(0.10) per diluted share, compared to a net loss of \$1.6 million, or \$(0.06) per diluted share, for the same period a year ago.

For The Six Months Ended June 30, 2019

Research and development revenue for the six months ended June 30, 2019, increased to approximately \$793,000 compared to \$346,000 for the same period a year ago revenue. Cost of research and development revenue for the six months ended June 30, 2019, increased to approximately \$650,000 compared to \$276,000 for the same period a year ago. The increase in revenue and cost of research and development revenue for the six months ended June 30, 2019 reflect seven on-going research collaborations compared to three collaborations for the same period a year ago.

Research and development expenses for the six months ended June 30, 2019 increased to approximately \$1,511,000 compared to \$1,178,000 for the same period a year ago. The increase primarily reflects the costs of additional internal research activities with third-party contract research organizations.

Research and development expenses - related party, for the six months ended June 30, 2019, was approximately \$726,000 compared to \$733,000 for the same period a year ago. These expenses reflect the research and development costs related to the R&D Agreements with BDI, which started in July 2017.

General and administrative expenses for the six months ended June 30, 2019, increased 48.9% to approximately \$3,299,000 compared to \$2,215,000 for the same period a year ago. The increase principally includes increases in noncash share-based compensation expenses of \$574,000 related to stock options granted in 2019 and options vested upon the April 2019 up-listing to the NASDAQ, SEC registration and

up-listing expenses of \$273,000, accrued annual bonuses and incentives for employees of \$264,000 and business development and investor relations costs of \$131,000, offset by reductions in compensation costs associated with Dyadic's former CFO of \$183,000.

Interest income for the six months ended June 30, 2019, increased 31.3% to approximately \$533,000 compared to \$406,000 for the same period a year ago. The increase reflects higher yield on Dyadic's investments in held-to-maturity, investment grade securities.

Net loss for the six months ended June 30, 2019 was approximately \$4.9 million, or \$(0.18) per diluted share, compared to a net loss of \$3.6 million, or \$(0.13) per diluted share, for the same period a year ago.

BALANCE SHEET

At June 30, 2019, cash and cash equivalents were approximately \$4.8 million compared to \$2.4 million at December 31, 2018. The carrying value of investment grade securities, including accrued interest at June 30, 2019 was \$34.0 million compared to \$39.1 million at December 31, 2018.

CONFERENCE CALL INFORMATION

Date: Tuesday, August 13, 2019

Time: 5:00 p.m. Eastern Time

Dial-in numbers: 844-369-8770 (U.S. or Canada) or + 862-298-0840 (International) No pass code is needed

Webcast Link: <https://www.investornetwork.com/event/presentation/50926>.

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 Dyadic'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 August 20, 2019. To access the teleconference replay, please dial 877-481-4010 or 919-882-2331 #50926.

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 *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. Recently, Dyadic has also begun exploring 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 create synergy by leveraging Dyadic's 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 as a result improve access and cost to patients and the healthcare system, and 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 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'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 Dyadic's most recent filings with the SEC. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. 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 at www.dyadic.com.

Contact:

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DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2019	December 31, 2018
	(Unaudited)	(Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,781,520	\$ 2,386,314
Short-term investment securities	32,104,149	38,816,441
Interest receivable	399,242	294,240
Accounts receivable	504,510	318,744
Income tax receivable	—	506,866
Prepaid research and development	98,924	253,446
Prepaid expenses and other current assets	112,136	172,001
Total current assets	38,000,481	42,748,052
Non-current assets:		
Long-term investment securities	1,516,670	—
Long-term income tax receivable	500,616	500,616
Other assets	51,575	52,139
Total assets	\$ 40,069,342	\$ 43,300,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 963,264	\$ 309,060
Accrued expenses	396,041	399,576
Deferred research and development obligations	90,572	141,002
Total current liabilities	1,449,877	849,638
Commitments and contingencies (See 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 - 39,364,659 and 38,966,988, outstanding shares - 27,111,157 and 26,713,486 as of June 30, 2019 and December 31, 2018	39,365	38,967
Additional paid-in capital	95,424,178	94,385,230
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(37,914,163)	(33,043,113)
Total stockholders' equity	38,619,465	42,451,169
Total liabilities and stockholders' equity	\$ 40,069,342	\$ 43,300,807

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Research and development revenue	\$ 390,874	\$ 161,286	\$ 793,401	\$ 345,616
Costs and expenses:				
Costs of research and development revenue	322,228	129,116	650,131	275,925
Research and development	818,240	601,199	1,510,610	1,178,083
Research and development - related party	336,310	340,849	725,783	733,398
General and administrative	1,870,678	921,542	3,298,745	2,214,539
Foreign currency exchange loss (gain), net	4,932	(15,198)	10,966	(10,358)
Total costs and expenses	3,352,388	1,977,508	6,196,235	4,391,587
Loss from operations	(2,961,514)	(1,816,222)	(5,402,834)	(4,045,971)
Interest income	265,722	219,585	532,684	406,042
Loss before income taxes	(2,695,792)	(1,596,637)	(4,870,150)	(3,639,929)
Provision for income taxes	—	—	900	—
Net loss	\$ (2,695,792)	\$ (1,596,637)	\$ (4,871,050)	\$ (3,639,929)
Basic and diluted net loss per common share	\$ (0.10)	\$ (0.06)	\$ (0.18)	\$ (0.13)
Basic and diluted weighted-average common shares outstanding	26,828,754	28,060,811	26,771,439	28,109,756