

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): March 30, 2020

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 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



DYADIC REPORTS 2019 YEAR END RESULTS AND RECENT DEVELOPMENTS

- ***New research license agreement with WuXi Biologics, a leading global CDMO***
- ***Two new fully funded collaborations and one expanded collaboration signed in 2020, including the third fully funded collaboration with a top tier animal health company***
- ***Six funded research collaborations and one expanded collaboration signed in 2019***
- ***Expanded strategic R&D relationships to assist in the development of COVID-19 vaccine and antibodies***
- ***Expanded internal product and platform pipeline***
- ***Robust scientific data demonstrates C1's strong capabilities, new attributes, and broader market opportunities***
- ***Cash and investment grade securities of \$36 million at year-end 2019***

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 and applying its proprietary C1 gene expression platform to speed up the development, lower production costs and improve the performance of biologic vaccines and drugs at flexible commercial scales, today announced its financial results for the year ended December 31, 2019, and recent developments.

"I am pleased to report that 2019 was another successful year for Dyadic as we achieved several important scientific and business milestones and expanded our global presence. While still early in 2020, we are seeing continued momentum. During 2019, we entered into six new proof of concept research collaborations to express different types of biologic vaccines and drugs for both human and animal health and entered into two research licenses. As a result, Dyadic's pipeline of opportunities is getting larger and more diverse. Last week, we entered into a nonexclusive research license with WuXi Biologics, a leading global Contract Development Manufacturing Organization ("CDMO") and another fully funded feasibility study with a leading animal health company. We are now working with three of the top four animal health companies," said Mark Emalfarb, Dyadic's Chief Executive Officer.

He further commented, "To assist in the global fight against the COVID-19 pandemic, we are working with the Israel Institute for Biological Research ("IIBR"), Ufovax, a spin-off vaccine company of Scripps Research, as well as a group of coronavirus experts from Erasmus Medical Center, Utrecht University, and the University of Veterinary Medicine Hannover (TiHo) along with a clinical contract research organization, CR20. We expect to use C1 to express a growing number of potential coronavirus vaccine and antibody candidates for a number of different parties. Our involvement in these COVID-19 initiatives further highlights the broad application potential of our C1 technology by helping to immediately address the coronavirus outbreak, be better prepared for future infectious diseases, pandemic and epidemic outbreaks, and advance biopharmaceutical manufacturing to help speed up development, lower the cost and improve the performance of biologic vaccines and drugs to make healthcare more accessible and affordable to patients globally."

"Supporting our growth strategy is our robust scientific data, solid financial position with approximately \$36 million in cash and investment grade securities, and on-going R&D collaborations funded by our partners. Our visibility in the investment community has significantly increased as well. In 2019, our shares were up-listed to the Nasdaq and we joined the Russell Microcap Index® further reinforcing the continued growth of our Company. We look forward to sharing additional new developments throughout the year as we remain confident in our vision of creating more efficient and commercially cost-effective healthcare solutions," concluded Mr. Emalfarb.

RECENT DEVELOPMENTS

- Dyadic entered into a funded collaboration with another top four animal health company to engage in a feasibility study regarding the production of two proteins using our C1 platform. Three of the top four animal health companies are currently funding research programs to evaluate C1.
- Dyadic entered into a nonexclusive research license with WuXi Biologics, one of the leading global Contract Development Manufacturing Organizations.

- The Israel Institute for Biological Research has expanded its collaboration with the Company to explore the potential of C1 to express gene sequences and targets developed by IIBR into both an rVaccine candidate and monoclonal antibodies ("mAbs") that may potentially help combat the COVID-19 outbreak.
- Data presented at the 15th European Conference on Fungal Genetics ("ECFG15") demonstrated that Dyadic's C1 strain has been glyco-engineered to achieve a core human-like G2 glycan level over 76%. Data also showed excellent progress we made in reducing the extracellular protease background by 50 times in C1. The elimination of protease activity makes the C1 cell line more efficient and stable, leading to even higher expression levels and lower cost.
- Dyadic entered into a new feasibility study with the University of Oslo on influenza vaccine.
- In response to COVID-19, the Company submitted proposals to various funding agencies and parties to develop SARS-CoV-2 vaccine candidates up to and through a Phase 1 trial.

SCIENTIFIC ACHIEVEMENTS

- Demonstrated further success of C1 with fermentation results of the ZAPI antigen against the Schmallenberg virus ("SBV") with a yield of 1,780 mg/l (time point 121h) or 17 times the initially targeted expression level or more than 35 times baculovirus, the next closest expression platform. In December, Dyadic received positive preliminary results for the ZAPI animal studies and expanded the funded research collaboration to express two additional proteins. Recent results shared with us from the ZAPI consortium indicated that Dyadic's C1 antigen demonstrated very strong performance in protecting both cattle and mice from the SBV. A publication reporting these results is expected to be available in the second quarter of 2020.
- Dyadic extended its research and development contract through June 2022 with VTT Technical Research Centre of Finland Ltd ("VTT"). Data generated through the collaborative scientific research efforts has exceeded our initial expectations and produced record levels of productivity for several different types of proteins. This was demonstrated by the very high expression level reached of a full-length monoclonal antibody of approximately 24.5 grams per liter in seven days or approximately 3.5 grams per liter per day, well above the current industry average.
- Data presented at the PEGS Lisbon conference demonstrated that our C1 strain has been glyco-engineered to achieve a core human-like G0 glycan level of about 95%.
- In our collaboration with The Israel Institute for Biological Research, it used C1 technology to express a proprietary IIBR Fc-fusion enzyme. The recombinant IIBR Fc-fusion enzyme provided longer lasting protection against nerve agents such as sarin and VX gas than Acetyl Choline Esterase which is commonly used.
- With regard to the Company's Sanofi collaboration, Dyadic 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.

2019 BUSINESS DEVELOPMENT HIGHLIGHTS

In 2019, we entered into six (6) new proof of concept research collaborations including the Serum Institute of India, two leading animal health companies, and three top tier human health companies, as well as an expanded collaboration with ZAPI. In addition, we signed two (2) sublicensing agreements and two (2) non-exclusive research license agreements.

- Dyadic announced a research and commercialization collaboration with the Serum Institute of India. Serum will apply 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. To date, more than half of the twelve gene sequences from the Serum Institute of India PVT., Ltd have been transferred to Dyadic.
 - Dyadic entered into two animal health collaborations with two of the top four animal health companies to demonstrate the C1 technology for expression and production of therapeutic proteins for companion and farm animal diseases. One of the animal collaborations has been expanded to express additional proteins.
 - Dyadic entered into a sub-licensing agreement with Luina Bio Pty Ltd. an Australian-based drug development and contract manufacturing organization with more than 20 years of contract manufacturing experience, to develop and commercialize a number of targeted products for use in the prevention and treatment of various ailments for companion animals. Dyadic will receive 20% equity stake in a new joint venture company, Novovet
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Pty Ltd ("Novovet"), plus royalties on future sales. To date, Novovet has not raised the capital required to move this opportunity forward, and therefore, the Company has not transferred its C1 technology to Novovet.

- Dyadic entered into a sub-licensing agreement with Alphazyme LLC ("Alphazyme"), a biotech company focused on producing molecular biology enzymes addressing markets for custom DNA and RNA molecules, genomic medicines and genetic testing. 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. However, efforts to complete the last step of their internal qualification of C1 has been delayed partly due to the travel restriction under the COVID-19 pandemic.
- Dyadic entered into two nonexclusive research licensing agreements with the University of Iowa and another one with an affiliate of a top 25 pharmaceutical company that supplies tools for life science research. The nonexclusive license allows for our collaborators to perform certain experiments and manipulations to C1 cell lines to create potential licensed products, and for any other internal noncommercial purpose determined by our collaborators to be necessary to evaluate the C1 technology. The collaborators will invest their own resources to evaluate C1 technology for research and their customers globally.

CORPORATE DEVELOPMENT

- On April 17, Dyadic uplisted to the NASDAQ Capital Market and on July 1, Dyadic was added to the Russell Microcap® Index.

RESULTS FOR THE YEAR ENDED DECEMBER 31, 2019

At December 31, 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 December 31, 2019 was \$31.2 million compared to \$39.1 million at December 31, 2018.

Research and development revenue for the year ended December 31, 2019, increased to approximately \$1,681,000 compared to \$1,295,000 for the year ended December 31, 2018.

Cost of research and development revenue for the year ended December 31, 2019, increased to approximately \$1,460,000 compared to \$1,027,000 for the year ended December 31, 2018.

The increases in revenue and cost of research and development revenue for the year ended December 31, 2019 reflects ten research collaborations compared to six research collaborations for the year ended December 31, 2018.

Interest income for the year ended December 31, 2019, increased 10.1% to approximately \$985,000 compared to \$895,000 for the year ended December 31, 2018. The increase in interest income reflects the higher yield on the Company's investment grade securities, which are classified as held-to-maturity.

Research and development expenses for the year ended December 31, 2019 increased to approximately \$3,088,000 compared to \$2,102,000 for the year ended December 31, 2018. The increase primarily reflects the costs of additional internal research projects.

Research and development expenses - related party, for the year ended December 31, 2019, decreased to approximately \$869,000 compared to \$1,216,000 for the year ended December 31, 2018. The decrease is primarily due to the completion of the research service agreement with BDI in June 2019.

General and administrative expenses for the year ended December 31, 2019, increased 22.0% to approximately \$5,520,000 compared to \$4,523,000 for the year ended December 31, 2018. The increase principally reflects increases in noncash share-based compensation expenses of \$717,000 related to 2019 stock options awards and options vested upon the April 2019 uplisting to the NASDAQ, business development and investor relations costs of \$186,000, and insurance costs of \$138,000, legal cost and NASDAQ uplisting expenses of \$125,000, offset by reductions in executive compensation costs, including the separation of the Company's former CFO, of \$168,000, which was a one-time expense in 2018.

Net loss for the year ended December 31, 2019 was approximately \$8.3 million, or \$(0.31) per share, compared to a net loss of \$5.7 million, or \$(0.21) per share, for the year ended December 31, 2018. The change was primarily due to the increases in general and administrative expenses of approximately \$1.0 million and research and

development expense of approximately \$0.6 million in 2019, as well as the income tax benefit of approximately \$1.0 million in 2018.

CONFERENCE CALL INFORMATION

Dyadic management will host a conference call today, Monday, March 30, 2020, at 5:00 PM ET to discuss the financial results for the year ended December 31, 2019. 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/2031/33572>.

An archive of the webcast will be available approximately three 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 this link: <https://www.webcaster4.com/Webcast/Page/2031/33572>. A dial-in replay of the call will also be available to those interested until April 30, 2020. To access the replay, dial (877) 481-4010 for U.S./Canada callers and +(919) 882-2331 for International callers and enter replay pass code: 33572.

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company 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

	Years Ended December 31,	
	2019	2018
Revenues:		
Research and development revenue	\$ 1,681,076	\$ 1,295,451
Costs and expenses:		
Costs of research and development revenue	1,459,701	1,027,278
Provision for contract losses	—	—
Research and development	3,087,597	2,101,628
Research and development - related party	868,720	1,215,536
General and administrative	5,519,922	4,522,676
Foreign currency exchange loss (gain), net	27,725	20,778
Total costs and expenses	10,963,665	8,887,896
Loss from operations	(9,282,589)	(7,592,445)
Interest income	984,930	894,532
Loss before income taxes	(8,297,659)	(6,697,913)
Provision for (benefit from) income taxes	10,306	(1,006,157)
Net loss	\$ (8,307,965)	\$ (5,691,756)
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.21)
Basic and diluted weighted-average common shares outstanding	27,003,695	27,673,300

See Notes to Condensed Consolidated Financial Statements in Part I of Dyadic's Annual Report on Form 10-K filed with Securities and Exchange Commission on March 30, 2020.

DYADIC INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,823,544	\$ 2,386,314
Short-term investment securities	29,399,146	38,816,441
Interest receivable	329,711	294,240
Accounts receivable	558,530	318,744
Income tax receivable	250,308	506,866
Prepaid research and development	—	253,446
Prepaid expenses and other current assets	277,999	172,001
Total current assets	35,639,238	42,748,052
Non-current assets:		
Long-term investment securities	1,511,636	—
Long-term income tax receivables	250,308	500,616
Other assets	51,314	52,139
Total assets	\$ 37,452,496	\$ 43,300,807
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 943,378	\$ 309,060
Accrued expenses	566,003	399,576
Deferred research and development obligations	78,644	141,002
Total current liabilities	1,588,025	849,638
Commitments and contingencies		
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 - 39,612,659 and 38,996,988, outstanding shares - 27,359,157 and 26,713,486 as of December 31, 2019 and 2018, respectively	39,613	38,967
Additional paid-in capital	96,105,851	94,385,230
Treasury stock, shares held at cost - 12,253,502	(18,929,915)	(18,929,915)
Accumulated deficit	(41,351,078)	(33,043,113)
Total stockholders' equity	35,864,471	42,451,169
Total liabilities and stockholders' equity	\$ 37,452,496	\$ 43,300,807

See Notes to Condensed Consolidated Financial Statements in Part I of Dyadic's Annual Report on Form 10-K filed with Securities and Exchange Commission on March 30, 2020.