

**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): **July 30, 2020**



India Globalization Capital, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Commission File Number: **001-32830**

Maryland

(State or other jurisdiction of incorporation)

20-2760393

(I.R.S Employer Identification Number)

10224 Falls Road, Potomac, Maryland 20854

(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(301) 983-0998**

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))

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, \$.01 par value	IGC	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1934 (§240.12b-2 of this chapter)

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.

CURRENT REPORT ON FORM 8-K
India Globalization Capital, Inc.
August 11, 2020

Item 8.01. Other Events.

India Globalization Capital, Inc. (“IGC” or the “Company”) (NYSE: IGC) announced today two recent events related to its Life Sciences business line.

On July 30, 2020, the U.S. Food and Drug Administration (FDA) notified IGC that it has authorized the Company to initiate a Phase 1 human trial study for the Company’s investigational cannabinoid formulation for the treatment of patients suffering from mild to severe dementia due to Alzheimer’s disease. After completion of administrative tasks, the Company plans to begin enrolling patients suffering from Alzheimer’s-related dementia for an safety Multiple Ascending Dose (MAD) Study. Conducting a trial is no guarantee that the formulation will prove to have the desired efficacy or that a new drug will be approved.

On August 5, 2020, the United States Patent and Trademark Office (“USPTO”) issued the Company a patent (#10751300) for the Company’s cannabinoid formulation (IGC-502) for the treatment of seizures in humans and veterinary animals. The Company had previously reported on July 8, 2020 that it had received a Notice of Allowance for IGC-502.

Cautionary Statement Pursuant to Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995:

“Safe Harbor” statement under the Private Securities Litigation Reform Act of 1995: This report contains forward-looking statements identified by the use of words such as should, believes, plans, goals, expects, may, will, or the negatives thereof, and other variations thereon or comparable terminology. Such statements are based on currently available information, which management has assessed but which is dynamic and subject to rapid change due to risks and uncertainties that affect our business. **Our success is highly correlated with the success of our product candidates. We may not be able to protect our intellectual property adequately or receive patents. We may not receive regulatory approval for our products, or trials. An additional risk factor worth highlighting specifically related to this patent licensing is that the patent application we have licensed may not be granted by the USPTO, even if the Company is in full compliance with USPTO requirements. We may not have adequate resources including financial resources to successfully conduct the requisite trials, to bring a product based on the above-referenced patented formulation to market, or to pay applicable maintenance fees over time. We may not be able to successfully commercialize our products even if they are successful and receive regulatory approval. Our projections anticipate stable pricing, which may not hold out over the next several years. Failure or delay with respect to any of the factors above could have a material adverse effect on our business, future results of operations, our stock price, and our financial condition.** Precautions including social distancing, travel restrictions, among others, surrounding the Covid-19 pandemic could lead to delays and a more expensive trial. These and other risks are detailed from time to time in our filings with the U.S. Securities and Exchange Commission. Any statements that express or involve discussions with respect to predictions, expectations, beliefs, plans, projections, objectives, goals, assumptions or future events or performance are not statements of historical fact and may be forward-looking statements. Forward-looking statements involve a number of risks and uncertainties which could cause actual results or events to differ materially from those presently anticipated. The Risk Factors identified in the Company’s annual report, filed on Form 10-K with the SEC on July 13, 2020, and in the Company’s quarterly reports, filed on Form 10-Q with the SEC on November 5, 2019 and February 10, 2020, are incorporated herein by reference. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this disclosure will in fact occur.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 11, 2020

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 thereunto duly authorized.

INDIA GLOBALIZATION CAPITAL, INC.

Date: August 11, 2020

By: /s/ Claudia Grimaldi
Claudia Grimaldi
Vice President and PFO

FDA Approves Initiation of IGC's Cannabinoid Trial on Alzheimer's Patients**IGC Announces FDA Removal of Clinical Hold for Multiple Ascending Dose Study of IGC-AD1, Targeting Patients Suffering from Alzheimer's-related Dementia**

Potomac, Maryland, August 11, 2020/ BusinessWire / India Globalization Capital ("IGC" or the "Company") (NYSE AMERICAN: IGC) announced today that on July 30, 2020, the U.S. Food and Drug Administration (FDA) notified IGC that it has authorized the Company to initiate a Phase 1 human trial study for the Company's investigational cannabinoid formulation for the treatment of patients suffering from mild to severe dementia due to Alzheimer's disease. After the completion of administrative tasks, the Company plans to begin enrolling patients suffering from Alzheimer's-related dementia for a 12-subject safety Multiple Ascending Dose (MAD) Study. The Company believes that the FDA's approval of the initiation of the Phase 1 trial is a significant next step in IGC's efforts to develop a potential therapy for treating patients suffering from a devastating disease.

As previously announced, in 2017, the Company acquired exclusive rights to a patent filing by the University of South Florida (USF) entitled "THC as a Potential Therapeutic Agent for Alzheimer's Disease," that uses ultra-low doses of cannabinoids combined with other compounds to create a formulation that is intended to assist in the treatment of Alzheimer's disease. The Company subsequently refiled the patent and filed an additional patent on the formulation that it intended to use as a treatment for Alzheimer's.

In 2018, the Company announced data indicating potential improvement in memory of transgenic mice suffering from Alzheimer's. Later in 2018, the Company also announced data indicating the formulation's potential efficacy on reducing plaques and tangles in Alzheimer's cell lines. Plaques and tangles are hallmarks of Alzheimer's.

In late 2018, the Company held a pre-Investigational New Drug Application (INDA) submission meeting with the FDA. In 2019, the Company received permission from the Institutional Review Board (IRB) of Puerto Rico to conduct a trial. And, later in 2019, the Company filed an INDA for a 100-person double blind placebo-controlled trial on patients suffering from Alzheimer's disease.

According to the Alzheimer's institute about 5.5 million individuals suffer from Alzheimer's in the United States and about 44 million suffer from the disease worldwide. Currently, there is no cure for Alzheimer's disease.

"Our strategy with IGC-AD1 is to initially conduct trials that establish the efficacy of IGC-AD1 on the Behavioral and Psychological Symptoms of Dementia (BPSD). Patients with moderate Alzheimer's suffer from BPSD that includes among other symptoms delusions, agitation, aggression, depression, anxiety, apathy, and sleep disorder. Eventually, we expect to evaluate the efficacy of IGC-AD1 on plaques and tangles, the hallmarks of Alzheimer's disease. We are excited with the progress made and that the FDA will allow the Company to initiate trial testing on human subjects using natural organic cannabis extracts. We believe that this a first human trial of this sort," said Ram Mukunda, CEO of IGC.

Forward-looking Statements:

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based largely on IGC's expectations and are subject to a number of risks and uncertainties, certain of which are beyond IGC's control. Actual results could differ materially from these forward-looking statements as a result of, among other factors, worsening of the COVID-19 outbreak in China, the U.S., and other parts of the world, the prolonged continuation of travel restrictions related to the outbreak, continued disruption of the Hong Kong economy, competitive conditions in the industries in which IGC operates, failure to meet operational goals and/or revenue and profit targets for products in various stages of production and commercialization, failure to commercialize one or more of the products or technologies of IGC, including any products or patented formulations identified herein, or the failure or inability to pay patent maintenance fees, unexpected trial results or trial results that do not support the efficacy of our formulation, potential rejection of any patent application even when the Company is in compliance with USPTO requirements, any changes in federal, state, or local law applicable to our businesses and the locations where we operate, general economic, political, and health and welfare conditions that are less favorable than expected, the FDA's general position regarding hemp-based and related products in particular, the FDA's decision to deny approval of further trials, or investigative new drug application, and other factors, many of which are discussed in our SEC filings. Precautions including social distancing, travel restrictions, among others, surrounding the Covid-19 pandemic could lead to delays and a more expensive trial. The Risk Factors identified in the Company's annual report, filed on Form 10-K with the SEC on July 13, 2020, and in the Company's quarterly reports, filed on Form 10-Q with the SEC on November 5, 2019 and February 10, 2020, are incorporated herein by reference. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will in fact occur.

About IGC:

IGC has two lines of business: infrastructure and life sciences, including hemp-derived medical cannabis/industrial hemp. The company is based in Maryland, U.S.A. Our website: www.igcpharma.com, www.igcinc.us. Twitter @IGCIR

Contact:

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