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): **December 1, 2021**

INDIA GLOBALIZATION CAPITAL, INC.
(Exact name of registrant as specified in charter)

Maryland	**001-32830**	**20-2760393**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

4336 Montgomery Ave., Bethesda, Maryland 20814
(Address of principal executive offices) (Zip Code)

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

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 (see General Instruction A.2. below):

☐ 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, $.0001 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. ☐

Item 7.01 Regulation FD Disclosure.

On December 2, 2021, India Globalization Capital, Inc. ("IGC," "our" or the "Company") issued a press to announce preliminary positive secondary end point findings from its Phase 1 clinical trial testing the safety and tolerability of IGC-AD1, IGC's investigational new drug candidate designed to treat certain symptoms of Alzheimer's disease. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibits 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission (the "SEC") made by IGC, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On December 2, 2021, the Company issued a press release presenting preliminary positive secondary end point findings from its Phase 1 clinical trial testing the safety and tolerability of IGC-AD1, the Company's proprietary THC-based investigational new drug candidate designed to treat symptoms of Alzheimer's disease.

Background:

To the best of our knowledge, this is the first human clinical trial using low doses of Tetrahydrocannabinol ("THC"), in combination with another molecule, to treat symptoms of dementia in Alzheimer's patients. THC is a naturally occurring cannabinoid produced by the cannabis plant. It is known for being a psychoactive substance that can impact mental processes in a positive or negative way depending on dosage. THC is biphasic, meaning that low and high doses of the substance may affect mental and physiological processes in substantially different ways. For example, in some patients, low doses may relieve a symptom, whereas high doses may amplify a symptom. Ultimately, the goal of IGC's research is to discover and analyze whether, and at what level of dosing, IGC-AD1 provides relief, as opposed to amplification of a given symptom. IGC's trial is based on low dosing and controlled trials on patients suffering from Alzheimer's disease.

A blinded, single-site, randomized, three cohort, multiple-ascending dose (MAD) clinical trial (FDA IND Number: 146069, NCT04749563) was conducted using the investigational new drug (IND) IGC-AD1. IGC received approval to proceed with the Phase 1 clinical trial from the U.S. Food and Drug Administration (FDA) on July 30, 2020. The primary objective was safety and tolerability in elderly patients suffering from Alzheimer's disease. The secondary objective was measuring changes in neuropsychiatric symptoms (NPS) using the neuropsychiatric inventory (NPI) as well as to assess the risk of suicide using the Columbia-Suicide Severity Rating Scale (C-SSRS). The exploratory objective was to measure the pharmacokinetics (PK) and the impact of polymorphisms of the gene CYP2C9 on PK. In all three cohorts, ten participants received IGC-AD1 and two received a placebo. There were at least four days of washout between the cohorts. In Cohort one, Cohort two, and Cohort three the doses were q.d. (once per day), b.i.d. (twice per day), and t.i.d. (three times per day), respectively.

On December 1, 2021, IGC submitted the Clinical/Statistical Report (CSR) to the FDA on its Phase 1 trial entitled "A Phase I Randomized Placebo-Controlled MAD Study to Evaluate Safety and Tolerability of IGC-AD1 In Subjects with Dementia Due to Alzheimer's Disease." Data that is relevant to the Phase 1 protocol and the design of Phase 2 or Phase 3 trials is presented here. The data presented here is not exhaustive.

- At the start of the trial, the participants receiving the active drug (N=11) had an average age and weight of 81.5 years (SD 5.5) and 138.8 lb (SD 24.7) respectively. The placebo participants (N=2) had an average age and weight of 75 years (SD 4.2) and 196.4 lb (SD 17.0) respectively. All participants (N-13) were Puerto Rican with 69.2% being female.

Primary Endpoint: Safety & Tolerability (S&T):

S&T was assessed by recording both solicited and non-solicited Adverse Events (AEs). The solicited AEs, assessed daily, were somnolence, falls, dizziness, asthenia, suicidal ideation, hypertension, psychiatric symptoms, and paradoxical nausea. All AEs were graded as mild, moderate, severe, life threatening, and serious (SAE).

- In all three Cohorts, a) there were no SAEs, b) no life-threatening AEs, and c) no deaths.
- One AE, mild dizziness, reported in Cohort 1, was deemed to be related to IGC-AD1. All other AEs across all cohorts were deemed to be not related to IGC-AD1 or to the placebo.
- In Cohort 1, in the group that received IGC-AD1 (N=10), 50% reported hypertension, 40% reported asthenia, 30% reported somnolence and dizziness, 20% reported psychiatric symptoms and 10% reported falls. One case of dizziness was deemed by the principal investigator (PI) to be related to IGC-AD1. In the placebo group (N=2) 100% reported hypertension, and 50% reported somnolence and falls.

- In Cohort 2 for the IGC-AD1 group, 60% reported psychiatric symptoms, 50% reported somnolence and asthenia, 30% reported hypertension, 20% reported nausea and dizziness, and 10% reported falls and suicidal ideation. In the placebo group 100% reported somnolence, 50% reported dizziness and hypertension.
- In Cohort 3 for the IGC-AD1 group, 70% reported somnolence, 60% reported psychiatric symptoms, 50% reported dizziness and asthenia, and 30% reported hypertension. In the placebo group 100% reported somnolence, and 50% reported hypertension and psychiatric symptoms.

Secondary Endpoints: Neuropsychiatric Inventory (NPI):

Neuropsychiatric Symptoms (NPS) such as delusions, hallucinations, agitation/aggression, depression, anxiety, elation/euphoria, apathy, disinhibition, irritability, aberrant motor behavior, sleep disorders, and appetite/eating disorders are prevalent in patients who have Alzheimer's disease (Phan et al., 2019). NPS in Alzheimer's is a significant burden on patients and caregivers, and at some point, in the progression of Alzheimer's disease, more than 97% of patients suffer from at least one symptom. The Neuropsychiatric Inventory (NPI) (Cummings et al., 1994) measures the severity of each symptom and establishes both individual symptom scores as well as an overall NPI score. Separately, the NPI also scores caregiver distress (NPI-D). The NPI is used by about 50% of neurologists to assess and treat Alzheimer's patients (Fernandez et al., 2010).

According to the NPI Test, a reduction of 4 points or 30% in the score is considered clinically meaningful. In addition, we also used a paired 2-tailed t-test with 9 degrees of freedom to assess the statistical significance of the decrease both in the overall NPI and individual NPI domains.

- In Cohort 1 for those on IGC-AD1, the mean NPI decreased from a baseline 31.5 (SD 27.2) to 16.7 (SD 16.2) on day 10 (p = 0.0044) and 14.8 (SD 16.0) on day 15 (p = 0.0095).
  - Individual domains that showed improvement were Agitation (p = .05), Dilutions (p = .05), Anxiety (p = .09), and Appetite and Eating Disorders (p = .01).

- In Cohort 2 for those on IGC-AD1, the mean NPI decreased from a baseline of 22.2 (SD 14.8) to 10.4 (SD 11.5) on day 10 (p = 0.0026) and 12.4 (SD14.7) on day 15 (p = 0.0127).
  - Individual domains that showed improvement were Agitation (p = .06), Irritability (p = .04), and Depression (p = .01).

- In Cohort 3 for those on IGC-AD1 the mean NPI decreased from a baseline of 16.0 (SD14.7) to 14.6 (SD10.9) on day 10 (p = 0.6751) and 7.9 (SD 9.0) on day 15 (p = 0.0113).
  - Individual domains that showed improvement was Agitation (p = .06).

- There was a non-clinically significant improvement between baseline and day 10 in Cohort 3 (NPI dropped less than 4 points and ($p >> .05$).
  - This may be related to the overall decrease of mean NPI between cohort baselines, Cohort 1 = 31.5, Cohort 2 = 22.2, Cohort 3 = 16.0 and that further improvement from a mean NPI = 16.0 takes longer, as measured on day 15 (mean NPI = 7.9).

Exploratory Endpoints, PK:

PK is used to describe the absorption, distribution, biotransformation/metabolism, and excretion of a compound. It is used to correlate dosing to blood concentrations with biological effects, (Turfus S. C. et al., 2017).

An exploratory endpoint of the trial was PK.

- The mean $T_{1/2}$ was 3.30 hours (range 0.7-12.87) and 3.30 hours (range 1.05-5.7) for THC and OH-THC respectively.
- The mean T_{max} was 2.15 hours (range 1.0-3.5) for $\Delta 9$-THC (THC), and 1.9 hours (range 1.0-4.0) for the active metabolite -11-OH-$\Delta 9$-THC (OH-THC).
- The mean AUC_{last} was 5.58 h*ng/ml (range 1.31-11.35) for THC and 17.03 h*ng/ml (range 5.16-65.9) for OH-THC

Exploratory Endpoints, PK and Genotyping (continued):

The CYP2C9 gene encodes cytochrome P450 2C9 enzyme that is the main enzyme that is known to metabolize and eliminate S-warfarin, tolbutamide, phenytoin, losartan, diclofenac, and celecoxib. It is a member of the cytochrome P450 superfamily and is highly polymorphic. Phenotypes are stratified into groups including poor (PM), intermediate (IM), normal (NM), and ultra-rapid (UM) metabolizing phenotypes (Gaedigk, et al., 2008; Caudle and Dunnenberger., 2017).

The two most common allelic variants, CYP2C9*2 and CYP2C9*3 have been shown to cause reductions in enzyme activity of 30% and 80% respectively (Crespi CL et al., 1997, Takanashi K et al., 2000). The carriers of CYP2C9*1 of the homozygous *1/*1 genotype are designated extensive or NM. Those carrying one of the heterozygous *1/*2 or *1/*3 alleles are designated IM. Those carrying the *2/*2, *2/*3, or *3/*3 alleles are designated as PM. In general, the metabolic ratio of unchanged drug to metabolite is higher in PM.

- Sixty-two percent of the study population (N=13) had a polymorphism of CYP2C9 characterized as Intermediate Metabolizer (IM) with the remaining were Normal Metabolizer (NM).
- For THC, the $T_{1/2}$ was 1.73 hours for the NM group and 5.09 hours for the IM group. For OH-THC the $T_{1/2}$ was 2.98 and 3.51 hours for the NM and IM groups, respectively.
- THC T_{max} was 2.38 and 2.00 hours for NM and IM, respectively. OH-THC T_{max} 1.75 and 2.00 hours for NM and IM, respectively.
- THC AUC_{last} was 6.72 h*ng/ml and 4.82 h*ng/ml for NM and IM, respectively. OH- THC AUC_{last} was 12.30 h*ng/ml and 20.18 h*ng/ml for NM and IM, respectively.
- AUC metabolite / Drug ratio was 1.8 and 4.2 for NM and IM, respectively.

IGC-AD1 is investigational and has not been approved as a new drug by any regulatory body in any country. Although the Phase 1 trial above has been completed, and certain data has been collected, the investigational new drug's safety and efficacy have not yet been established. As Phase 2 trials require FDA approval, it cannot yet be estimated if and when the FDA may approve a Phase 2 trial to commence.

Any forward-looking statements contained herein are based largely on IGC's expectations and are subject to several 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, the Company's failure or inability to commercialize one or more of the Company's products or technologies, including the investigational new drug or formulation described in this release, or failure to obtain FDA approval for the investigational new drug or additional clinical trials; testing results from human clinical trials that may not be favorable or as anticipated or consistent with the results obtained from Phase 1 trials; general economic conditions that are less favorable than expected, including as a result of the ongoing COVID-19 pandemic; the FDA's general position regarding cannabis- and hemp-based products; and other factors, many of which are discussed in IGC's SEC filings. IGC incorporates by reference the human trial disclosures and Risk Factors identified in its Annual Reports on Form 10-K filed with the SEC on June 14, 2021, and Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2021, and October 29, 2021, as if fully incorporated and restated herein. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will occur. All forward-looking statements contained in this filing and press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No.	**Description**
99.1	Press release issued by India Globalization Capital, Inc. on December 2, 2021.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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.

INDIA GLOBALIZATION CAPITAL, INC.

Dated: December 2, 2021

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

Exhibit 99.1

Phase 1 Clinical Trial Data Indicate IGC's THC-based Investigational New Drug May Reduce Symptoms of Dementia in Alzheimer's Patients

POTOMAC, MD, December 2, 2021, (NYSE American: IGC), India Globalization Capital, Inc. (IGC) is excited to present preliminary positive secondary end point findings from its Phase 1 clinical trial for IGC-AD1. The investigational new drug, IGC-AD1, is IGC's proprietary Tetrahydrocannabinol (THC)-based candidate designed to treat certain symptoms of Alzheimer's disease. The results of the clinical trial have been submitted in the Clinical/Statistical Report ("CSR") filed with the FDA, and relevant data is also available on Form 8-K filed with the SEC on December 2, 2021.

Alzheimer's disease impacts about 50 million people worldwide and about 5.5 million individuals in the U.S. Over 70% of these patients face one or more debilitating symptoms, including anxiety, depression, and agitation (Mendez, 2021). Agitation in dementia patients can include excessive physical movement and verbal activity, restlessness, pacing, belligerence, aggression, screaming, crying, and wandering. Currently, there is no FDA-approved medication to alleviate symptoms of dementia, such as agitation, due to Alzheimer's disease.

To the best of our knowledge, this is the first human clinical trial combining low doses of THC with another molecule to treat symptoms of dementia in Alzheimer's patients. THC is a naturally occurring cannabinoid produced by the cannabis plant. It is known for being a psychoactive substance that can impact mental processes in a positive or negative way depending on dosage. THC is biphasic, meaning that low and high doses of the substance may affect mental and physiological processes in substantially different ways. Our trial is based on low or microdosing, which is hypothesized to potentially have a promising effect on Alzheimer's patients.

As previously disclosed the recently closed trial was approved to proceed by the U.S. Food and Drug Administration (FDA) on July 30, 2020. The trial included three cohorts, with 12 patients in each cohort. Patients in Cohort-1, Cohort-2 and Cohort-3 received the medication once, twice, and thrice per day, respectively, for 14 days. To evaluate one of the secondary end points for the study, neuropsychiatric symptoms of patients, across all cohorts, were assessed on day zero of each cohort to establish a baseline, as well as on day 10, and day 15 of each cohort.

Based solely on the data collected over the course of the Phase 1 trial, we saw evidence of clinical improvements in anxiety, depression, and agitation. On the anxiety and depression scales, we documented a decrease of approximately 50% to 60% in patients who received the drug. For agitation, we documented a decrease of approximately 35% to 60% in patients who received the drug. The degree of the decrease varied by cohort. Based on the preliminary data obtained to date, IGC estimates that the most effective dosage of the drug may be once or twice per day, depending on the symptom. As previously disclosed, we have received an initial patent, and filed additional patents to protect our intellectual property.

As this was a Phase 1 trial, data collected related to neuropathic symptoms are preliminary in nature and are not a guarantee of future positive results. Nevertheless, IGC is encouraged by these initial promising and exciting results, as the potential to improve the quality of life of Alzheimer's patients and their caregivers could be significant if similar results are repeated in future trials with larger patient pools. We are in the process of using the results from this Phase 1 study to design and subsequently pursue, based on FDA approval, a placebo-controlled, multi-site trial with a significantly expanded patient population to further test the efficacy of IGC-AD1 on agitation, anxiety, and depression in Alzheimer's patients. The details of a clinical trial process in general are documented in IGC's annual report.

IGC-AD1 is an investigational new drug that has not been approved as a medication by any regulatory body in any country. Although the Phase 1 trial has been completed, and certain data has been collected, IGC-AD1's safety and efficacy need to be further established through trials on larger and more diverse groups of Alzheimer's patients.

About IGC:
India Globalization Capital, Inc. (IGC) engages in the development of cannabinoid-based therapies for healthcare applications. The company currently operates two lines of business: life sciences and infrastructure. The life sciences business recently completed the first safety and tolerability clinical trial to treat symptoms of Alzheimer's patients using a THC-based investigational new drug. In addition, we produce and sell over-the-counter hemp-based women's health products, including for post menstrual symptoms (PMS) and dysmenorrhea. The second line of business is an infrastructure business based in India. IGC headquartered in Potomac, MD.
www.igcinc.us, www.igcpharma.com.

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 several 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, the Company's failure or inability to commercialize one or more of the Company's products or technologies, including the investigational new drug or formulation described in this release, or failure to obtain FDA approval for the investigational new drug or additional clinical trials; testing results from human clinical trials that may not be favorable or as anticipated or consistent with the results obtained from Phase 1 trials; general economic conditions that are less favorable than expected, including as a result of the ongoing COVID-19 pandemic; the FDA's general position regarding cannabis- and hemp-based products; and other factors, many of which are discussed in IGC's SEC filings. IGC incorporates by reference the human trial disclosures and Risk Factors identified in its Annual Reports on Form 10-K filed with the SEC on June 14, 2021, and Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2021, and October 29, 2021 as if fully incorporated and restated herein. In light of these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will occur.

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