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 20, 2024**

IGC PHARMA, 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.)

10024 Falls Road, Potomac, Maryland 20859
(Address of principal executive offices) (Zip Code)

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

(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 (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 Wednesday, March 20, 2024, IGC Pharma Inc. ("IGC" or the "Company") issued a press release announcing positive interim results for IGC-AD1 in reducing Alzheimer's agitation. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under Item 7.01 and Item 9.01 of this Current Report on Form 8-K, including the exhibit, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, nor shall it be deemed incorporated by reference in any registration statement or other filings of the Company under the Securities Act of 1933, as amended, except as shall be set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 20, 2024, the Company issued a press release announcing the results of an interim analysis of its ongoing Phase 2 trial investigating IGC-AD1 as a treatment for Agitation in dementia from Alzheimer's Disease ("AAD").

The interim data demonstrates a clinical and statistically significant reduction in agitation compared to placebo in patients with Alzheimer's disease, indicating strong therapeutic potential for IGC-AD1.

The study's primary goal is to assess the change in AAD after six weeks using a standard scale, the Cohen Mansfield Agitation Inventory ("CMAI"). Based on interim data, patients taking IGC-AD1, on average, experienced a more significant reduction in agitation scores compared to those on placebo, and the positive effects were observed as early as week two of the trial.

At the primary outcome, assessing the change in agitation as measured by the CMAI at week 6, the Cohen's d effect size indicating the superiority of IGC-ADI over placebo was 0.66. The CMAI Least Square ("LS") mean difference between active, and placebo was -10.45, with a p-value of 0.037 (for combined week two and week six results). In addition, at the pre-specified secondary endpoint, change at week two, the effect size was 0.79. The Cohen's d is a standardized statistical effect size that describes the magnitude of the difference between two groups, taking into account the variability in outcomes.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	**Description**
99.1	Press Release dated March 20, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

About IGC Pharma Inc. (IGC):

IGC Pharma Inc. ("IGC") is focused on Alzheimer's disease, developing innovative solutions to address this devastating illness. The Company's mission is to transform the landscape of Alzheimer's treatment with a robust pipeline of five promising drug candidates. IGC-AD1 and LMP target the hallmarks of Alzheimer's disease, including neuroinflammation, Aβ plaques, and neurofibrillary tangles. IGC-AD1 is currently undergoing a Phase 2 clinical trial for agitation in dementia associated with Alzheimer's (clinicaltrials.gov, CT05543681). TGR-63 disrupts the progression of Alzheimer's by targeting Aβ plaques. IGC-M3, currently in preclinical development, aims to inhibit the aggregation of Aβ plaques, potentially impacting early-stage Alzheimer's. IGC-1C, also in preclinical stages, targets tau protein and neurofibrillary tangles, representing a forward-thinking approach to Alzheimer's therapy. In addition to its drug development pipeline, IGC Pharma seeks to leverage Artificial Intelligence ("AI") for Alzheimer's research. Their AI projects encompass various areas, including clinical trial optimization and early detection of Alzheimer's.

Forward-Looking Statements:

This 8-K contains forward-looking statements. These forward-looking statements are based largely on IGC Pharma's expectations and are subject to several risks and uncertainties, certain of which are beyond IGC Pharma'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 products or formulations described in this release, or failure to obtain regulatory approval for the products or formulations, where required, or government regulations affecting AI or the AI algorithms not working as intended or producing accurate predictions; general economic conditions that are less favorable than expected; the FDA's general position regarding cannabis- and hemp-based products; and other factors, many of which are discussed in IGC Pharma's U.S. Securities and Exchange Commission ("SEC") filings. IGC Pharma incorporates by reference the human trial disclosures and Risk Factors identified in its Annual Report on Form 10-K filed with the SEC on July 7, 2023, and Quarterly Report on Form 10-Q filed with the SEC on February 14, 2024, as if fully incorporated and restated herein. Considering these risks and uncertainties, there can be no assurance that the forward-looking information contained in this release will occur.

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.

IGC Pharma, Inc.

Dated: March 21, 2024

By: /s/ Ram Mukunda
Name: Ram Mukunda
Title: CEO

Exhibit 99.1

IGC Pharma Announces Positive Interim Results for IGC-AD1 in Reducing Alzheimer's Agitation

- Interim Data: Study Achieves Primary End Point Demonstrating Clinical and Statistically Significant Reductions Compared to Placebo in Agitation Associated with Dementia Due to Alzheimer's Disease -

Potomac, MD, March 20, 2024 – IGC Pharma, Inc. ("IGC Pharma", "IGC", or the "Company") (NYSE American: IGC) today announced the results of an interim analysis of its ongoing Phase 2 trial investigating IGC-AD1 as a treatment for Agitation in dementia from Alzheimer's Disease ("AAD"). The interim data demonstrates a clinical and statistically significant reduction in agitation compared to placebo in patients with Alzheimer's disease, indicating strong therapeutic potential for IGC-AD1.

The study's primary goal is to assess the change in AAD after six weeks using a standard scale, the Cohen Mansfield Agitation Inventory ("CMAI"). Based on interim data, patients taking IGC-AD1, on average, experienced a more significant reduction in agitation scores compared to those on placebo, and the positive effects were observed as early as week two of the trial.

At the primary outcome, assessing the change in agitation as measured by the CMAI at week 6, the Cohen's d effect size indicating the superiority of IGC-ADI over placebo was 0.66. The CMAI Least Square ("LS") mean difference between active, and placebo was -10.45, with a p-value of 0.037 (for combined week two and week six results). In addition, at the pre-specified secondary endpoint, change at week two, the effect size was 0.79. The Cohen's d is a standardized statistical effect size that describes the magnitude of the difference between two groups, taking into account the variability in outcomes.

Pre-Specified Interim Results:

The IGC-AD1 Phase 2 is an ongoing multi-site, randomized, double-blind, placebo-controlled clinical trial that continues to enroll. IGC-AD1 is an oral liquid formulation administered twice daily for six weeks with no placebo run-in and titration to full dose over two days. Agitation is rated at the trial site, at baseline, week 2, and week 6, by a trained practitioner using the CMAI, a scale designed to measure AAD.

"We are excited with the positive interim results from the Phase 2 trial of IGC-AD1 for agitation in dementia due to Alzheimer's disease. IGC-AD1's interim results demonstrate a clinical and statistically significant reduction in agitation compared to placebo, suggesting a strong plausibility to address a substantial unmet medical need. This interim data validates IGC-AD1's potential as a transformative therapeutic option with a large market opportunity in Alzheimer's disease management. We are actively pursuing next steps, including with regulators, and remain committed to advancing IGC-AD1 toward commercialization. We foresee a medication that can help alleviate caregiver burden and family distress as managing Alzheimer's patients, especially ones with agitation, can have a significant emotional toll on families. With IGC-AD1's promising clinical profile, we are confident in its ability, subject to further trials, to improve patient outcomes and drive shareholder value," said Ram Mukunda, CEO of IGC Pharma.

IGC-AD1 interim Statistics

Table 1 sets out the difference in LS mean from the baseline CMAI score for the active and the placebo groups at week six. The LS mean CMAI score difference between the active and placebo groups at week six is -10.45. At weeks 2 and 6, the interim Cohen's d effect size is 0.79 and 0.66, respectively, with a p-value of 0.037 for weeks 2 and 6 combined. This interim data suggests clinical and statistically significant improvement in AAD for the group receiving IGC-AD1 compared to placebo.

Comparison with Existing Treatment

In May 2023, the U.S. Food and Drug Administration ("FDA") approved Brexpiprazole, an atypical antipsychotic, with a boxed warning. This approval followed a significantly larger 12- week Phase 3 trial, which showed a difference in LS mean from baseline CMAI between active and placebo of -5.32, a Cohen's d effect size of 0.35, and a p-value of 0.003 (Lee et al., 2023). The findings from several Brexpiprazole trials are summarized in Table 1 below.

Table 1. Results of IGC-AD1 Interim Analysis and Illustrative Brexpiprazole Phase 3 Results[1]

	IGC AD1	**Brexpiprazole Phase 3**		
	Phase 2 Interim results	**Phase 3 Two fixed doses (Lee et al. 2023)**	**Phase 3 fixed dose (Grossberg et al. 2020)**	**Phase 3 Post Hoc (subgroup) (Grossberg et al. 2020)**
Trial Duration	**6-weeks**	12-weeks	12-weeks	12-weeks
ClinicalTrials.gov ID	**NCT05543681**	NCT03548584	NCT01862640	NCT01922258
Dosing	**1 ml (bid)**	2mg/3mg (qd)	2mg (qd)	2mg (qd)
End Of Treatment (EOT)	**Week 6**	Week 12	Week 12	Week 12
Primary Outcome	**Baseline to Week 6**	Baseline to Week 12	Baseline to Week 12	Baseline to Week 12
Statistical Model	**MMRM**	MMRM	MMRM	MMRM
Agitation Scale	**CMAI**	CMAI	CMAI	CMAI
Treatment Difference in LS Mean from Baseline CMAI between Active and Placebo at EOT (95% CI)	**-10.46 (-20.20, -0.72)**	-5.32 (-8.77, -1.87)	-3.77 (-7.38, -0.17)	-5.06 (-8.99, -1.13)
Cohen's d Effect Size	**0.66**	0.35	0.25	0.41
p-value	**0.037**	0.003	0.040	0.012

1. The comparison is for illustrative purposes and is not intended to provide a direct comparison of effectiveness between IGC-AD1 and Brexpiprazole.

IGC-AD1 as a Treatment for Agitation in Alzheimer's Disease

In 2023, the number of Americans living with Alzheimer's was estimated at 6.7 million. According to one estimate, as many as 76% of them suffer from AAD (Van der Mussele et al., 2015), which is associated with an accelerated cognitive decline, increased caregiver burden, increased hospitalization, and increased need for medication, all significantly diminishing the quality of life for patients. Current therapies carry black box warnings, indicative of serious adverse reactions that may lead to death or serious injury. IGC-AD1 is designed to target AAD's underlying causes and address the unmet need for a safe and effective therapy.

Neuroinflammation, neurotransmitter imbalance, and CB1 receptor dysfunctions are all associated with agitation in Alzheimer's disease (Yasuno et al., 2023; Manuel et al., 2014). In addition, upregulation of inflammasome-3 has been shown to lead to neuroinflammation, consequently leading to aggressive behavior (Yu et al., 2023). IGC-AD1's formulation combines a CB1 receptor partial agonist with anti-neuroinflammatory properties that help balance neurotransmitter imbalance and an inflammasome inhibitor that targets the upregulation of inflammasome-3.

The 146-pateint IGC-AD1 trial, for which these interim results are presented, continues to enroll in the U.S. and Canada. As the interim results are based on a small number of patients (n=26), there is no guarantee that the positive interim results will hold up as more patients are enrolled in the trial. Learn more and find information about recruitment centers at https://clinicaltrials.gov/study/NCT05543681.

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Forward-Looking Statements:

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