

**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): November 20, 2023**

**IN8bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39692**  
(Commission  
File Number)

**82-5462585**  
(IRS Employer  
Identification No.)

**350 5th Avenue, Suite 5330**  
**New York, New York**  
(Address of Principal Executive Offices)

**10118**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 646 600-6438**

**Not Applicable**  
(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))

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, \$0.0001 par value	INAB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange 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.

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**Item 8.01. Other Events**

On November 20, 2023, IN8bio, Inc. (the “Company”) issued a press release announcing updated clinical data from the Phase 1 INB-200 trial, which was presented at the Society for Neuro-Oncology 28th Annual Meeting in Vancouver, British Columbia on November 17, 2023. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release, dated November 20, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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.

**IN8bio, Inc.**

Date: November 20, 2023

By: \_\_\_\_\_ /s/ Patrick McCall  
**Patrick McCall**  
**Chief Financial Officer and Secretary**  
*(Principal Financial and Accounting Officer)*



### **IN8bio's INB-200 Demonstrates Extended Progression-Free Survival in Patients with Newly Diagnosed Glioblastoma**

*All patients treated with INB-200 who completed mandated doses to date have exceeded a progression-free survival (PFS) of seven months*

*Most patients exceeded the expected median PFS based on age and tumor status; two patients from Cohort 2 remain alive beyond two years*

*Additional enrolled patients await dosing with completion of enrollment in Cohort 3 expected in 2023 and long-term follow up to be presented at medical meetings in 2024*

NEW YORK, November 20, 2023 (GLOBE NEWSWIRE) – IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company developing innovative gamma-delta (gd) T cell therapies, presented data demonstrating that all patients treated with INB-200 who completed mandated doses have exceeded a progression-free survival (PFS) of seven months to date. This survival data shows the potential of IN8bio's DeltEx Drug Resistant Immunotherapy (DRI)—genetically modified and chemotherapy-resistant gamma-delta T cells to treat patients with newly diagnosed glioblastoma (GBM). The poster highlighting the updated clinical data from the Phase 1 INB-200 trial was presented at the Society for Neuro-Oncology (SNO) 28<sup>th</sup> Annual Meeting in Vancouver, British Columbia on November 17, 2023.

“Every patient in the Phase 1 trial that completed the mandated doses has exceeded the standard-of-care median progression-free survival of four to seven months, with one patient in Cohort 2 remaining alive and progression free past 28.5 months following three doses,” said Trishna Goswami, MD, Chief Medical Officer at IN8bio. “We are excited by the safety and efficacy results across cohorts in this study and look forward to dosing additional patients with the added hope of improving their treatment outcomes. Following up on our oral presentation at this year's ASCO Annual Meeting, these encouraging results demonstrate the early promise of IN8bio's DeltEx DRI gamma-delta T cells for treating GBM patients and potentially other solid tumor cancers.”

The current standard-of-care regimen for newly diagnosed GBM consists of primary resection, six weeks of chemoradiation therapy followed by six cycles of maintenance monthly temozolomide therapy, which achieves a median PFS of 7 months and an overall survival (OS) of approximately 14 to 16 months. The Phase 1 trial assesses the safety and preliminary efficacy of the addition of DeltEx DRI gamma-delta T cells to standard-of-care maintenance therapy. The trial assesses three different dosing regimens from a single dose delivered on cycle 1 day 1 in Cohort 1, to three doses delivered on day 1 of cycles 1-3 in Cohort 2, to finally six doses delivered on day 1 of cycles 1-6 in Cohort 3. All patients receive  $1 \times 10^7$  cells per dose, however the number of doses varies depending on the cohort of enrollment.

The poster presentation at SNO included efficacy and safety data as of the data cutoff on October 20, 2023. Ten patients have been treated with INB-200: three in Cohort 1 (1 dose), four in Cohort 2 (3 doses) and three in Cohort 3 (6 doses). Key findings from the ongoing study include:

- All patients who completed mandated doses surpassed a PFS of seven months, with most also exceeding the expected PFS based on their age and tumor status.
- One patient (009) with an IDH-mutant glioma remains alive and progression free at 28.5+ months; comparative data published in the New England Journal of Medicine (NEJM) in August 2023 demonstrate that IDH-mutant patients in the control arm of a clinical trial demonstrated a median PFS of 11.1 months.
- No treatment-related serious adverse events (SAEs), dose-limiting toxicities (DLTs), cytokine release syndrome (CRS), infusion reactions, or immune effector cell-associated neurotoxicity syndrome (ICANS) have been reported in any cohort.
- The most common treatment-emergent adverse events (TEAEs) were mostly Grade 1-2 toxicities consisting of white blood cell and platelet count decreases related to standard-of-care temozolomide.
- Preserved gamma-delta T cells found in relapsed tumor 148 days after initial DRI infusion, pointing to durability of gamma-delta T cells in treating cancer.
- The poster is available on the Company's website here.

### **About INB-200**

INB-200 is a genetically modified autologous DRI product candidate for the treatment of solid tumors. This novel platform utilizes genetic engineering to generate chemotherapy-resistant gamma delta T cells which can be administered concurrently with standard-of-care treatment in solid tumors. This is a powerful, synergistic treatment approach enabling gamma-delta T cells to persist in the presence of chemotherapy, and maintain their natural ability to recognize, engage and kill cancer cells.

INB-200 is the first genetically engineered gamma-delta T cell therapy to be administered to patients with solid tumors and our initial indication is in GBM.

### **About IN8bio**

IN8bio is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell product candidates for solid and liquid tumors. Gamma-delta T cells are a specialized population of T cells that possess unique properties, including the ability to differentiate between healthy and diseased tissue. IN8bio's DeltEx platform employs allogeneic, autologous, iPSC and genetically modified approaches to develop cell therapies, designed to effectively identify and eradicate tumor cells.

IN8bio has initiated a Phase 2 trial of INB-400 in GBM at multiple centers across the United States and has two ongoing Phase 1 trials in solid and hematological tumors, including INB-200 for GBM and INB-100 for patients with hematologic malignancies undergoing transplantation. IN8bio also has a broad portfolio of preclinical programs focused on addressing other hematological and solid tumor cancers. For more information about IN8bio and its programs, please visit [www.IN8bio.com](http://www.IN8bio.com).

## Forward Looking Statements

This press release may contain forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding the potential of INB-200 to treat patients with newly diagnosed GBM, including future outcomes of the INB-200 program; the ability of the DeltEX platform to effectively identify and eradicate tumor cells; the development and continued progress and success of our preclinical and clinical trials and programs and product candidates; and IN8bio’s ability to achieve anticipated milestones, including expected data readouts from its trials, enrollment of additional patients in its clinical trials, advancement of clinical development plans and to develop new preclinical programs. IN8bio may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including: risks to site initiation, clinical trial commencement, patient enrollment and follow-up, as well as IN8bio’s ability to meet anticipated deadlines and milestones; uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of IN8bio’s product candidates; the risk that IN8bio may not realize the intended benefits of its DeltEx platform; availability and timing of results from preclinical studies and clinical trials; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that trials and studies may be delayed and may not have satisfactory outcomes; potential adverse effects arising from the testing or use of IN8bio’s product candidates; expectations for regulatory approvals to conduct trials or to market products; IN8bio’s reliance on third parties, including licensors and clinical research organizations; and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements. These and other factors are described in greater detail in the section entitled “Risk Factors” in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 9, 2023, as well as in other filings IN8bio may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and IN8bio expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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