

**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 16, 2021

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	NASDAQ Global Select Market

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.

Item 8.01. Other Events.

On December 16, 2021, IN8bio, Inc. (the “Company”) issued a press release providing an update from the ongoing Phase 1 clinical trial of INB-100. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by IN8bio, Inc., dated December 16, 2021
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: December 16, 2021

By: _____ /s/ Patrick McCall
Patrick McCall
Chief Financial Officer and Secretary



**IN8bio Provides Update from the Ongoing Phase 1 Clinical Trial of its
Allogeneic Gamma-Delta T Cell Therapy in Leukemia Patients
Undergoing Hematopoietic Stem Cell Transplant**

- *The ongoing Phase 1 trial of INB-100 is the first and most clinically advanced program administering large systemic doses of allogeneic gamma-delta T cells to patients*
- *3 patients have been treated to date, all of whom remain in remission with the first two patients at ~20 months and ~18 months post treatment, respectively, and the most recent at ~6 months*
- *Of the 3 patients that were dosed with INB-100, two patients have achieved a complete response (CR) and one patient has achieved a morphologic CR (mCR); to date, durable responses of >1.5 years were observed in two patients*
- *INB-100 continues to demonstrate a manageable safety profile to-date, with no dose-limiting toxicities, no treatment-related grade 3 or greater adverse events, and no cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS)*

NEW YORK, Dec. 16, 2021 — IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative gamma-delta T cell therapies utilizing its DeltEx platform, today provided an update from the ongoing Phase 1 clinical trial of INB-100, a donor-derived gamma-delta T cell therapeutic in development for patients with leukemia undergoing haploidentical hematopoietic stem cell transplant (HSCT). The three patients with relapsed acute myeloid leukemia (AML) treated to date demonstrate that allogeneic gamma-delta T cell therapy has a manageable toxicity profile with the potential for durable responses in high-risk patients. Haploidentical HSCT patients have high relapse rates of up to 50% at one-year post-treatment. All three of the INB-100 treated patients remain in remission with two patients in remission at 18 and 20 months, respectively. No treatment-related grade 3 or greater adverse events, infusion reactions or dose-limiting toxicities were observed. The trial continues to track these patients and enroll additional patients.

“We believe that the encouraging early data from the first patients dosed in this clinical trial suggest the potential of gamma-delta T cells to offer a novel treatment option for patients with aggressive hematologic malignancies,” said Trishna Goswami, MD, Chief Medical Officer at IN8bio. “Multiple complete responses with durability greater than 1.5 years is especially promising for patients with high-risk leukemias, who have high rates of post-HSCT relapse. The absence of grade 3 or greater graft versus host disease (GvHD) 100 days post gamma-delta T cell infusion is also encouraging for an allogeneic therapy. We continue to enroll patients in this Phase 1 clinical trial and look forward to reporting additional data from this program in 2022.”

This Phase 1 clinical trial (NCT03533816) is a dose-escalation trial of allogeneic, or donor-derived, gamma-delta T cells that have been expanded and activated *ex vivo* and administered systemically to patients with leukemia following haploidentical HSCT. Three high-risk AML patients with complex cytogenetics have been treated to-date, including patients with trisomy 8, del7 mutations. The single-institution clinical trial is currently being conducted at The University of Kansas Cancer Center (KUCC). The primary endpoints of this trial are safety and tolerability, and secondary endpoints include rates of GvHD, relapse rate and overall survival.

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.

The proprietary IN8bio DeltEx platform is designed to overcome many of the challenges associated with the expansion, genetic engineering and scalable manufacturing of gamma-delta T cells. The DeltEx platform employs allogeneic, autologous and genetically modified approaches to develop cell therapies, designed to effectively identify and eradicate tumor cells. This approach allows us to expand the cells *ex vivo* to administer a potentially therapeutic dose to patients, harnessing the unique properties of gamma-delta T cells, including their ability to broadly recognize cellular stress signals on tumor cells. We have used the DeltEx platform to create our deep pipeline of innovative allogeneic, autologous and/or genetically modified product candidates designed to effectively target and potentially eradicate disease and improve patient outcomes.

IN8bio is currently conducting two investigator-initiated Phase 1 clinical trials for its lead gamma-delta T cell product candidates: INB-200 for the treatment of newly diagnosed glioblastoma and INB-100 for the treatment of patients with leukemia undergoing hematopoietic stem cell transplantation. IN8bio also has a broad portfolio of preclinical programs focused on addressing other solid tumor types.

For more information about IN8bio and its programs, please visit www.IN8bio.com.

Forward Looking Statements

Certain statements herein concerning the Company's future expectations, plans and prospects, including without limitation, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for the Company's product candidates; and the prospects for such candidates and underlying technology, constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," the negative of these and other similar expressions are intended to identify such forward looking statements. Such statements, based as they are on the current expectations of management, inherently involve numerous risks and uncertainties, known and unknown, many of which are beyond the Company's control. Consequently, actual future results may differ materially from the anticipated results expressed in such statements. Specific risks which could cause actual results to differ materially from the Company's current expectations include: scientific, regulatory and technical developments; failure to demonstrate safety, tolerability and efficacy; potential for interim, top-line and preliminary data to change as audit and verification procedures are completed; difficulties enrolling patients; expense and uncertainty of obtaining regulatory approval, including from the

U.S. Food and Drug Administration; and the Company's reliance on third parties, including licensors and clinical research organizations. Do not place undue reliance on any forward-looking statements included herein, which speak only as of the date hereof and which the Company is under no obligation to update or revise as a result of any event, circumstances or otherwise, unless required by applicable law.

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