

**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 28, 2022

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 March 28, 2022, IN8bio, Inc. (the “Company”) issued a press release providing an update from the ongoing Phase 1 clinical trial of INB-100 and clinical correlative data recently presented at the 48th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) in March 2022. 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, dated March 28, 2022.
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: March 28, 2022

By: _____ /s/ Patrick McCall
Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)



IN8bio Presents Clinical Update from the Ongoing Phase 1 Trial of INB-100, an Allogeneic Gamma-Delta T Cell Therapy in Leukemia Patients Undergoing Hematopoietic Stem Cell Transplant

- *All three patients with high-risk or relapsed acute-myeloid leukemia (AML) dosed to-date with INB-100 demonstrated durable remissions at 23.3, 21.0, and 9.3 months post-BMT, respectively.*
- *Immune systems robustly reconstituted in patients at six months post-treatment with INB-100, including T cells, B cells, and gamma-delta T cells.*
- *Safety profile continues to be manageable with no dose-limiting toxicities, no treatment-related Grade 3 or greater adverse events, including graft versus host disease (GvHD), and no cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS).*
- *Update was presented at the European Society for Blood and Marrow Transplantation (EBMT) 48th Annual Meeting*

NEW YORK, March 28, 2022 — 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, presented a clinical update from the ongoing Phase 1 trial of INB-100. This program is an allogeneic, or donor-derived, gamma-delta T cell therapeutic candidate in development for patients with leukemia undergoing haploidentical hematopoietic stem cell transplant (HSCT). Two of the INB-100 patients treated have been in remission for nearly two years, and the third patient is in continuing remission at nine months post-treatment.

The exploratory clinical correlative data highlights the robust reconstitution of the immune system of treated patients. The data show positive trends in levels of immune cells, including alpha-beta T cells, B cells and gamma-delta T cells. This suggests that the systemic immune system may show long-term positive trends in treated patients. The toxicity profile continues to be manageable with no treatment-related Grade 3 or greater adverse events. The clinical and correlative update was presented at the virtual European Society for Blood and Marrow Transplantation (EBMT) 48th Annual Meeting.

“We are encouraged by the patients’ responses to INB-100 treatment given this population’s high risk for recurrence,” said Lawrence S. Lamb, Ph.D., Chief Scientific Officer and co-founder of IN8bio. “As we near the two-year mark in remission for our first and longest enrolled patient, we continue to monitor data from our ongoing clinical correlative studies, which are indicating a positive systemic immune response following the infusion of INB-100. Patient recruitment in this trial is continuing, and we look forward to releasing further clinical and correlative data with additional patients later this year.”

About the INB-100 Phase 1 Trial

The Phase 1 clinical trial ([NCT03533816](#)) is a dose-escalation trial of allogeneic 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. 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. IN8bio's DeltEx platform employs allogeneic, autologous and genetically modified approaches to develop cell therapies, designed to effectively identify and eradicate tumor cells.

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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