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 10, 2024

IN8bio, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39692**	**82-5462585**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

350 5th Avenue, Suite 5330 **New York, New York** **(Address of Principal Executive Offices)**	**10118** **(Zip Code)**

646 600-6438
(Registrant's Telephone Number, Including Area Code)

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 (see General Instructions 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, $0.0001 par value per share	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. ☐

Item 8.01 Other Events.

On December 10, 2024, IN8bio, Inc. (the "Company") issued a press release announcing the presentation of updated data demonstrating continued progression-free survival in its Phase 1 investigator-sponsored trial of INB-100 allogeneic gamma-delta T cells for leukemias at the 2024 American Society of Hematology Annual Meeting. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release, dated December 10, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IN8bio, Inc.

Dated: December 10, 2024

By: /s/ Patrick McCall

Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

IN8bio Reports Continued Progression-Free Survival in Phase 1 Investigator-Sponsored Trial of INB-100 Allogeneic Gamma-Delta T Cells for Leukemias at the 2024 American Society of Hematology Annual Meeting

- *INB-100 continues to demonstrate durable complete remissions (CR) with no relapses observed in any acute myeloid leukemia (AML) patients including those with high-risk disease after a median follow-up of 19.7 months.*
- *Data highlights INB-100's long-term impact, exhibiting durable in vivo expansion and persistence of allogeneic gamma-delta T cells 365 days following a single administration of INB-100, demonstrating the first-ever durable persistence and expansion of an allogeneic cellular therapy.*
- *New clinical data, including results from the INB-100 expansion cohort and control data, expected to be available in the first half of 2025.*

NEW YORK, December 10 2024 — IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced updated data from the ongoing Phase 1 trial of INB-100, an allogeneic, haploidentical gamma-delta T cell therapy in older patients with hematologic malignancies undergoing haploidentical stem cell transplant (HSCT) with reduced intensity conditioning (RIC) at the 2024 American Society of Hematology (ASH) Annual Meeting, being hosted in San Diego, CA.

"This data demonstrates the potential of allogeneic INB-100 gamma-delta T cells to provide durable relapse-free remissions in high-risk or relapsed AML patients undergoing HSCT," said Dr. Joseph P. McGuirk, Schutte-Speas Professor of Hematology-Oncology, Division Director, Hematologic Malignancies and Cellular Therapeutics Medical Director, Blood and Marrow Transplant, The University of Kansas Cancer Center. "Older, frailer patients who receive non-myeloablative, reduced intensity conditioning regimens typically have a significant risk of relapse. Historically, approximately 25% of AML patients undergoing HSCT would be expected to have a leukemic relapse within the first 100 days post-transplant, with up to nearly 50% of such patients experiencing relapse by one-year, which remains the primary cause of death. The longer AML patients remain in remission post-HSCT, the greater their probability of survival. These observed long-term durable remissions using allogeneic gamma-delta T cells are very encouraging and we look forward to announcing additional data next year."

In a poster presentation, IN8bio reported that there have been no newly reported deaths or relapses as of September 30, 2024. As of that cutoff date, median CR was at 16.4 months following a median of 19.2 months of follow-up. As previously reported, all patients (n=10) remained alive, progression-free, and in durable CR through one-year. 100% of AML patients remain in CR after a median 19.7 months of follow-up with three patients with high-risk cytogenetic AML and receiving no maintenance therapy remaining in mCR for greater than three years.

INB-100 continues to demonstrate *in vivo* expansion and persistence of an haplo-matched allogeneic, or donor-derived cellular, therapy at 365 days with blood levels of gamma-delta T cells surpassing levels previously observed to be associated with greater survival. The persistence of these cells is suggestive of continued gamma-delta T cell surveillance against leukemic relapse.

In addition to the reported complete responses, INB-100 continued to demonstrate a well-tolerated safety profile with no cytokine release syndrome (CRS) or neurotoxicity (ICANS) observed and limited mild infections. Based upon these encouraging results, the INB-100 trial has been expanded to enroll additional patients at Dose Level (DL) 2, the recommended Phase 2 dose (RP2D). Enrollment of additional patients into the expansion cohort is on-going and updated data, are expected to be reported in the first half of 2025.

Summary of Data Presented at ASH

The Phase 1 investigator-sponsored trial enrolled and treated ten patients at one of two dose levels (D1 or D2). The median age was 68 years with the majority of patients diagnosed with AML in CR1. Two patients (009 and 011) had TP53 mutations, a tumor suppressor that results in poor prognosis, rapid progression and reduced lifespan due to an inability to respond to mutated or damaged DNA.

The latest INB-100 trial data on immune reconstitution continues to show significant allogeneic gamma-delta T cell expansion and persistence in patients through the first 365 days post-treatment. As of September 30, 2024, 100% of patients (n=10) surpassed one-year survival following their haplo-matched transplant and treatment with INB-100. Historically, approximately 25% of patients relapse by 100 days and 40-50% of patients relapse by one year.

Updated safety data includes:

- No dose limiting toxicities (DLTs) and no treatment related deaths were observed.
- Low grade (1-2) acute graft versus host disease (GvHD) observed in 60% of patients treated. Cases were all steroid responsive.
- Treatment-related serious adverse events included Grade 2 rash (60%) and Grade 3 nausea (20%).
- One patient death previously reported due to idiopathic pulmonary syndrome likely related to the underlying HSCT at 15.5 months, without disease progression.
- No ICAN, CRS, or major infections were observed.
- Seven patients across DL 1 and DL 2 remained on study and in CR, with three having surpassed three years, including one now remaining progression free for over four years.

About IN8bio

IN8bio is a clinical-stage biopharmaceutical company developing gamma-delta T cell-based immunotherapies for cancer patients. 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 company's lead program, INB-100, is focused on AML evaluating haplo-matched allogeneic gamma-delta T cells given to patients following a hematopoietic stem cell transplant. The company is also evaluating autologous DeltEx DRI gamma-delta T cells, in combination with standard of care, for glioblastoma. For more information about IN8bio, visit 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: IN8bio's ability to deliver on the potential of INB-100; the potential of allogeneic INB-100 gamma-delta T cells to provide durable relapse-free remissions in high-risk or relapsed AML patients undergoing HSCT; IN8bio's ability to achieve anticipated milestones, including expected presentations and data readouts from its trials, enrollment of additional patients in its clinical trials, and advancement of clinical development plans; and other statements that are not historical fact. 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 be unable to raise additional capital and could be forced to delay, further reduce or to explore other strategic options for certain of our development programs, or even terminate its operations; IN8bio's ability to continue to operate as a going concern; 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; the uncertainty of 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, 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 12, 2024, 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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