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): April 17, 2023

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**	**10118**
(Address of Principal Executive Offices)	**(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. ☐

Item 8.01. Other Events

On April 17, 2023, IN8bio, Inc. issued a press release announcing certain preclinical data relating to its novel non-signaling CAR platform and the launch of its INB-330 program in acute myeloid leukemia. 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.

Exhibit No.	Description
99.1	Press Release, dated April 17, 2023
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: April 17, 2023

By: /s/ Patrick McCall

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

IN8bio Announces Positive Preclinical Data for Gamma-Delta CAR Platform and Launches New CD33 Program at AACR Annual Meeting 2023

- *INB-300, a gamma-delta T cell chimeric antigen receptor (CAR) platform, demonstrated the ability to target cancer cells while sparing healthy tissue when both express the CAR-targeted antigen.*

- *CAR platform leverages the ability of gamma-delta T cells to selectively target tumor cells supporting the potential of this approach in previously "undruggable" solid-and liquid-tumor targets.*

- *Company announces new INB-330 program targeting CD33 in acute myeloid leukemia (AML).*

NEW YORK, April 17, 2023 (GLOBE NEWSWIRE) — IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company discovering and developing innovative gamma-delta T cell therapies, today announced positive preclinical data for its novel non-signaling CAR (nsCAR) platform and the launch of its INB-330 program in AML. The new data included preliminary results for the nsCAR platform targeting CD33, a challenging but potentially impactful target in AML. The data were presented in a poster session (abstract #1777) at the American Association for Cancer Research (AACR) Annual Meeting 2023.

"The pairing of an nsCAR with the innate killing ability of gamma-delta T cells has the potential to become a cornerstone in the treatment of both solid and liquid cancers, given the increased anti-tumor efficacy and preservation of healthy cells," remarked William Ho, CEO and co-founder of IN8bio. "IN8bio's unique knowledge of the biology and manufacturing of gamma-delta T cells positions it as a leader in next generation CAR platforms for the treatment of previously undruggable targets."

IN8bio's nsCAR platform is based on the natural ability of gamma-delta T cells to distinguish between healthy and malignant tissue. By using a CAR that lacks a signaling domain, IN8bio believes it has created a technology that enables these cells to differentiate between tumor and healthy tissue, even when both express the CAR-targeted antigen. The power of the nsCAR technology to selectively target tumor cells was shown in proof-of-concept studies against the validated target of CD19. Preliminary data showed a gamma-delta CD19 nsCAR (ns19CAR) killed 80% of leukemia cells versus only 5% of healthy B cells, which both express the CD19 target.

The new data presented at AACR includes early preclinical results for the INB-330 program targeting CD33 for AML, an important but challenging target due to its expression on both leukemic cells and hematopoietic stem cells (HSCs). Previous therapies targeting CD33 were limited due to the significant side effects resulting from the unintended targeting of these HSCs. The data presented at AACR showed that a CD33 targeting nsCAR construct (ns33CAR) was successfully engineered into gamma-delta T cells. The ns33CAR cells were able to distinguish

between leukemic cells and healthy monocytes isolated from peripheral blood, both of which express CD33. The ns33CAR demonstrated anti-leukemic activity against AML, B-cell acute lymphoblastic leukemia (B-ALL), and chronic myeloid leukemia (CML) cell lines. These preliminary findings support the ongoing evaluation of INB-330 in AML and improvements in transduction and CAR optimization are ongoing.

“We are thrilled to present this promising preclinical data from our next-generation nsCAR platform, which shows the potential of our INB-300 platform and INB-330 program to differentiate between cancerous and healthy tissue,” said Lawrence Lamb, Ph.D., co-founder and Chief Scientific Officer of IN8bio. “Our goal is to improve upon existing technologies with a targeted but potentially less toxic approach for patients who require more innovative therapies. The ability of this platform to avoid on-target off-tumor killing also allows us to explore previously “undruggable” targets in complex diseases such as AML and solid tumors. We are encouraged by these results and look forward to seeking potential partners and further evaluating the nsCAR platform with additional targets.”

About INB-300

INB-300, is a non-signaling CAR (nsCAR) gamma-delta T cell platform, with several preclinical product candidates, including the INB-330 program against AML targets, that combine our expertise in gamma-delta T cells and genetic engineering. These nsCAR constructs lack signaling domains in order to take advantage of the unique properties of gamma-delta T cells to differentiate between healthy and tumor tissues. IN8bio is advancing new nsCAR constructs against multiple targets to treat both solid and liquid tumors.

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 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 is initiating INB-400, a company-sponsored Phase 2 clinical trial in newly diagnosed glioblastoma following IND clearance in late 2022. 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

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: future positive results in clinical data relating to the INB-300 study or the nsCAR platform; the nsCAR platform's potential to distinguish between tumor cells and healthy tissue; the timing and initiation of IN8bio's clinical trials; INB-300's ability to improve upon existing technologies; and IN8bio's ability to evaluate nsCAR programs in additional promising targets such as CD3 for AML. 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, presented by the ongoing COVID-19 pandemic as well as rising inflation and regulatory developments; 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, are described in greater detail in the section entitled "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 30, 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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