

**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 09, 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 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 2.02 Results of Operations and Financial Condition.**

On November 9, 2023, IN8bio, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
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99.1	<a href="#">Press Release, dated November 9, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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 9, 2023

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

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## IN8bio Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- *Completed dose escalation in Phase 1 Trial of INB-100 with updated clinical data to be presented at the American Society of Hematology (ASH) Annual Meeting on December 11, 2023 (Abstract Number: 4853)*
- *Held Research & Development Day, featuring Leo Luznik, M.D. from Johns Hopkins University and Michael Bishop, M.D. from The University of Chicago, highlighting IN8bio's differentiated clinical and scientific programs and multiple upcoming clinical catalysts*
- *Presented positive updated biologic correlative data on INB-200 in glioblastoma (GBM) and preclinical data on INB-500 featuring induced pluripotent stem cell (iPSC) derived gamma-delta T cells at the Society for Immunotherapy of Cancer (SITC) 38th Annual Meeting*
- *Initiated enrollment for Phase 2 trial of INB-400 in newly diagnosed GBM (NCT05664243)*
- *Updated Phase 1 clinical data from INB-200 to be presented at Society for Neuro-Oncology (SNO) on November 17, 2023*

NEW YORK, November 9, 2023 (GLOBE NEWSWIRE) – IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies, today announced financial results, operational highlights and recent corporate developments for the third quarter ended September 30, 2023.

“We have continued to execute and to make impressive clinical progress across the breadth of our pipeline, which we shared at our recent Research & Development Day,” said William Ho, CEO and co-founder of IN8bio. “Having completed enrollment in the dose escalation portion of the Phase 1 trial of INB-100 in hematologic malignancies and initiated enrollment for the Phase 2 trial of INB-400 in newly diagnosed glioblastoma, we are making strides towards our mission of exploring the full potential of gamma-delta T cells as a much-needed treatment option for cancer patients. We are encouraged by the positive data we have seen thus far and are excited to share additional clinical updates on our INB-100 and INB-200 programs at the upcoming SNO and ASH meetings.”

### Business Highlights and Recent Developments

- **Presented two posters reporting biologic correlative data from the ongoing Phase 1 clinical trial of INB-200 in GBM and preclinical data on IN8bio's iPSC gamma-delta T cell platform at SITC.** The data presented from the
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INB-200 trial demonstrate the potential of single and repeat doses of DeltEx drug-resistant immunotherapy (DRI) to induce T cell persistence and sustained immune responses. Updated patient, enrollment and survival data from the ongoing INB-200 study will be presented at the SNO Annual Meeting on November 17, 2023. Data from IN8bio's iPSC platform demonstrate the ability to kill multiple cancer types including ovarian cancer, GBM, CML and AML cell lines along with the potential to generate billions of iPSC-derived Vδ1+ T cells.

- **Completed dose escalation in the Phase 1 Trial of INB-100 in leukemia patients and will present clinical data at the upcoming ASH Annual Meeting on December 11, 2023.** Enrollment in the dose escalation phase of the Phase 1 clinical trial (NCT03533816) of INB-100 is now closed. The presentation at ASH will highlight clinical data updating the efficacy results of INB-100 including complete responses (CRs) and durability.
- **Initiated enrollment for the company-sponsored Phase 2 trial of INB-400 in GBM.** The Phase 2 clinical trial of INB-400 (NCT05664243), a genetically engineered gamma-delta T cell therapy, is open for enrollment and plans to enroll approximately 40 patients in "Arm A" of the study, in which autologous gamma delta cells will be used to treat patients with newly diagnosed GBM. The primary endpoint of the study is 12-month overall survival (OS) rate, and key secondary endpoints include tolerability, progression-free survival (PFS), overall response rate (ORR) and time to progression (TTP). The University of Louisville and The Cleveland Clinic are the first clinical sites activated to enroll patients. The company will present a poster at the SNO Annual Meeting.
- **Hosted R&D Day on October 12, 2023, highlighting IN8bio's unique Gamma-Delta T cell platform.** The event offered the opportunity to gain Key Opinion Leader (KOL) insights into IN8bio's clinical programs. Featured presentations included those from IN8bio's management team on gamma-delta T cells, IN8bio's manufacturing capabilities, an overview of the INB-100, INB-200, and INB-400 clinical programs, as well as presentations from key oncology thought leaders Leo Luznik, M.D., Professor of Oncology at Johns Hopkins Medicine and Michael Bishop, M.D., Director of the David and Etta Jones Center for Cellular Therapy at the University of Chicago, featuring the topics of allogeneic transplantation and the challenges of leukemic relapse. A replay of the webcast event can be found [here](#).

### Upcoming Pipeline Milestones and Events

- **INB-100:** Presenting updated Phase 1 trial clinical data from patients with hematological malignancies undergoing HSCT at the ASH Annual Meeting on December 11, 2023.
  - **INB-200:** Complete enrollment of Cohort 3 in the Phase 1 trial; will present updated data at SNO on November 17, 2023 with longer-term follow-up at medical meetings throughout 2024.
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- **INB-300:** Present additional preclinical data demonstrating proof-of-concept for the nsCAR platform targeting CD33 and CD123 at a medical meeting in first half of 2024.
- **INB-400:** Present a poster at the SNO Annual Meeting on November 17, 2023; file investigational new drug (IND) application for allogeneic arms (Arms B and C) of the Phase 2 trial in newly diagnosed and relapsed GBM in 2024.

### Third Quarter 2023 Financial Highlights

- **Research and Development (R&D) expenses:** R&D expenses were \$3.8 million for the three months ended September 30, 2023, compared to \$4.3 million for the comparable prior year period. The decrease was primarily due to a reduction in contract research organization expenses for INB-400 related to the IND filing in the prior year period, partially offset by increased personnel-related costs, including salaries, benefits, and non-cash stock-based compensation due to increased headcount.
- **General and administrative (G&A) expenses:** G&A expenses were \$3.4 million for the three months ended September 30, 2023, compared to \$3.1 million for the comparable prior year period. The increase was primarily due to an increase in professional services.
- **Net loss:** The Company reported a net loss of \$7.2 million, or \$0.23 per basic and diluted common share, for the three months ended September 30, 2023, compared to \$7.4 million, or \$0.34 per basic and diluted common share, for the comparable prior year period.
- **Cash position:** As of September 30, 2023, the Company had cash of \$12.9 million, compared to \$17.0 million as of June 30, 2023.

### 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 company-sponsored Phase 2 trial of INB-400 in glioblastoma (GBM) at multiple centers across the United States and has two ongoing Phase 1 trials in solid and hematological tumors, including INB-200 for newly diagnosed GBM and INB-100 for leukemia patients 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).

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## **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 development and continued progress and success of our preclinical studies and clinical trials and programs and product candidates; the timing of initiation, progress (including as to enrollment) and scope of clinical trials, including for INB-100, INB-200 and INB-400; the success of gamma delta T cells as a treatment option for patients with both solid and hematological cancers; the timing of filing of an IND application for INB-400; 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 August 10, 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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**IN8BIO, INC.**  
**CONDENSED BALANCE SHEETS**  
(In thousands, except share and per share data)

	September 30, 2023 (unaudited)	December 31, 2022
<b>Assets</b>		
Current assets		
Cash	\$ 12,854	\$ 18,182
Prepaid expenses and other current assets	3,695	4,052
<b>Total Current Assets</b>	<u>16,549</u>	<u>22,234</u>
Non-current assets		
Property and equipment, net	3,738	4,397
Construction in progress	145	29
Restricted cash	254	252
Right-of-use assets - finance leases	1,579	1,691
Right-of-use assets - operating leases	3,688	4,181
Other non-current assets	255	255
<b>Total Non-Current Assets</b>	<u>9,659</u>	<u>10,805</u>
<b>Total Assets</b>	<u>\$ 26,208</u>	<u>\$ 33,039</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
Current liabilities		
Accounts payable	\$ 748	\$ 2,091
Accrued expenses and other current liabilities	2,440	2,342
Short-term finance lease liability	715	682
Short-term operating lease liability	783	707
<b>Total Current Liabilities</b>	<u>4,686</u>	<u>5,822</u>
Long-term finance lease liability	695	811
Long-term operating lease liability	3,069	3,674
<b>Total Non-Current Liabilities</b>	<u>3,764</u>	<u>4,485</u>
<b>Total Liabilities</b>	<u>8,450</u>	<u>10,307</u>
<b>Stockholders' Equity</b>		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively. No shares issued and outstanding	—	—
Common stock, par value \$0.0001 per share; 490,000,000 shares authorized at September 30, 2023 and December 31, 2022; 31,975,929 and 24,545,157 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	4	3
Additional paid-in capital	101,375	83,941
Accumulated deficit	(83,621)	(61,212)
<b>Total Stockholders' Equity</b>	<u>17,758</u>	<u>22,732</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 26,208</u>	<u>\$ 33,039</u>



**IN8BIO, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(In thousands, except share and per share data)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 3,786	\$ 4,255	\$ 12,305	\$ 10,140
General and administrative	3,383	3,144	10,434	10,583
Total operating expenses	7,169	7,399	22,739	20,723
Other income	—	—	330	—
Loss from operations	(7,169)	(7,399)	(22,409)	(20,723)
Net loss	\$ (7,169)	\$ (7,399)	\$ (22,409)	\$ (20,723)
Net loss per share – basic and diluted	\$ (0.23)	\$ (0.34)	\$ (0.79)	\$ (1.05)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	31,545,783	21,661,544	28,275,193	19,774,070

**Company Contact:**

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**Investors & Media Contact:**

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