

**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): May 12, 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 May 12, 2023, IN8bio, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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.

Exhibit No.	Description
99.1	Press Release, dated May 12, 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: May 12, 2023

By: _____ /s/ Patrick McCall

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

IN8bio Reports First Quarter 2023 Financial Results and Provides Corporate Update

- *Presented positive INB-100 data showing long-term complete remissions (CR) and elevated gamma-delta T cell levels in 100% of evaluable treated leukemia patients; Dose Level 2 selected as the recommended Phase 2 dose (RP2D) for the ongoing expansion with clinical updates expected in late 2023.*
- *Progress across preclinical programs, including data demonstrating that gamma-delta T cells have the ability to target other solid tumors, including ovarian cancer, expanding the scope of their potential application beyond brain tumors, as well as encouraging preclinical data in the new INB-330 CAR-T program targeting acute myeloid leukemia (AML).*
- *Obtained FDA orphan drug designation (ODD) for INB-400 and INB-410, which covers a broad range of malignant gliomas, including newly diagnosed glioblastoma multiforme (GBM).*
- *Recently raised net proceeds of \$9.9 million through ATM program, bolstering cash position.*

NEW YORK, May 12, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company focused on innovative gamma-delta T cell therapies, today announced financial results and operational highlights for the first quarter ended March 31, 2023. In addition, the Company provided an overview of recent corporate developments through May 2023.

“We made significant progress in advancing our gamma-delta T-cell programs in the first quarter of 2023,” said William Ho, CEO and co-founder of IN8bio. “Recently we announced positive clinical data from our Phase 1 trial of INB-100, which demonstrated long-term complete remissions and corresponding biomarker data demonstrating elevated gamma-delta T cell levels in all patients. For the first time, we have demonstrated persistence and in vivo expansion with an allogeneic donor derived cell therapy product. We will continue the ongoing expansion of this study, with updated data expected at a major medical meeting later this year.”

Mr. Ho continued, “In addition, we are honored to have been selected as one of only a handful of oral abstract presentations for a Phase 1 clinical trial at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting. Our team is committed to advancing the potent tumor-targeting capabilities of our gamma-delta T cell platform, with the aim of improving outcomes for patients in need of new and innovative treatment options. We continue to explore the potential of gamma-delta T cells to treat multiple cancer types,

as evidenced by our recent preclinical progress in solid tumors and in AML. The IN8bio team is excited about our unique next generation technologies and look forward to providing additional updates on our progress in the coming months.”

Business Highlights and Recent Developments

- **New preclinical data in ovarian cancer will be presented in a poster at the American Society of Cell & Gene Therapy (ASGCT) 26th Annual Meeting.** The abstract, to be presented on May 17, 2023, details new preclinical data from the INB-400 program demonstrating the potential of gamma-delta T cells to target and kill solid tumor cells outside the brain.
- **New INB-200 Phase 1 data will be featured in an oral abstract presentation at the ASCO 2023 Annual Meeting.** Abstract details including new data from the Phase 1 study evaluating INB-200 in patients with newly diagnosed GBM will be available on May 25, 2023.
- **Received FDA Orphan Drug Designation for INB-400 (autologous) and INB-410 (allogeneic) for the treatment of a broad spectrum of malignant gliomas, including newly diagnosed GBM.** This milestone marks the first time a genetically modified gamma-delta T cell therapy has received this designation, qualifying the Company for incentives, including potential seven year market exclusivity. Enrollment in the autologous arm of the Phase 2 trial targeting newly diagnosed GBM is anticipated to begin in the second half of 2023.
- **Presented encouraging preclinical data for novel non-signaling CAR (nsCAR) platform and announced the launch of the INB-330 program in AML at the American Association for Cancer Research (AACR) Annual Meeting.** Preliminary findings demonstrated that a CD33 targeting nsCAR construct (ns33CAR) was able to selectively differentiate between tumor and healthy tissue, potentially overcoming a critical challenge associated with this previously “undruggable” target.
- **Presented new, positive INB-100 data from the Phase 1 study showing long-term CRs and elevated gamma-delta T cells in 100% (n=7) of evaluable patients at the 49th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT).** INB-100 treatment achieved durable CRs in 100% of treated patients, including high-risk AML patients and a patient with acute lymphoblastic leukemia (ALL) who had failed 4 prior lines of therapy, including CAR-T. All evaluable patients remain alive at last assessment and one patient surviving beyond 3 years.

Corporate Updates:

- **Appointed Jeremy R. Graff, Ph.D., to the Company’s Board of Directors.** Dr. Graff brings significant drug development and leadership experience in the biotechnology and pharmaceutical sectors including 17 years at Eli Lilly and Company, where he built and led the translational oncology group, supporting and advancing 31 clinical assets in Eli Lilly’s oncology portfolio.
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First Quarter 2023 Financial Highlights

- **Cash position:** As of March 31, 2023, the Company had cash of \$10.9 million, compared to \$18.2 million as of December 31, 2022. Subsequent to March 31, 2023, the Company raised an additional \$9.9 million in net proceeds through the Company's at-the-market (ATM) program.
- **Research & Development (R&D) expenses:** R&D expenses were \$4.4 million for the three months ended March 31, 2023, compared to \$2.4 million for the comparable prior year period. The increase in R&D expenses was primarily due to (i) contract research organization expenses related to our INB-400 and INB-100 clinical programs, (ii) increased facility-related costs from opening our new laboratory space in Birmingham, Alabama and (iii) increased personnel-related costs, including salaries, benefits, and stock-based compensation due to increased headcount.
- **General and administrative (G&A) expenses:** G&A expenses were \$3.5 million for the three months ended March 31, 2023, compared to \$3.8 million for the comparable prior year period. The decrease was primarily due to a decrease in professional services and facility related costs.
- **Net loss:** The Company reported a net loss of \$7.5 million, or \$0.30 per basic and diluted common share, for the three months ended March 31, 2023, compared to a net loss of \$6.1 million, or \$0.33 per basic and diluted common share, for the comparable prior year period.

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 hematological and 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 the development and continued progress and success of our preclinical and clinical trials and programs; the intended incentives conferred by orphan drug designation for INB-400 and INB-410, including the potential for market exclusivity; the timing of initiation, progress and scope of clinical trials, including expectations regarding regulatory filings; future results in clinical data relating to the INB-100, INB-200 and INB-300 studies or the nsCAR platform; the nsCAR platform’s ability to distinguish between tumor cells and healthy tissue; the timing, initiation, and readout of clinical data from IN8bio’s clinical trials, including expectations regarding enrollment and the timing of data therefrom; IN8bio’s ability to evaluate nsCAR programs in additional promising targets such as CD33 for AML; the potential of INB-100 to maintain durable CRs in patients with ALL; the ability of gamma-delta T to target additional solid tumors and their application beyond brain tumors; 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 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.

IN8BIO, INC.
BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets		
Cash	\$ 10,860	\$ 18,182
Prepaid expenses and other current assets	3,542	4,052
Total Current Assets	<u>14,402</u>	<u>22,234</u>
Non-current assets		
Property and equipment, net	4,198	4,397
Construction in progress	45	29
Restricted cash	253	252
Right-of-use assets - finance leases	1,503	1,691
Right-of-use assets - operating leases	4,022	4,181
Other non-current assets	255	255
Total Non-Current Assets	<u>10,276</u>	<u>10,805</u>
Total Assets	<u>\$ 24,678</u>	<u>\$ 33,039</u>
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	\$ 870	\$ 2,091
Accrued expenses and other current liabilities	1,492	2,342
Short-term finance lease liability	654	682
Short-term operating lease liability	732	707
Total Current Liabilities	<u>3,748</u>	<u>5,822</u>
Long-term finance lease liability	664	811
Long-term operating lease liability	3,478	3,674
Total Non-Current Liabilities	<u>4,142</u>	<u>4,485</u>
Total Liabilities	<u>7,890</u>	<u>10,307</u>
Stockholders' Equity		
Preferred stock, par value \$0.0001 per share; 10,000,000 shares authorized at March 31, 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 March 31, 2023 and December 31, 2022; 24,960,869 and 24,545,157 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	85,522	83,941
Accumulated deficit	(68,737)	(61,212)
Total Stockholders' Equity	<u>16,788</u>	<u>22,732</u>
Total Liabilities and Stockholders' Equity	<u>\$ 24,678</u>	<u>\$ 33,039</u>

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

	Three Months Ended	
	March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 4,385	\$ 2,381
General and administrative	3,470	3,764
Total operating expenses	7,855	6,145
Other income	330	—
Loss from operations	(7,525)	(6,145)
Net loss	\$ (7,525)	\$ (6,145)
Net loss per share – basic and diluted	\$ (0.30)	\$ (0.33)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	24,732,580	18,800,546

Company Contact:

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