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 30, 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** **(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 March 30, 2023, IN8bio, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2022. 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 March 30, 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: March 30, 2023

By: /s/ Patrick McCall

Patrick McCall

Chief Financial Officer and Secretary

(Principal Financial and Accounting Officer)

Exhibit 99.1

IN8bio Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Corporate Update

- *All Cohort 1 leukemia patients have maintained durable morphological complete responses (CR) beyond 18 months and up to 2.7 years in an ongoing Phase 1 trial of INB-100 as of December 9, 2022; Updated clinical data to be reported at the EBMT Annual Meeting in April 2023.*
- *INB-200 continued to show durable and favorable responses, with ongoing patients extending beyond 1.5 years and 1.2 years progression free through year-end 2022; currently enrolling patients in Cohort 3; Updated clinical data expected in mid-2023.*
- *Presented positive proof-of-concept data demonstrating the potential of INB-300, a next-generation gamma-delta T cell CAR technology, to target tumors while sparing healthy tissue; Additional updates to this program to be reported at the AACR Annual Meeting in April 2023.*

NEW YORK, March 30, 2023 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company discovering and developing innovative gamma-delta T cell therapies, today announced financial results and operational highlights for the fourth quarter and full-year ended December 31, 2022. In addition, the Company provided an overview of recent corporate developments.

“We are extremely pleased with the outstanding progress IN8bio has made in the past year and the encouraging clinical results we have observed across our gamma-delta T cell platform in both solid and liquid tumors," remarked William Ho, CEO and co-founder of IN8bio. "Our lead clinical programs, INB-100 and INB-200, continue to deliver promising outcomes with longer than expected relapse free and overall survival rates. Last year, we showcased our manufacturing, regulatory and clinical capabilities by filing and receiving clearance for our first corporate-sponsored IND from the FDA for INB-400. Additionally, our team remains committed to leveraging our profound knowledge of gamma-delta T cell biology to drive innovation in next-generation chimeric antigen receptor (CAR) technology. Most recently, we disclosed new preclinical data from our INB-300 platform, demonstrating a CAR construct that can differentiate between tumor and healthy tissue when both express the targeted antigen. We eagerly anticipate releasing additional clinical updates and unveiling our continued progress throughout this year.”

Business Highlights and Recent Developments

- **Presented initial preclinical data demonstrating how INB-300, the Company's novel non-signaling gamma-delta CAR-T platform (nsCAR) has the unique ability to distinguish between tumor and healthy tissue.** Using the well-established CD-19 target, the proof-of-concept study revealed that INB-300 (ns19CAR) eliminated 80% of the B cell leukemia cell line and only 5% of healthy B cells when both expressed CD19. These results demonstrating the wider therapeutic index support the potential expansion of CAR technology for previously "undruggable" cancer targets in indications including acute myeloid leukemia (AML) and solid tumor cancers.

- **Provided a clinical update from the ongoing INB-200 Phase 1 trial in patients with newly diagnosed glioblastoma (GBM), highlighting encouraging progression free survival results.** As of December 31, 2022, eight patients with newly diagnosed glioblastoma (GBM) had been dosed with INB-200: three in Cohort 1 (single dose), four in Cohort 2 (three doses) and one in Cohort 3 (six doses). Two Cohort 2 patients died of unrelated causes with no evidence of progression before death, while two other patients in the same cohort remained alive, progression-free and clinically asymptomatic at 1.5 and 1.2 years, respectively.

- **Presented new data at the American Society of Hematology (ASH) Annual Meeting demonstrating the potential of INB-100 to achieve long-term, durable responses in patients with high-risk or relapsed hematologic malignancies.** The findings were based on the ongoing Phase 1 trial of INB-100, a single-dose allogeneic gamma-delta T cell therapy, administered to patients with hematologic malignancies undergoing haploidentical stem cell transplantation (HSCT). All trial participants remained progression-free as of December 9, 2022, with the longest response durations extending beyond 2.7 years.

- **Obtained U.S. Food and Drug Administration (FDA) clearance for the Company-sponsored INB-400 Investigational New Drug (IND) application.** This will enable the initiation of a Phase 2 clinical trial for INB-400, a genetically modified autologous gamma-delta T cell therapy targeting newly diagnosed GBM. The study will evaluate safety, efficacy, and tolerability at leading medical centers across the United States.

Upcoming Pipeline Milestones and Events

- **INB-100:** Report updated Phase 1 trial data from leukemia patients undergoing HSCT at the European Society for Blood and Marrow Transplantation (EBMT) Annual Meeting in April 2023; define recommended Phase 2 dose for INB-100.

- **INB-200:** Complete enrollment of Cohort 3 in the Phase 1 trial; report updated data and results with longer-term follow-up at medical meetings throughout 2023.

- **INB-300:** Present additional preclinical data demonstrating proof-of-concept for the nsCAR platform at the American Association of Cancer Research (AACR) Annual Meeting in April 2023.

- **INB-400:** Initiate patient enrollment in the company-sponsored Phase 2 trial of INB-400, a genetically modified autologous gamma-delta T cell therapy, targeting newly diagnosed GBM in the second half of 2023.
- **INB-410:** Submit a new IND to the FDA for a Phase 1b trial of INB-410, a genetically modified allogeneic gamma-delta T cell therapy in newly diagnosed and relapsed GBM in late 2023.
- **New solid tumor indications:** Announce and present relevant data at a scientific conference in the first half of 2023.

Fourth Quarter and Full Year 2022 Financial Highlights

- **Cash position:** As of December 31, 2022, the Company had cash of $18.2 million, compared to $37.0 million as of December 31, 2021. The decrease in cash was primarily due to cash used by the Company in R&D and continued operations to advance its programs along with ongoing construction of a state-of-the-art ~10,000 sq. ft. R&D facility in Birmingham, AL.
- **Research & Development (R&D) expenses:** R&D expenses were $4.0 million for the three months ended December 31, 2022, compared to $2.7 million for the comparable prior year period. R&D expenses were $14.1 million for the year ended December 31, 2022, compared to $7.3 million in the prior year. The increase in R&D expenses was primarily due to contract research organization expenses related to the INB-400 program and IND, increased third-party clinical trial and IND-related activities, increased facility-related costs from opening our new laboratory space in Birmingham, Alabama and 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 $3.9 million for the three months ended December 31, 2022, compared to $3.2 million for the comparable prior year period. G&A expenses were $14.5 million for the year ended December 31, 2022, compared to $7.3 million in the prior year. The increase was primarily due to increased personnel-related costs, including salaries, benefits, and stock-based compensation reflecting an increased headcount, facility-related costs, insurance costs, and expenses associated with operating as a public company.
- **Net loss:** The Company reported a net loss of $7.8 million, or $0.32 per basic and diluted common share, for the three months ended December 31, 2022, compared to a net loss of $5.9 million, or $0.44 per basic and diluted common share, for the comparable prior year period. For the full year, net loss was $28.5 million, or $1.36 per basic and diluted common share, compared to a net loss of $14.7 million, or $1.47 per basic and diluted common share, for the comparable prior year.

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 plans to initiate 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: the potential of IN8Bio's DeltEx platform to develop cell therapies to effectively identify and eradicate tumor cells; future results in clinical data relating to the INB-100, 1NB-200 and INB-300 studies or the nsCAR platform; the nsCAR platform's potential 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; INB-300's ability to improve upon existing technologies; IN8bio's ability to evaluate nsCAR programs in additional promising targets such as CD3 for AML; the potential of INB-100 to achieve long-lasting durable responses in patients with high-risk or relapsed hematologic malignancies; IN8Bio's ability to identify potential clinical sites to participate in the multi-center Phase 2 clinical trial for INB-400; IN8bio's ability to achieve planned milestones, including data readouts from its trials; and the ability of IN8Bio 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, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 10, 2022, 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)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash	$ 18,182	$ 37,021
Prepaid expenses and other current assets	4,052	1,959
Total Current Assets	22,234	38,980
Non-current assets		
Property and equipment, net	4,397	97
Construction in progress	29	403
Restricted cash	252	251
Right of use assets - financing leases	1,691	704
Right of use assets - operating leases	4,181	1,630
Other non-current assets	255	158
Total Non-Current Assets	10,805	3,243
Total Assets	$ 33,039	$ 42,223
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	$ 2,091	$ 395
Accrued expenses and other current liabilities	2,342	1,235
Short-term financing lease liability	682	392
Short-term operating lease liability	707	234
Total Current Liabilities	5,822	2,256
Long-term financing lease liability	811	269
Long-term operating lease liability	3,674	1,515
Total Non-Current Liabilities	4,485	1,784
Total Liabilities	10,307	4,040
Stockholders' Equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized at December 31, 2022 and 2021, respectively. No shares issued and outstanding	—	—
Common stock, par value $0.0001 per share; 490,000,000 shares authorized at December 31, 2022 and 2021; 24,545,157 and 18,781,242 shares issued and outstanding at December 31, 2022 and 2021, respectively	3	2
Additional paid-in capital	83,941	70,872
Accumulated deficit	(61,212)	(32,691)
Total Stockholders' Equity	22,732	38,183
Total Liabilities and Stockholders' Equity	$ 33,039	$ 42,223

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 14,062	$ 7,347
General and administrative	14,459	7,306
Total operating expenses	28,521	14,653
Loss from operations	(28,521)	(14,653)
Net loss	$ (28,521)	$ (14,653)
Net loss per share – basic and diluted	$ (1.36)	$ (1.47)
Weighted-average number of shares used in computing net loss per common share – basic and diluted	20,967,955	9,969,733

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