

**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, 2022

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, 2022, IN8bio, Inc. issued a press release announcing its financial results for the quarter ended March 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
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99.1	Press Release, dated May 12, 2022.
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, 2022

By: _____ /s/ Patrick McCall

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

IN8bio Reports First Quarter 2022 Financial Results and Provides Corporate Update

- *Phase 1 clinical trial of INB-100 in leukemia patients and INB-200 in newly diagnosed glioblastoma multiforme (GBM) patients continue to generate encouraging data.*
- *INB-100 patient update at European Group for Blood and Marrow Transplantation (EBMT) 48th Annual Meeting demonstrated that all three treated patients remain in morphologic complete response (CR) with two patients approaching relapse free survival of 21 to 23 months as of March 2022.*
- *INB-200 continues to enroll and treat patients in cohort 2 with one patient having received all three anticipated repeat doses of INB-200, the first-ever repeat dosing of a genetically modified gamma-delta T cell therapy. A clinical update is expected at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022 (Abstract # 2044).*
- *In May 2022, IN8bio unveiled a new program focused on developing induced pluripotent stem cell (iPSC) derived gamma-delta T cells with initial data to be presented at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting (Abstract # 387).*

NEW YORK, May 12, 2022 -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative gamma-delta T cell therapies utilizing its DeltEx platform, today announced financial results and operational highlights for the quarter ended March 31, 2022. In addition, the Company provided an overview of recent corporate developments.

“Our team continues to execute and advance our programs on multiple fronts despite these challenging times in biotech,” said William Ho, CEO and co-founder of IN8bio. “Our Phase I clinical trials for both DeltEx gamma-delta product candidates, INB-200 in GBM and INB-100 in leukemia patients, continue to progress with encouraging early data. We added key clinical and regulatory expertise to our senior management team and we will be introducing our iPSC derived gamma-delta T cell platform at ASGCT next week. The IN8bio team will continue to be disciplined with our capital and we will use our resources to continue to accelerate the growth and momentum in our Company.”

Business Highlights & Updates

- In January 2022, IN8bio provided a clinical update from the Phase 1 clinical trial of its genetically modified gamma-delta T cell therapy candidate, INB-200, in newly diagnosed GBM. In the single ascending dose cohort 1 (n=3), all three
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patients showed no dose limiting toxicities (DLTs), no cytokine release syndrome (CRS) or neurotoxicity and demonstrated a manageable safety profile. Cohort 2, which will receive three repeat doses of INB-200, includes one patient who has already received all three doses without any DLTs or significant cell therapy related adverse events. All of the patients treated have exceeded their expected progression-free survival (PFS) interval based on age and MGMT status and exceeded median expected PFS of up to seven months with encouraging trends in overall survival.

- IN8bio presented a clinical update from the ongoing Phase 1 clinical trial of INB-100, an allogeneic gamma-delta T cell therapeutic candidate in leukemia patients undergoing hematopoietic stem cell transplantation. All three patients treated remain in morphologic CR with durable remissions ranging from nine to 23 months through March 2022. We observed robust immune reconstitution in the patients including T cells, B cells and gamma-delta T cells. INB-100's safety profile continues to be manageable with no DLTs, no grade 3 or greater graft vs. host disease (GvHD), no CRS and no neurotoxicity. The data were presented at the EBMT 48th Annual Meeting. These are encouraging results given up to 51% are expected to relapse within a year with standard of care treatment.
- In April 2022, IN8bio announced the continued expansion of its clinical and regulatory teams with the appointments of Urvashi Patel, Ph.D., Vice President, Regulatory Affairs, and Stacey Bilinski, Vice President, Clinical Operations. They bring deep clinical and regulatory experience to the IN8bio team, from early to late-stage development across the biotechnology and pharmaceutical industry with more than 45 years of combined experience. Dr. Patel has provided regulatory guidance to biopharmaceutical companies, including WindMIL Therapeutics, Precision for Medicine, Janssen, Elan Pharmaceuticals and Genentech. Ms. Bilinski has initiated numerous first in-human and early-phase clinical development programs at biopharmaceutical companies, including Taiho Oncology, Onconova, Insmad, Amicus Therapeutics and Covance.

Upcoming Milestones and Events

- In May 2022, IN8bio unveiled a new preclinical program focused on developing iPSC derived gamma-delta T cells to be presented at the ASGCT Annual Meeting, which will be held from May 16-19, 2022. Scalable iPSC-based cellular manufacturing is designed to create for a uniform and renewable therapeutic product available "off-the-shelf" for patients. IN8bio will be holding an investor event via webcast at the conference to introduce the program to the investment community on May 17, 2022, at 6:00 p.m. EDT. A link to the webcast will be available on the Events & Presentations page of the Company's website.
 - IN8bio plans to submit an investigational new drug (IND) application for a Phase 1b/2 clinical trial of INB-400 in GBM during the second half of 2022.
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Expected Upcoming Presentations

- **ASGCT 25th Annual Meeting, Washington, D.C., May 2022:** introducing a new program on “*The Development of Off-the-Shelf Manufacturing Strategies for iPSC-Based Gamma-Delta T Cells*” along with an oral presentation by Dr. Lamb, “*Off the Shelf Cell Therapies – Beyond T Cells (Education Session) and The Next Generation of $\gamma\delta$ T Cell-based Therapies*” by Dr. Lamb.
- **Advanced Therapies Congress Live, London, May 2022:** presenting “*New Directions in the Treatment of Solid Tumors with gdT Cells*” by Dr. Lamb.
- **Cambridge Healthcare Immuno-Oncology Therapeutic Development, London, May 2022:** presenting “*Genetically Modified gamma delta T cells in combination with chemotherapy: now in the clinic*” by Dr. Lamb
- **Cell Engager summit, Boston, May 2022:** presenting “*Gamma-Delta T-cells: Novel approaches to genetic engineering and cell-type specific therapeutic applications*” by Dr. Rochlin.
- **H.C. Wainwright Global Investment Conference, May 2022:** Mr. Ho will participate in a fireside chat on May 25, 2022, at 2 p.m. EDT.
- **American Society for Clinical Oncology (ASCO), June 2022:** presenting “Phase 1 study of drug-resistant immunotherapy (DRI) with gene-modified autologous $\gamma\delta$ T cells in patients with newly diagnosed glioblastoma multiforme (GBM) receiving maintenance temozolomide (TMZ)” by Louis B. Nabors, M.D.
- **Jefferies Healthcare Conference, June 2022:** Mr. Ho will present at 1:30 p.m. EDT on Wednesday, June 8, 2022.

First Quarter 2022 Financial Highlights

- **Cash position:** As of March 31, 2022, the Company had cash of \$32.1 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 research and development and continued operations to advance its programs.
 - **Research and Development (R&D) expenses:** R&D expenses were \$2.4 million for the three months ended March 31, 2022, compared to \$1.2 million for the comparable prior year period. The increase in R&D expenses were primarily due to (i) increased third-party clinical trial and IND-related activities, (ii) contract manufacturing costs for the ongoing INB-200 clinical trial and (iii) increased personnel-related costs, including salaries, benefits and stock-based compensation due to increased headcount.
 - **General and administrative expenses:** General and administrative expenses were \$3.8 million for the three months ended March 31, 2022, compared to \$1.1 million for the comparable prior year period. The increase was primarily
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due to increased legal expenses, insurance costs and expenses associated with operating as a public company.

- **Net loss:** The Company reported a net loss attributable to common stockholders of \$6.1 million, or \$0.33 per basic and diluted common share, for the three months ended March 31, 2022, compared to a net loss attributable to common stockholders of \$3.1 million, or \$0.82 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 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 timing of initiation, progress and scope of clinical trials for IN8bio's product candidates; the potential of IN8bio's DeltEx platform to discover and develop innovative product candidates, including iPSC-derived cell therapies; and IN8bio's ability to achieve planned milestones, including data readouts from its trials and plans to file an IND application. 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; 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-K filed with the Securities and Exchange Commission (SEC) on March 17, 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.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current assets		
Cash	\$ 32,107	\$ 37,021
Prepaid expenses and other current assets	1,167	1,959
Total Current Assets	<u>33,274</u>	<u>38,980</u>
Non-current assets		
Property and equipment, net	240	97
Construction in progress	497	403
Restricted cash	251	251
Right of use assets - financing leases	555	704
Right of use assets - operating leases	1,563	1,630
Other non-current assets	158	158
Total Non-Current Assets	<u>3,264</u>	<u>3,243</u>
Total Assets	<u>\$ 36,538</u>	<u>\$ 42,223</u>
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	\$ 553	\$ 395
Accrued expenses and other current liabilities	884	1,235
Short-term financing lease liability	325	392
Short-term operating lease liability	306	234
Total Current Liabilities	<u>2,068</u>	<u>2,256</u>
Long-term financing lease liability	201	269
Long-term operating lease liability	1,434	1,515
Total Non-Current Liabilities	<u>1,635</u>	<u>1,784</u>
Total Liabilities	<u>3,703</u>	<u>4,040</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock, par value \$0.0001 per share; 490,000,000 shares authorized at March 31, 2022 and December 31, 2021; 18,812,267 and 18,781,242 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	71,669	70,872
Accumulated deficit	(38,836)	(32,691)
Total Stockholders' Equity	<u>32,835</u>	<u>38,183</u>
Total Liabilities and Stockholders' Equity	<u>\$ 36,538</u>	<u>\$ 42,223</u>

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 2,381	\$ 1,245
General and administrative	3,764	1,118
Total operating expenses	6,145	2,363
Loss from operations	(6,145)	(2,363)
Net loss	\$ (6,145)	\$ (2,363)
Net loss attributable to common stockholders	\$ (6,145)	\$ (3,069)
Net loss per share attributable to common stockholders – basic and diluted	\$ (0.33)	\$ (0.82)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	18,800,546	3,764,488

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