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 17, 2022

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 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 17, 2022, IN8bio, Inc. issued a press release announcing its financial results for the year ended December 31, 2021. 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 17, 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: March 17, 2022

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 2021 Financial Results and Provides Corporate Update

- *All patients treated with INB-200, in clinical development for the treatment of glioblastoma multiforme (GBM), have shown a well-tolerated safety profile and longer than anticipated progression free survival (PFS) to date.*
- *All patients treated with INB-100, in clinical development for the treatment of leukemia undergoing hematopoietic stem cell transplantation (HSCT), have remained in remission, two for more than 1.5 years.*
- *Closed initial public offering raising gross proceeds of $40 million to advance genetically modified gamma-delta T cell therapeutic candidates into clinical development and to expand the pipeline.*

NEW YORK, Mar. 17, 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 fourth quarter and full-year ending December 31, 2021. In addition, the Company provided an overview of recent corporate developments.

“Our leading clinical programs, INB-100 in leukemia and INB-200 in newly diagnosed GBM, are advancing and generating promising early clinical results,” said William Ho, Chief Executive Officer and co-founder of IN8bio. “We are encouraged by these data and hopeful that these trends will translate to real long-term benefits for cancer patients in terms of durable remissions and increased time with respect to survival. We look forward to providing clinical updates and announcing exciting new preclinical programs throughout this year.”

Business Highlights & Updates

- In October 2021, IN8bio announced the peer-reviewed publication of preclinical results that provide the foundational support for the Phase 1 trial of its DeltEx Drug Resistant Immunotherapy (DRI) in newly diagnosed GBM. This work, published in *Scientific Reports,* a Nature Portfolio journal, focused on the use of gamma-delta T cells genetically engineered to be chemotherapy resistant through the addition of a gene encoding the O6-Methylguanine-DNA Methyltransferase (MGMT) protein. Concurrent dosing of DRI cells with temozolomide (TMZ) chemotherapy resulted in 80% long-term survivors and complete eradication of tumor in a patient-derived xenograft model of classical primary high-grade gliomas.

- In November 2021, IN8bio presented preclinical data on the potential for their DeltEx DRI in combination with poly (ADP-ribose) polymerase (PARP) inhibitors in solid tumors at the 36th Annual Meeting of the Society for Immunotherapy Conference (SITC; Poster 158). The research, conducted in collaboration with the laboratory of Dr. Anita Hjelmeland, at the University of Alabama at Birmingham (UAB), demonstrated that gamma-delta T cell therapy could be enhanced through therapeutic combinations that drive increased mRNA expression of immune markers (NKG2DL) by as much as 2,800%.

- In November 2021, IN8bio appointed Trishna Goswami, M.D., as Chief Medical Officer. Dr. Goswami has extensive experience managing the clinical development and regulatory approval of oncology product candidates, including those for both solid and hematologic tumors.

- In December 2021, IN8bio promoted Kate Rochlin, Ph.D., to Chief Operating Officer. Dr. Rochlin had previously served as the Company's Vice President, Operations and Innovation.

- In December 2021, IN8io provided an update from the ongoing Phase 1 clinical trial of its allogeneic gamma-delta T cell therapy, INB-100, in leukemia patients undergoing HSCT. Of the three patients treated, all remain in morphologic remission with durable responses of greater than 1.5 years observed in two patients. The third patient remains in remission for six months as of December 2021.

- In January 2022, IN8bio provided a clinical update from the Phase 1 clinical trial of its genetically modified gamma-delta T cell therapy candidate in newly diagnosed GBM. In the single ascending dose cohort 1 (n=3), all three patients showed no dose limiting toxicities (DLTs), cytokine release syndrome, or neurotoxicity and showed a manageable safety profile. Cohort 2, which received three repeat doses of DeltEx DRI gamma-delta T cells, includes one patient who has received all three doses without any DLTs or significant drug related adverse events. Of the four patients treated as of the last clinical update on January 6, 2022, all have exceeded their expected progression-free survival interval based on age and MGMT status and with encouraging trends in overall survival.

Upcoming Milestones and Events

- Second half of 2022: Plan to file an investigational new drug (IND) application for a Phase 1b/2 clinical trial of INB-400 in GBM.

- May 2022: plan to hold an investor event during the American Society of Gene + Cell Therapy (ASGCT) 25th Annual Meeting.

- 2022: Plan to announce new preclinical programs and indications.

Recent and Expected Upcoming Scientific Presentations

- European Society for Medical Oncology (ESMO) Targeted Anticancer Therapies Congress 2022 (virtual), March 2022: presenting preclinical data on novel gamma-delta CAR-T approaches for systemic delivery in solid tumors (Poster 23P).

- 48th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) (hybrid), Prague, Czech Republic, March 2022: presenting on INB-100 clinical status and correlative biology.

- American Association of Cancer Research (AACR) Annual Meeting 2022, New Orleans, April 2022: two presentations; (1) "Dual chlorotoxin and methylguanine-DNA methyltransferase (MGMT) gamma-delta T cells for drug resistant immunotherapy" (INB-300) and (2) "maintenance-phase temozolomide as a lymphodepletion platform for intracranial-adoptive gamma-delta T cell-based therapy in primary high-grade gliomas" (INB-200).

- International Society for Cell & Gene Therapy (ISCT) 2022, San Francisco, May 2022.

- ASGCT 25th Annual Meeting, Washington, D.C., May 2022: Presenting new programs along with an oral presentation by Lawrence Lamb, Ph.D., Off the Shelf Cell Therapies – Beyond T Cells (Education Session); The Next Generation of γδ T Cell-based Therapies.

Fourth Quarter and Full Year 2021 Financial Highlights

- **Cash position:** As of December 31, 2021, the Company had cash of $37.0 million, compared to $18.0 million as of December 31, 2020. The increase in cash was primarily due to the initial public offering proceeds, net of cash used by the Company in operations to advance its programs and research and development.

- **Research & Development (R&D) expenses:** R&D expenses were $2.7 million for the three months ended December 31, 2021, compared to $1.5 million for the comparable prior year period. R&D expenses were $7.3 million for the year ended December 31, 2021, compared to $5.4 million in the prior year. The increase in R&D expenses were primarily due to increased personnel-related costs, including salaries, benefits and stock-based compensation. In addition, for the year, the increase in R&D expenses were related to increased third-party clinical trial-related activities and contract manufacturing costs for the ongoing clinical trials.

- **General and administrative expenses:** General and administrative expenses were $3.2 million for the three months ended December 31, 2021, compared to $0.8 million for the comparable prior year period. General and administrative expenses were $7.3 million for the year ended December 31, 2021, compared

to $3.2 million in the prior year. The increase was primarily due to increased personnel costs, including salaries, benefits and stock-based compensation, increased legal expenses, facilities and costs associated with operating as public company.

- **Net loss:** The Company reported a net loss of $5.9 million, or $0.44 per basic and diluted common share, for the three months ended December 31, 2021, compared to a net loss of $2.3 million and a net loss attributable to common stockholders of $3.0 million, or $0.82 per basic and diluted common share, for the comparable prior year period. For the full year, net loss was $14.7 million, or $1.47 per basic and diluted common share compared to a net loss of $8.6 million and a net loss attributable to common stockholders of $10.3 million, or $3.02 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 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 and preclinical trials for IN8bio's product candidates; the potential of IN8bio's DeltEx platform to discover and develop innovative product candidates; and IN8bio's ability to achieve planned milestones, including data readouts from its trials. 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-Q filed with the Securities and Exchange Commission (SEC) on November 10, 2021, 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)

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash	$ 37,021	$ 17,994
Prepaid expenses and other current assets	1,959	150
Total Current Assets	38,980	18,144
Non-current assets		
Property and equipment, net	97	186
Construction in progress	403	—
Restricted cash	251	141
Deferred offering costs	—	2,439
Right of use assets - financing leases	704	—
Right of use assets - operating leases	1,630	—
Other non-current assets	158	—
Total Non-Current Assets	3,243	2,766
Total Assets	$ 42,223	$ 20,910
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Liabilities		
Current liabilities		
Accounts payable	$ 395	$ 620
Accrued expenses and other current liabilities	1,235	1,778
Short-term financing lease liability	392	—
Short-term operating lease liability	234	—
Loan payable, current	—	174
Total Current Liabilities	2,256	2,572
Deferred rent	—	17
Long-term financing lease liability	269	—
Long-term operating lease liability	1,515	—
Total Non-Current Liabilities	1,784	17
Total Liabilities	4,040	2,589
Commitments and Contingencies		
Convertible preferred stock, Series A	—	34,900
Stockholders' Equity (Deficit)		
Common stock, par value $0.0001 per share; 490,000,000 and 50,700,000 shares authorized at December 31, 2021 and 2020, respectively; 18,781,242 and 3,764,488 shares issued and outstanding at December 31, 2021 and 2020, respectively	2	1
Additional paid-in capital	70,872	1,458
Accumulated deficit	(32,691)	(18,038)
Total Stockholders' Equity (Deficit)	38,183	(16,579)
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)	$ 42,223	$ 20,910

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

	December 31, 2021	December 31, 2020
Operating expenses:		
Research and development	$ 7,347	$ 5,378
General and administrative	7,306	3,179
Total operating expenses	14,653	8,557
Loss from operations	(14,653)	(8,557)
Net loss	$ (14,653)	$ (8,557)
Net loss attributable to common stockholders	$ (14,653)	$ (10,340)
Net loss per share attributable to common stockholders – basic and diluted	$ (1.47)	$ (3.02)
Weighted-average number of shares used in computing net loss per common share – basic and diluted	9,969,733	3,419,075

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