IN8bio Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 12, 2022

- Unveiled a new preclinical program focused on developing iPSC derived gamma-delta T cells and presented early findings at the ASGCT Annual Meeting.
- Presented data from Phase 1 clinical trial of INB-200 in patients with newly diagnosed GBM showing five of six fully dosed patients exceeded both median and expected progression free survival (PFS), with a sixth patient early in follow up; two patients have exceeded overall survival (OS) benchmarks established by Stupp et al, 2005 to-date.
- Continued to demonstrate durable morphologic complete responses from INB-100 Phase 1 clinical trial in leukemia patients with two of three patients relapse free at two years to date and all three relapse free past one year.
- Appointed seasoned executives to the roles of Senior Vice President, Business Development, Vice President, Regulatory Affairs, and Vice President, Clinical Operations.

NEW YORK, Aug. 12, 2022 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a clinical-stage biopharmaceutical company focused on discovering and developing innovative gamma-delta T cell therapies that utilize its DeltEx platform, today announced financial results and operational highlights for the quarter ended June 30, 2022. In addition, the Company provided an overview of recent corporate developments.

“Our team continues to execute and advance our gamma-delta programs on multiple fronts. Our Phase 1 clinical trials for both DeltEx product candidates, INB-200 in GBM and INB-100 in leukemia patients undergoing stem cell transplantation, continue to progress with encouraging durability data. We introduced our iPSC derived gamma-delta T cell platform at the ASGCT annual meeting, and we have been receiving positive feedback on this new program,” said William Ho, CEO and co-founder of IN8bio. “During the quarter and into July, we continued to expand our management team; we have attracted talented individuals who have built their careers and established their reputations in well-recognized companies like Genentech, Novartis, Janssen, Bristol Myers Squibb and Covance. We believe they will be instrumental in shaping IN8bio’s future. The IN8bio team continues to be disciplined, and we are working to dedicate our resources to accelerating IN8bio’s growth and momentum.”

Business Highlights & Clinical Updates

- In May 2022, IN8bio unveiled a new preclinical program focused on developing induced pluripotent stem cell (iPSC) derived gamma-delta T cells and presented its early findings at the American Society of Gene and Cell Therapy (ASGCT) Annual Meeting. Uniquely, IN8bio has been able to demonstrate the ability to derive both Vd1+ and Vd2+ iPSC gamma-delta T cell clones. These iPSC-derived gamma-delta T cells demonstrated robust cytotoxicity and can be genetically modified with an internally developed chimeric antigen receptor (CAR-T) construct at a high transduction yield. Scalable iPSC-based cellular manufacturing is designed to create for a uniform and renewable therapeutic product available “off-the-shelf” for patients.
- In June 2022, IN8bio provided an update on the INB-200 Phase 1 clinical trial in newly diagnosed glioblastoma multiforme (GBM) patients at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. Five of six fully dosed patients exceeded both median and expected progression-free survival (PFS), and two patients exceeded the expected overall survival (OS) benchmarks as of June 3, 2022. All patients demonstrated a manageable toxicity profile with no evidence of cytokine release syndrome (CRS), tumor lysis syndrome (TLS) or immune effector cell-associated neurotoxicity syndrome (ICANS).
- In June 2022, IN8bio held a successful pre-investigational new drug application (pre-IND) meeting with the Food and Drug Administration. The meeting provided guidance and confirmed IND filing requirements for the INB-400 program. IN8bio expects to file the IND by year-end.
- In July 2022, IN8bio announced a patent covering the composition of matter for IN8bio’s Drug Resistant Immunotherapy (DRI) platform. The patent broadens the Company’s intellectual property coverage of genetically engineered innate immune cells beyond gamma-delta T cells to include NK cells.
- In July 2022, IN8bio provided an update from the ongoing Phase 1 clinical trial of INB-100 in leukemia patients undergoing haploidentical stem cell transplantation. All three high-risk AML patients from the first cohort continue to demonstrate durable morphologic complete responses (CR) and remain progression-free and alive for more than one year. Two of the three patients remain in morphologic CR for more than two years. The safety profile continues to be manageable with no dose-limiting toxicities.

Recent Team Growth

- In April 2022, IN8bio announced the 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 more than a combined 45 years of clinical and regulatory experience to the IN8bio team.

- In July 2022, IN8bio appointed Kenneth R. LaMontagne, Ph.D., as Senior Vice President, Business Development to lead the Company's business development activities. Dr. LaMontagne is an industry leader with more than 20 years of experience, including licensing, collaborations, search and evaluation, M&A and corporate strategy including in the fields of cell therapy and oncology. He gained his experience in both large pharma and small biopharmaceutical companies.

Second Quarter 2022 Financial Results

Research and development (R&D) expenses were $3.5 million for the three months ended June 30, 2022, compared to $2.1 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 were $3.7 million for the three months ended June 30, 2022, compared to $1.0 million for the comparable prior year period. The increase was primarily due to increased headcount, insurance, legal expenses, and expenses associated with operating as a public company.

The Company reported a net loss attributable to common stockholders of $7.2 million, or $0.38 per basic and diluted common share, for the three months ended June 30, 2022, compared to a net loss attributable to common stockholders of $3.8 million, or $1.00 per basic and diluted common share, for the comparable prior year period.

As of June 30, 2022, the Company had cash of $25.7 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.

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; IN8bio's ability to achieve planned milestones, including data readouts from its trials and plans to file an IND application; and the impact recent management team additions will have on the progression of the Company. 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 May 12, 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)

	June 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets		
Cash	$ 25,742	$ 37,021
Prepaid expenses and other current assets	1,257	1,959
Total Current Assets	26,999	38,980
Non-current assets		

Property and equipment, net	220	97
Construction in progress	1,405	403
Restricted cash	252	251
Right of use assets - financing leases	453	704
Right of use assets - operating leases	1,413	1,630
Other non-current assets	246	158
Total Non-Current Assets	3,989	3,243
Total Assets	$ 30,988	$ 42,223
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	$ 887	$ 395
Accrued expenses and other current liabilities	1,525	1,235
Short-term financing lease liability	299	392
Short-term operating lease liability	261	234
Total Current Liabilities	2,972	2,256
Long-term financing lease liability	132	269
Long-term operating lease liability	1,316	1,515
Total Non-Current Liabilities	1,448	1,784
Total Liabilities	4,420	4,040
Commitments and Contingencies		
Stockholders' Equity		
Common stock, par value $0.0001 per share; 490,000,000 shares authorized at June 30, 2022 and December 31, 2021; 18,838,471 and 18,781,242 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	72,581	70,872
Accumulated deficit	(46,015)	(32,691)
Total Stockholders' Equity	26,568	38,183
Total Liabilities and Stockholders' Equity	$ 30,988	$ 42,223

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 3,504	$ 2,064	$ 5,885	$ 3,310
General and administrative	3,675	986	7,439	2,103
Total operating expenses	7,179	3,050	13,324	5,413
Loss from operations	(7,179)	(3,050)	(13,324)	(5,413)
Net loss	$ (7,179)	$ (3,050)	$ (13,324)	$ (5,413)
Net loss attributable to common stockholders	$ (7,179)	$ (3,765)	$ (13,324)	$ (6,834)
Net loss per share attributable to common stockholders – basic and diluted	$ (0.38)	$ (1.00)	$ (0.71)	$ (1.82)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	18,828,680	3,764,488	18,814,691	3,764,488

Company Contact:
IN8bio, Inc.
Patrick McCall
+ 1 646.600.6GDT (6438)
info@IN8bio.com

Investors:
Solebury Trout
David Buck
+ 1 646.378.2927
dbuck@soleburytrout.com

Media:

Burns McClellan, Inc.
Katie Larch / Robert Flamm, Ph.D.
+1 212.213.0006
klarch@burnsmc.com / rflamm@burmsmc.com