IN8bio Reports Third Quarter 2024 Financial Results and Recent Corporate Highlights

November 12, 2024

- Reported 100% of Acute Myeloid Leukemia (AML) patients treated in INB-100 remain in complete remission (CR) at the 2024 European Hematology Association Congress and received FDA guidance for a future INB-100 registrational trial
- INB-100 trial currently expanding enrollment up to approximately 25 patients at the recommended Phase 2 dose (RP2D) along with the potential to add additional centers and a prospective parallel observational cohort as a control
- Closed private placement for net proceeds of $11.6 Million in October 2024 extending cash runway through 2025

NEW YORK, Nov. 12, 2024 (GLOBE NEWSWIRE) -- IN8bio, Inc. (Nasdaq: INAB), a leading clinical-stage biopharmaceutical company developing innovative gamma-delta T cell therapies for cancer, today reported financial results for the third quarter ended September 30, 2024, and recent corporate highlights.

“This past quarter marked a critical moment for IN8bio. We streamlined our operations and refined our pipeline to focus our resources. This strategic realignment enhances our capacity to deliver on the potential of gamma-delta T cell therapies, which are increasingly gaining recognition for their significant contributions to immunity.” said William Ho, CEO and co-founder of IN8bio. “INB-100 is our allogeneic therapy in development for the treatment of patients with leukemias. The FDA’s guidance received in a Type B meeting over the summer provides a clear path forward for a potential registrational trial. We’ve secured additional funding to advance INB-100 through the ongoing expansion cohort in the Phase 1 study that will provide additional data to further de-risk the program. With a leaner, more focused organization, we are advancing INB-100 and seeking opportunities to potentially partner assets in our pipeline.”

Corporate Highlights and Recent Developments

- IN8bio will present updated clinical trial results from INB-200 in a Plenary Oral Presentation at the Society for Neuro-Oncology (SNO) in November 2024.
- A poster presentation updating patient data from the INB-100 trial will be presented at the American Society of Hematology (ASH) in December 2024.
- Secured net proceeds of $11.6 million from a private placement that is expected to provide cash runway into the first quarter of 2026.
    - Funding is expected to be used to continue to advance development of INB-100, future product candidates and for working capital and other general corporate purposes.
    - Focusing on continued enrollment in the Phase 1 expansion cohort of up to approximately 25 patients at the RP2D of INB-100, with plans to potentially add additional centers and include a parallel observational arm to provide control data.
- Received FDA guidance in a Type B meeting, on the registrational path for INB-100 in AML, an allogeneic gamma-delta T cell therapy demonstrating early signs of activity in high-risk leukemia patients.
    - All AML patients treated with INB-100 have remained in CR as of August 31, 2024.
    - Older, high-risk leukemia patients receiving non-myeloablative, reduced intensity conditioning (RIC), have exceeded the expected one-year progression-free survival (PFS) rate of approximately 40-50% post-haploidentical transplantation.
    - These data continue to demonstrate the broad clinical potential of gamma-delta T cells for difficult-to-treat cancers and provides support for the advancement of these therapies into pivotal trials.
    - Significant dose-dependent in vivo expansion and long-term persistence of circulating gamma-delta T cells has been observed up to 365 days.
- IN8bio implemented a plan to optimize resource allocation through pipeline prioritization and a strategic workforce reduction that was completed in the third quarter of 2024. IN8bio also suspended enrollment in its Phase 2 clinical trial of INB-400 for newly diagnosed glioblastoma (GBM) but will continue monitoring previously treated GBM patients in both the Phase 2 INB-400 and the Phase 1 INB-200 clinical trials to assess progression-free and overall survival. Updated data to be presented at future medical meetings.

Third Quarter 2024 Financial Highlights

Research and Development (R&D) expenses: R&D expenses were $3.3 million, compared to $3.8 million for the comparable prior year period. The decrease of $0.5 million was primarily due to a decrease of $0.6 million in personnel expenses, including salaries and stock-based compensation (SBC) as a result of our workforce reduction and a decrease of $0.1 million in facility-related and other expenses primarily due to decreases in R&D activities in connection with our pipeline prioritization, partially offset by an increase of $0.2 million in direct costs related to our clinical trials, primarily related to the INB-400 program. As part of the Company's pipeline prioritization announced in September 2024, further clinical development on INB-400 has been suspended.

General and Administrative (G&A) expenses: G&A expenses were $2.7 million, compared to $3.4 million for the comparable prior year period. The decrease of $0.7 million was primarily due to a decrease in salaries and bonus expense in connection with our workforce reduction and cost savings related to directors' and officers' insurance premiums, partially offset by an increase in professional services.

Severance and related charges: Severance and related charges were $1.1 million for the three months ended September 30, 2024, compared to zero for the comparable prior year period. The increase of $1.1 million was due to one-time costs related to the September 2024 workforce reduction, including SBC expense of $0.8 million resulting from acceleration in full of outstanding unvested stock options at the separation date for the impacted employees, and $0.3 million related to severance payments.

Net loss: Net loss was $7.1 million, or $0.15 per basic and diluted common share, compared to a net loss of $7.2 million, or $0.23 per basic and diluted common share, for the comparable prior year period.

Cash position: As of September 30, 2024, the Company had cash of $4.0 million, compared to $10.2 million, as of June 30, 2024. Subsequently in October 2024 closed a Private Placement of $11.6 Million in net proceeds.

About IN8bio

IN8bio is a clinical-stage biopharmaceutical company developing gamma-delta T cell-based immunotherapies for cancer patients. 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. The company's lead program, INB-100, is focused on AML evaluating haplo-matched allogenic gamma-delta T cells given to patients following a hematopoietic stem cell transplant. The company is also evaluating autologous DeltEx DRI gamma-delta T cells, in combination with standard of care, for glioblastoma. For more information about IN8bio, 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: IN8bio's ability to realize the expected benefits of its pipeline prioritization and workforce reduction, including ensuring IN8bio's sustainability and delivering on the potential of INB-100; IN8bio's ability to add a parallel control cohort to the INB-100 trial; IN8bio's cash runway and expected capital requirements, including the sufficiency of IN8bio's cash to advance INB-100 through the expansion cohort of the Phase 1 study; IN8bio's expected use of the proceeds from its October 2024 private placement; the broad clinical potential of gamma-delta T cells for difficult-to-treat cancers; IN8bio's ability to achieve anticipated milestones, including expected presentations and data readouts from its trials, enrollment of additional patients in its clinical trials, and advancement of clinical development plans; and other statements that are not historical fact. 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 be unable to raise additional capital and could be forced to delay, further reduce or to explore other strategic options for certain of our development programs, or even terminate its operations; IN8bio's ability to continue to operate as a going concern; 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; the uncertainty of 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 August 8, 2024, 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)

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets		
Cash	$ 4,001	$ 21,282
Prepaid expenses and other current assets	2,702	3,343
Total Current Assets	6,703	24,625
Non-current assets		
Property and equipment, net	3,081	3,514
Construction in progress	—	182
Deferred issuance costs	181	—
Restricted cash	259	256
Right-of-use assets - finance leases	1,302	1,364
Right-of-use assets - operating leases	4,116	3,513

Other non-current assets	324	255
Total Non-Current Assets	9,263	9,084
Total Assets	$ 15,966	$ 33,709
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	$ 1,137	$ 924
Accrued expenses and other current liabilities	769	2,955
Short-term finance lease liability	809	694
Short-term operating lease liability	920	820
Total Current Liabilities	3,635	5,393
Long-term finance lease liability	399	525
Long-term operating lease liability	3,344	2,854
Total Non-Current Liabilities	3,743	3,379
Total Liabilities	7,378	8,772
Stockholders' Equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively. No shares issued and outstanding	—	—
Common stock, par value $0.0001 per share; 490,000,000 shares authorized at September 30, 2024 and December 31, 2023; 46,786,948 and 43,287,325 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	5	4
Additional paid-in capital	124,079	116,152
Accumulated deficit	(115,496)	(91,219)
Total Stockholders' Equity	8,588	24,937
Total Liabilities and Stockholders' Equity	$ 15,966	$ 33,709

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 3,309	$ 3,786	$ 13,368	$ 12,305
General and administrative	2,732	3,383	10,007	10,434
Severance and related charges	1,068	—	1,068	—
Total operating expenses	7,109	7,169	24,443	22,739
Interest income	23	—	166	—
Other income	—	—	—	330
Loss from operations	(7,086)	(7,169)	(24,277)	(22,409)
Net loss	$ (7,086)	$ (7,169)	$ (24,277)	$ (22,409)
Net loss per share – basic and diluted	$ (0.15)	$ (0.23)	$ (0.53)	$ (0.79)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	47,321,394	31,545,783	45,690,587	28,275,193

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