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IN8bio, Inc. (INAB: NASDAQ)

INAB: AML & GBM Clinical Update

IN8Bio's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. Additionally, we apply a success probability of 20% to the γδ T Cell programs selecting acute myeloid leukemia (AML) and glioblastoma multiforme (GBM) as move forward indications. The adjustments recognize regulatory and commercialization risks. The model includes contributions from the United States and the developed world.

Current Price (8/14/2024)	$0.65
Valuation	**$5.00**

OUTLOOK

IN8Bio is a clinical-stage, oncology-focused biotechnology company using γδ T cells against solid and hematological tumors. Its pipeline is built on the DeltEx platform & drug-resistant immunotherapy (DRI) technology which have produced clinical candidates targeting leukemia & GBM. INB-100 is evaluating leukemia in a Ph1 study, while INB-200 & INB-400 are Ph1 and Ph2 assets evaluating GBM.

INB-100 is an allogeneic DeltEx-produced cell therapy for leukemia patients undergoing HSCT transplant. Leukemia patients see a high rate of recurrence which may be effectively treated by INB-100. INB-200 is a DeltEx DRI product completing Ph1 studies in GBM. INB-400 is the successor to INB-200. It is an autologous DeltEx DRI product to treat newly diagnosed and recurrent GBM, dosing first patients in 2024. It may add autologous treatment arms in 2025. The DRI genetic modification allows it to resist chemotherapy and persist in the tumor microenvironment.

While initial clinical studies target leukemia & GBM, we see DeltEx DRI as a platform that can expand beyond these initial initiations. Combination studies with chemotherapy, checkpoint and PARP inhibitors may emerge in future iterations.

SUMMARY DATA

52-Week High	**2.48**
52-Week Low	**0.61**
One-Year Return (%)	**-44.4**
Beta	**0.1**
Average Daily Volume (sh)	**397,145**
Shares Outstanding (mil)	**47.4**
Market Capitalization ($mil)	**30.8**
Short Interest Ratio (days)	**2.25**
Institutional Ownership (%)	**36.2**
Insider Ownership (%)	**21.6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.30 A	-$0.27 A	-$0.23 A	-$0.24 A	-$1.00 A
2024	-$0.20 A	-$0.19 A	-$0.14 E	-$0.13 E	-$0.65 E
2025					-$0.68 E
2026					-$0.60 E

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What's New?

IN8bio, Inc (NASDAQ: INAB) reported second quarter 2024 financial results and achievements on August 8th followed a few days later by an update on the INB-100 and INB-200 programs and the anticipated path forward. In addition to showing continued impressive survival duration, IN8bio also shared the anticipated registrational trial design for INB-100 in acute myeloid leukemia (AML). In June, the company presented INB-100 and INB-200 data at the European Hematology Association (EHA) Congress and the American Society of Clinical Oncology (ASCO) Annual Meeting. Other recent highlights include presentation of γδ T cell manufacturing processes at the International Society for Cell & Gene Therapy meeting and participation in investor conferences.

IN8bio released second quarter 2024 earnings along with the filing of its Form 10-Q on August 8th. IN8bio generated no revenues in 2Q:24 and incurred operating expense of $8.7 million, producing a net loss of ($8.6) million or ($0.19) per share.

For the quarter ending June 30th, 2024 and versus the same comparable prior year period:

- Research & development expenses totaled $5.2 million, rising 25% from $4.1 million due to higher personnel related costs and direct clinical costs. By program, more spending on the INB-100 and INB-400 program were partially offset by lower INB-200 spending. Preclinical expenses were also down;
- General & administrative expenses were $3.5 million, falling 1% from $3.6 million;
- Interest income was $60,000 versus $0 with the contribution arising interest income;
- Net loss was ($8.6) million, or ($0.19) per share, compared to ($7.7) million, or ($0.27) per share.

At the end of 2Q:24, cash and marketable securities totaled $10.2 million, compared to year end 2023 cash balance of $21.3 million. Cash burn for the second quarter was ($6.2) million versus ($5.4) million in the comparable prior year period. For the first half, cash burn was ($14.2) vs. ($13.2) in 1H:23. Cash from financing was $3.1 million in 1H:24 which was mostly related to proceeds from stock issuance. This compares to $12.0 million of cash from financing in 1H:23.

EHA INB-100

IN8bio presented updated results from its Phase I INB-100 trial at the European Hematology Association (EHA) Congress on June 13th in Madrid, Spain. Details of the presentation were provided in a press release and conference call after the close on June 13th, 2024 along with a slide deck to guide the discussion. Stakeholders had been eagerly awaiting the update on this trial since impressive data was presented back in December 2023 at the American Society of Hematology (ASH) Annual Meeting. Six months later, all (N=10) of the treated leukemia patients achieved complete remission at the one-year mark. Of the 10 patients evaluated, 30% have achieved overall survival in excess of three years and one beyond four years. Only one patient has died, and this was attributed to idiopathic pulmonary fibrosis and not the experimental medication nor leukemia. Multiple resources suggest that about 50% of patients relapse 12 months after hematopoietic stem cell transplant for hematological malignancies, highlighting the remarkable results that were achieved with no patients relapsing during the year long period.

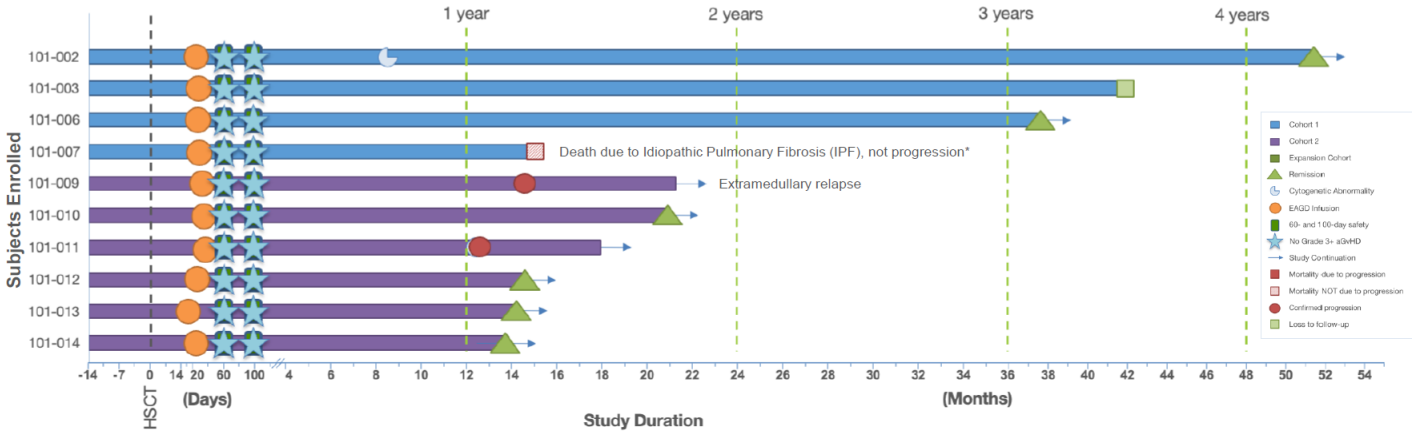
The achievement is even more impressive when subject risk profiles are considered. The average age of the 10-patient group was approximately 68 years[1] and over half had mutations or unfavorable cytogenetics associated with worse performance. Complete remission at one year is an excellent result that provides more confidence of success in a registrational trial which will be the topic of IN8bio's next interaction with the FDA.

IN8bio will expand the trial to enroll another 10 patients at the recommended Phase II dose which is a single dose of 3 x 10^6 γδ T cells/kg. Further updates from the trial are expected over the remainder of 2024 and in 2025. The company plans to discuss the details of a registrational trial with the FDA in a Type B meeting this summer.

In a follow up presentation on August 12th, IN8bio provided INB-100 patient status as of August 1st. Survival for all of the AML patients had continued from the prior update on May 31st, extending overall survival for each patient by two months. Three patients have now remained relapse-free for over three years compared to two in May.

[1] In the Luznik 2008 paper, median age was 46 years. Luznik, L. *et al*. HLA-Haploidentical Bone Marrow Transplantation for Hematologic Malignancies Using Nonmyeloablative Conditioning and High-Dose, Post-transplantation Cyclophosphamide. Biology of Blood and Marrow Transplantation 14:641-650 (2008)

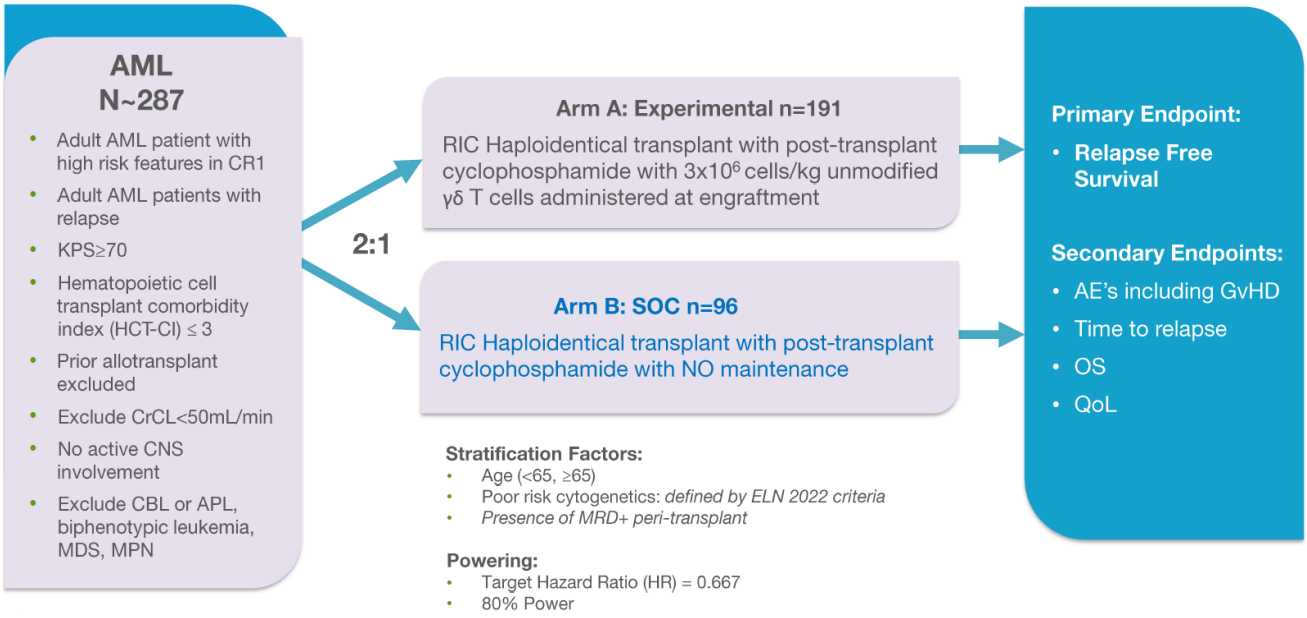
Exhibit I – INB-100 Patient Progression



Source: IN8bio August 2024 Program Update Slide Deck

IN8bio has met with the FDA for guidance on pivotal study design that can support the filing of a biologic license application (BLA). The trial will enroll just under 300 AML patients in a 2:1 randomization. The primary endpoint for the trial will be relapse free survival with secondary endpoints revolving around safety, time to relapse, overall survival and quality of life metrics.

Exhibit II – Registrational Phase II Trial Design for INB-100 in AML

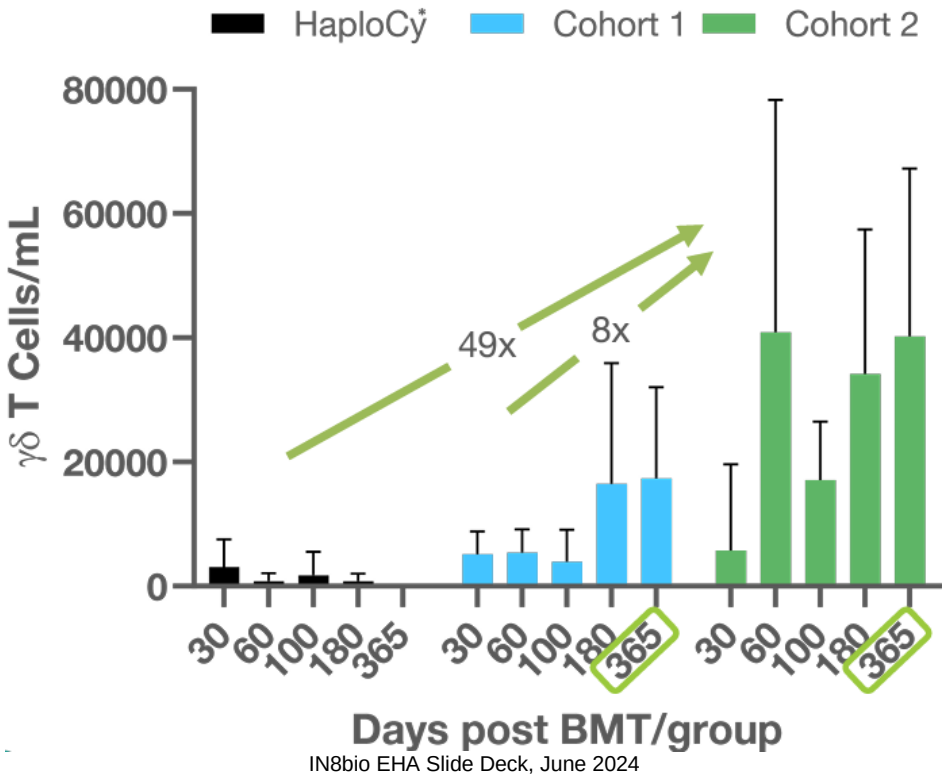


Source: IN8bio August 2024 Program Update Slide Deck

Persistence

In the December 2023 update, IN8bio presented data showing a year of persistence for γδ T cells in the two trial cohorts. The persistence was especially strong in the second dosing level, which also demonstrated *in vivo* expansion. The data six months later reinforced this finding and closely matched December's data as shown in the following exhibit.

Exhibit III – γδ T Cell Count Following Infusion



IN8bio EHA Slide Deck, June 2024

Safety

Safety was another strong point reinforced in the updated information for INB-100. No dose limiting toxicities, cytokine release syndrome (CRS), neurotoxicity or immune effector cell-associated neurotoxicity syndrome (ICANS) were observed. There have been few serious infections which can arise during immune system reconstitution. One patient died due to idiopathic pulmonary fibrosis, which is an associated adverse response to transplants. The patient population presented several high-risk features including trisomy of chromosome 8 and deletion of chromosome 7 as well as other difficult mutations that appeared in six of the ten evaluable subjects. Below we summarize the treatment-emergent adverse events (TEAEs) that occurred in 2 or more subjects.

Exhibit IV – Summary of Patient Adverse Events

Adverse Events	Total (%)	Grade 1/2 (%)	Grade 3 (%)	Grade 4 (%)
Platelet count decreased	100	40	60	
WBC decreased	90	50	30	10
ANC decreased	80	40	10	30
ALC decreased	60		40	20
Anemia	90	50	40	
Hypomagnesemia	60	60		
Creatinine increased	50	50		
Hyperglycemia	20	10	10	
Hypokalemia	40	40		
Hyponatremia	40	40		
Hypertension	30	30		
Hypotension	20	20		
Nausea	20	10	10	
Vomiting	20	20		
Diarrhea	20	20		
Dry Mouth	40	40		
Decreased appetite	20		20	
Peripheral edema	20	20		
Peripheral sensory neuropathy	20	20		
Dyspnea	30	30		
Insomnia	20	20		
Pollakiuria	20	20		
Rash maculopapular	60	50	10	

IN8bio EHA Slide Deck, June 2024. Data is as of May 15, 2024.

The INB-100 trial will continue with 10 more subjects planned and IN8bio. 100% remission for over one year for all 10 patients and persistence and durability of γδ T cells are strong indicators of the success of this program. Safety has been a strong attribute of INB-100, with most of the adverse events related to transplantation and not the γδ intervention. Graft vs. host disease (GvHD) has been limited with no greater than Grade 2 GvHD and 30% incidence of chronic GvHD.

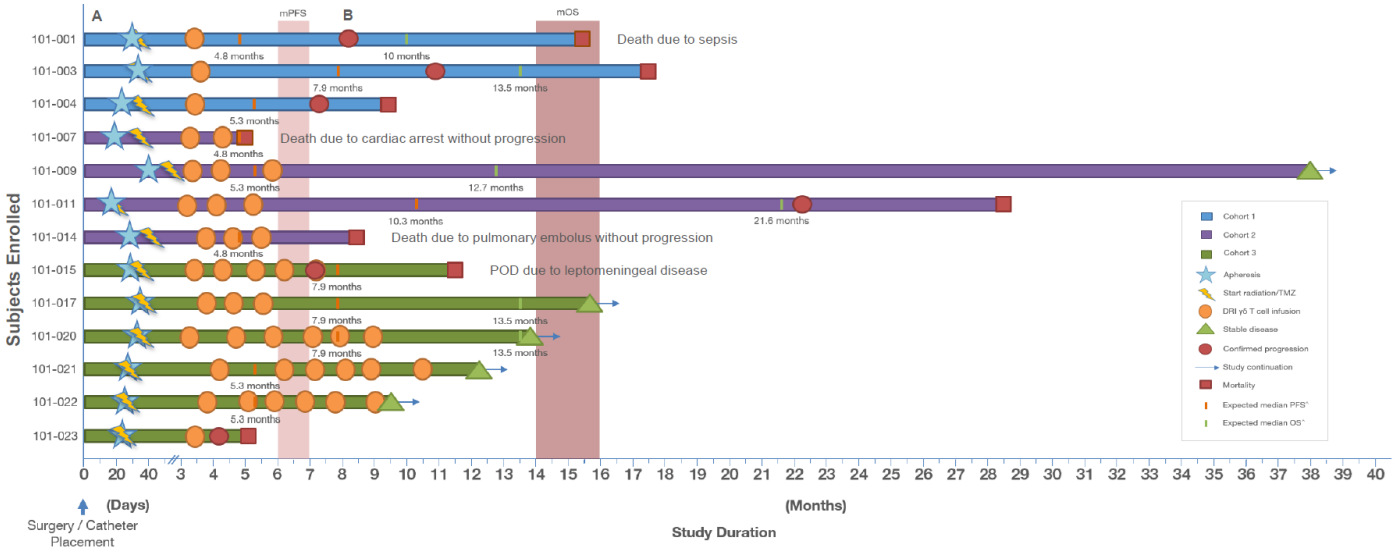
ASCO INB-200

IN8bio provided preliminary results from its Phase I INB-200 clinical trial at the American Society of Clinical Oncology (ASCO) 2024 meeting on June 1st. Sponsored by the University of Alabama, the trial is evaluating the use of γδ T cell therapy for treatment of patients with newly diagnosed glioblastoma (GBM). As of the cutoff date on May 1, 2024, 83% of evaluable patients had exceeded a median of seven months of progression free survival (PFS). Data from the trial was included in a poster presented at ASCO on June 1st in Chicago. The poster title is INB-200: Fully enrolled Phase 1 study of gene-modified autologous gamma-delta (γδ) T cells in patients with newly diagnosed glioblastoma multiforme (GBM) receiving maintenance temozolomide (TMZ). The presenter was Dr. Mina Lobbous of the University of Alabama at Birmingham.

IN8bio updated INB-200 patient status in its August 12th update call using an August 1st cutoff. This is three months after the May 1st data which was presented at ASCO. No patients died over the three-month period increasing the average time that evaluable patients have exceeded the Stupp Regimen median progression free survival of seven months to 92%. This compares to the 83% that were reported at ASCO and associated with the May 1st cutoff.

One patient remains progression free at 38 months. Overall survival (OS) was not calculated as five of thirteen remain alive and measurements are ongoing. Safety appears to be good with no cell therapy related toxicities such as immune effector cell-associated neurotoxicity syndrome or cytokine release syndrome reported in patients receiving up to the maximum dose of six infusions.

Exhibit V – INB-200 Patient Survival



Source: IN8bio August 2024 Program Update Slide Deck. Data is as of August 1, 2024

Standard of care (SoC) for newly diagnosed GBM requires primary resection, six weeks of daily chemoradiation therapy followed by six cycles of monthly maintenance temozolomide therapy (Stupp regimen). SoC produces a median PFS of 7 months and an overall survival (OS) of approximately 14 to 16 months as reported by IN8bio.

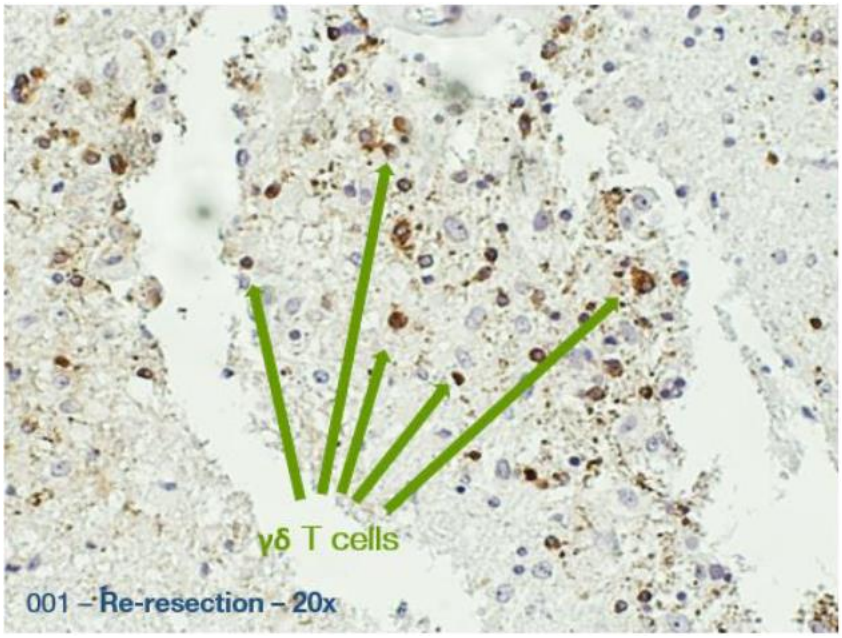
Our own review finds a range of reported survival of nine months to the upper twenty-month range depending upon specific characteristics. Most of the more recent resources we reviewed were 15 months or less. Factors associated with differing survival rates include age, further tumor treatment after surgery and MGMT promoter methylation among other contributors.[2,3,4,5,6,7]

[2] Brown, N.F. *et al*. Survival Outcomes and Prognostic Factors in Glioblastoma. Cancers. July 2022. (9.2 months)
[3] Hertler, C. *et al*. Long-term survival with IDH wildtype glioblastoma: first results from the ETERNITY Brain Tumor Funders' Collaborative Consortium. European Journal of Cancer, 2023 (9.9 months)
[4] Bjorland, L.S. *et al*. Treatment approach and survival from glioblastoma: results from a population-based retrospective cohort study from Western Norway. Oncology, 2021. (10.2 months)

Key Findings
All patients who completed the protocol mandated doses surpassed the median PFS of seven months with a majority also exceeding expected PFS based on age and O^6-methylguanine-DNA methyltransferase (MGMT) status. 92% exceeded mPFS of seven months as of May 30, 2024. The most common treatment-emergent adverse events were Grade 1 or 2 toxicities consisting of white blood cell and platelet count decreases related to temozolomide.

- Radiographic evaluation pre- and post-treatment included resolution of midline shift in one patient with evidence of changes in enhancement attributed to treatment effect in multiple patients;
- One subject was found to have a 36% decrease in a lesion attributed to positive treatment effect;
- Preserved γδ T cells were found in relapsed tumors 148 days after initial drug-resistant immunotherapy (DRI) infusion in one patient with paired biopsies, pointing to durability of DRI γδ T cells.

Exhibit VI – Biopsy Stain, 148 Days After Single Dose



IN8bio ASCO Poster, June 2024.

In this first study evaluating the use of γδ T cells in GBM, there has been promising data so far that exceeds SoC thresholds for PFS. γδ T cells have shown that they are safe with limited negative side effects and strong synergies with temozolomide which functions as an effective lymphodepleting regimen for use with cellular therapy. The DRI feature of IN8bio's modified γδ T cells allows the therapy to thrive in the tumor environment, immune from the effects of temozolomide and alerted to the cancer cells which are more visible to γδ T cell therapy when exposed to temozolomide. Early data from the INB-200 study shows that repeat doses result in longer time to progression. Positive results from the trial so far support further study. A follow-on trial for candidate INB-400 will take the baton from INB-200 and evaluate a larger group of patients.

INB-400 (Autologous and Allogeneic)

INB-400 is carrying on the effort initiated with INB-200 in the DeltEx DRI γδ T cell therapy for GBM. It is a Phase Ib/II study that will deploy activated, modified (DRI) γδ T cells along with TMZ for recurrent or newly diagnosed GBM. The trial's title is A Phase 1b / 2 Drug Resistant Immunotherapy with Activated, Gene Modified Allogeneic or Autologous γδ T Cells (DeltEx) in Combination with Maintenance Temozolomide in Subjects With Recurrent or Newly Diagnosed Glioblastoma. Trial details are provided on clinicaltrials.gov under the identifier NCT05664243.

The study has three arms. Arm A that will incorporate autologous cells, while Arms B and C will incorporate allogeneic cells. Arms A and C will enroll patients with newly diagnosed disease while Arm B will enroll individuals with re-

[5] Stupp R. *et al*. Radiotherapy plus concomitant and adjuvant Temozolomide for glioblastoma. N Engl J Med. 2005. (14.6 months)
[6] Chang, K. *et al*. Multimodal imaging patterns predict survival in recurrent glioblastoma patients treated with bevacizumab. Neuro-Oncology. 2016. (15 months)
[7] Alafandi, A. *et al*. Association of pre-radiotherapy tumour burden and overall survival in newly diagnosed glioblastoma adjusted for MGMT promoter methylation status. European Journal of Cancer. 2023. (27 methylated & 14 unmethylated).

lapsed disease. Subjects will receive SoC. During surgical resection of the tumor, a Rickham catheter will be placed so that INB-400 therapy can be delivered directly. Following resection, Arm A patients will undergo apheresis to extract γδ T cells that will be modified to be TMZ resistant. Allogeneic donors will provide cell product for Arms B and C. Subjects in all arms will then receive six weeks of chemotherapy with TMZ and radiation. The patients will take a break as they recover from the initial round of SoC then maintenance therapy will begin.

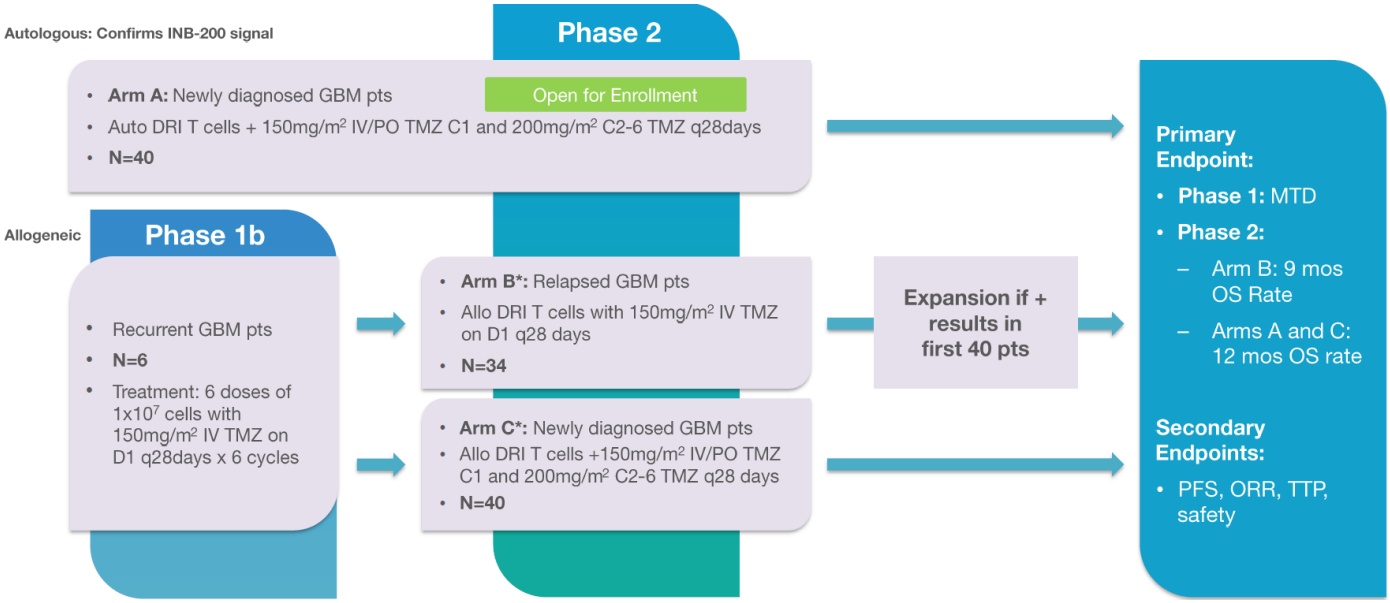
The Phase Ib portion of the trial will further develop the safety and efficacy profile for allogeneic cells (INB-400 DeltEx DRI allogeneic cells) administered to relapsed GBM patients. If determined safe, two cohorts of patients with either relapsed disease (Arm B) or newly diagnosed disease (Arm C) will receive allogeneic γδ T cells. Trial objectives seek to:

- establish the safety of allogeneic, genetically modified γδ T cells;
- assess the efficacy of these cells in treating patients with relapsed GBM; and
- assess the relative benefit and risk of treating newly diagnosed GBM patients with either allogeneic or autologous genetically modified γδ T cells.

Primary outcome measures are overall survival (OS) and maximum tolerated dose. Secondary measures include further safety assessments, overall response rate (ORR), time to progression, and progression free survival (PFS) among others.

Twelve sites in the United States have been identified to enroll patients and three are open and enrolling. An April 30th press release announced that IN8bio had dosed its first patient in the Phase II trial. An expansion cohort will enroll 10 additional patients and data from the trial will be gathered to support an investigational new drug (IND) submission to allow for a Phase II study. INB-400 is actively enrolling and dosing subjects in the Phase II trial and should report initial data from the study in 2025.

Exhibit VII –Clinical Trial Design for INB-400



Source: IN8bio August 2024 Program Update Slide Deck

Previous work has been conducted evaluating allogeneic products showing that they may benefit from a younger and healthier donor These have demonstrated direct anti-tumor cytotoxicity. However, further elaboration and validation of the autologous product is necessary. The allogeneic version is considered a separate product from the autologous cell therapy and requires a separate investigational new drug (IND) application.

IN8bio's longer term goal with this program is to move towards an allogeneic therapy that would allow for an off-the-shelf alternative. This approach would provide a number of benefits relative to an autologous version. Some of these advantages include lower manufacturing costs, immediate availability of drug product and sourcing of γδ T cells from subjects with younger, healthier and better-balanced immune systems.

Poster Presentations at ISCT

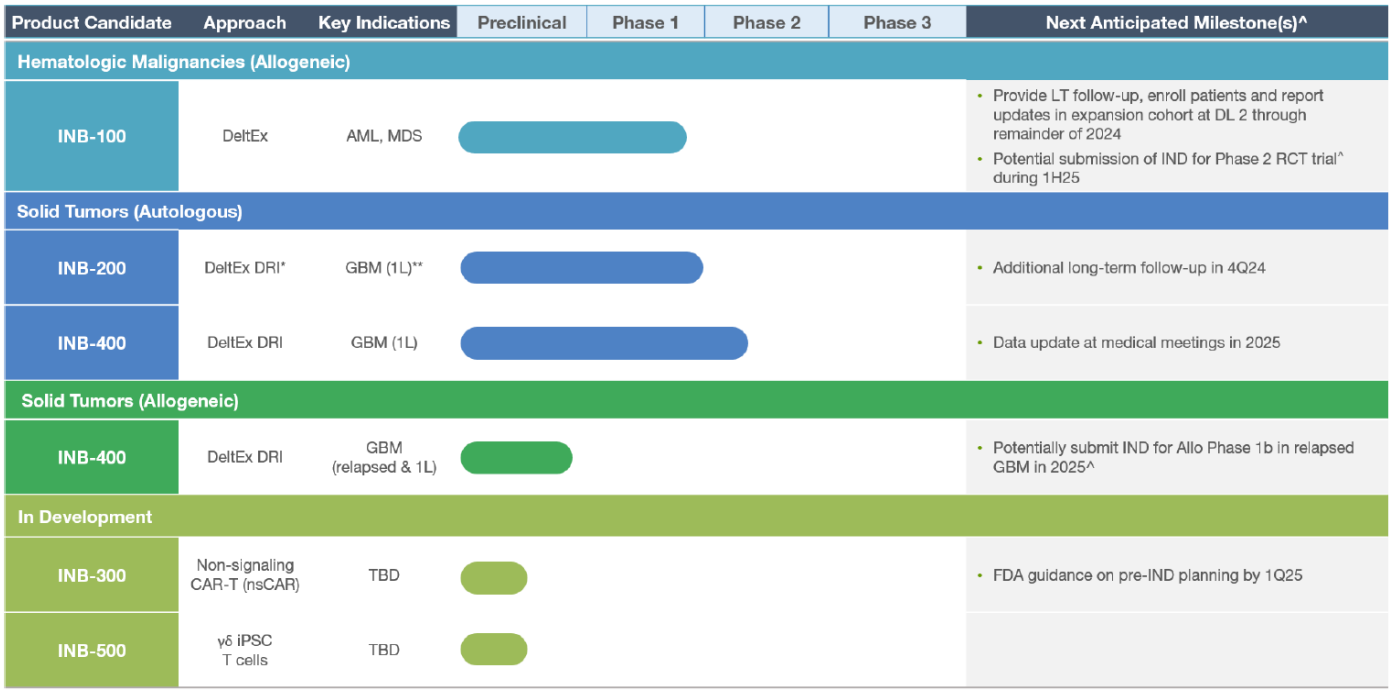
Two posters were presented at the International Society of Cell and Gene Therapy (ISCT) on May 29th, 2024. The documents presented IN8bio's manufacturing processes and how they influence cellular product characteristics and generating a robust and reproducible final product. Chief Operating Officer Dr. Kate Rochlin provided topical details in a press release.

- INB-400 DeltEx drug resistant immunotherapy (DRI) multi-center clinical trial product logistics management
  - Presented by Guoling Chen, Senior Director Quality Operations, IN8bio
- Healthy donor vs. Patient manufactured autologous DeltEx DRI product; TCR Repertoire sequencing
  - Mariska ter Haak, Senior Director Analytical Development, IN8bio

ASGCT Presentation

IN8bio presented its γδ T cell manufacturing platform at the American Society of Gene & Cell Therapy (ASGCT) 2024 Annual Meeting on May 10th, in Baltimore, Maryland. The oral presentation was titled Healthy Donor vs Patient Manufactured Autologous Deltex DRI Product; Immunophenotyping Gene Expression. The data demonstrated that the company's proprietary manufacturing process can produce investigational products with upregulated markers of potency, effector functions and trafficking capabilities, which IN8bio believes represents a significant advancement in the characterization of γδ T cell-based therapies. IN8bio's Chief Operating Officer Dr. Kate Rochlin, noted that the data presented provide additional clarity on the complex gene-expression changes that occur throughout the manufacturing process. This understanding helps improve the consistency and robustness of γδ T cell manufacture. One of the conclusions is that the characteristics of the final product are tied more closely to the process used to manufacture it rather than the individual γδ T cell donor profiles.

Exhibit VIII – IN8bio Pipeline



Source: IN8bio August 2024 Program Update Slide Deck

Milestones

- Future goals outlined for IN8bio – January 2024
- Present additional preclinical data for INB-300 (nsCAR) at AACR (poster) – April 2024
- Dosing of first patient in INB-400 trial – April 2024
- Oral presentation at American Society of Gene & Cellular Therapy (ASGCT) - May 2024
- Two poster presentations at International Society for Cell & Gene Therapy (ISCT) - May 2024
- ASCO INB-200 presentation – June 2024
- EHA presentation: INB-100 & -200 (important data expected) – June 2024
- Attend HC Wainwright Immune Cell Engager Conference – June 2024
- IND filing for allogeneic arms of INB-400 – 2025
- August 1st, 2024 patient survival update for INB-100 & INB-200 – August 2024
- Topline announcement for INB-100 expansion cohort – 2025
- Submission of IND Phase II in AML – 1H:25
- Submission of IND for allogeneic Phase Ib in relapsed GBM - 2025

Summary

IN8bio provides yet another update to its INB-100 and INB-200 trials following the report of its second quarter financial results. No patients have died over the prior two months in either trial, even further underlining the durability of the γδ T cell platform. IN8bio has held meetings with the FDA to guide its design of a registrational Phase II trial for INB-100. The trial will focus on AML patients and will engage from 30 to 50 sites in the United States. Since the report of first quarter results, IN8bio has participated in several scientific conferences, providing details of its lead programs and manufacturing prowess. The results that the γδ T cell platform has produced in especially difficult populations are well in excess of survival for standard of care regimens. While these Phase I trials have not been designed to provide statistically significant efficacy results, the data that has been generated so far suggests that supportive registrational results are likely. We maintain our price target of $5.00 per share.

PROJECTED FINANCIALS

IN8bio, Inc. - Income Statement

IN8bio, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Research & Development	$16,827	$4,903	$5,156	$3,601	$3,675	$17,335	$24,326	$22,150
General & Administrative	$13,510	$3,742	$3,533	$2,920	$3,000	$13,195	$13,591	$12,542
Income from Operations	($30,337)	($8,645)	($8,689)	($6,521)	($6,675)	($30,530)	($37,917)	($34,692)
Other Items	$330	$0	$60	$0	$0	$60	$0	$0
Pre-Tax Income	($30,007)	($8,562)	($8,629)	($6,521)	($6,675)	($30,387)	($37,917)	($34,692)
Net Income	**($30,007)**	**($8,562)**	**($8,629)**	**($6,521)**	**($6,675)**	**($30,387)**	**($37,917)**	**($34,692)**
Net Margin								
Reported EPS	**($1.00)**	**($0.20)**	**($0.19)**	**($0.14)**	**($0.13)**	**($0.65)**	**($0.68)**	**($0.60)**
YOY Growth								
Basic Shares Outstanding	29,865	43,287	45,126	46,810	52,225	46,862	56,000	58,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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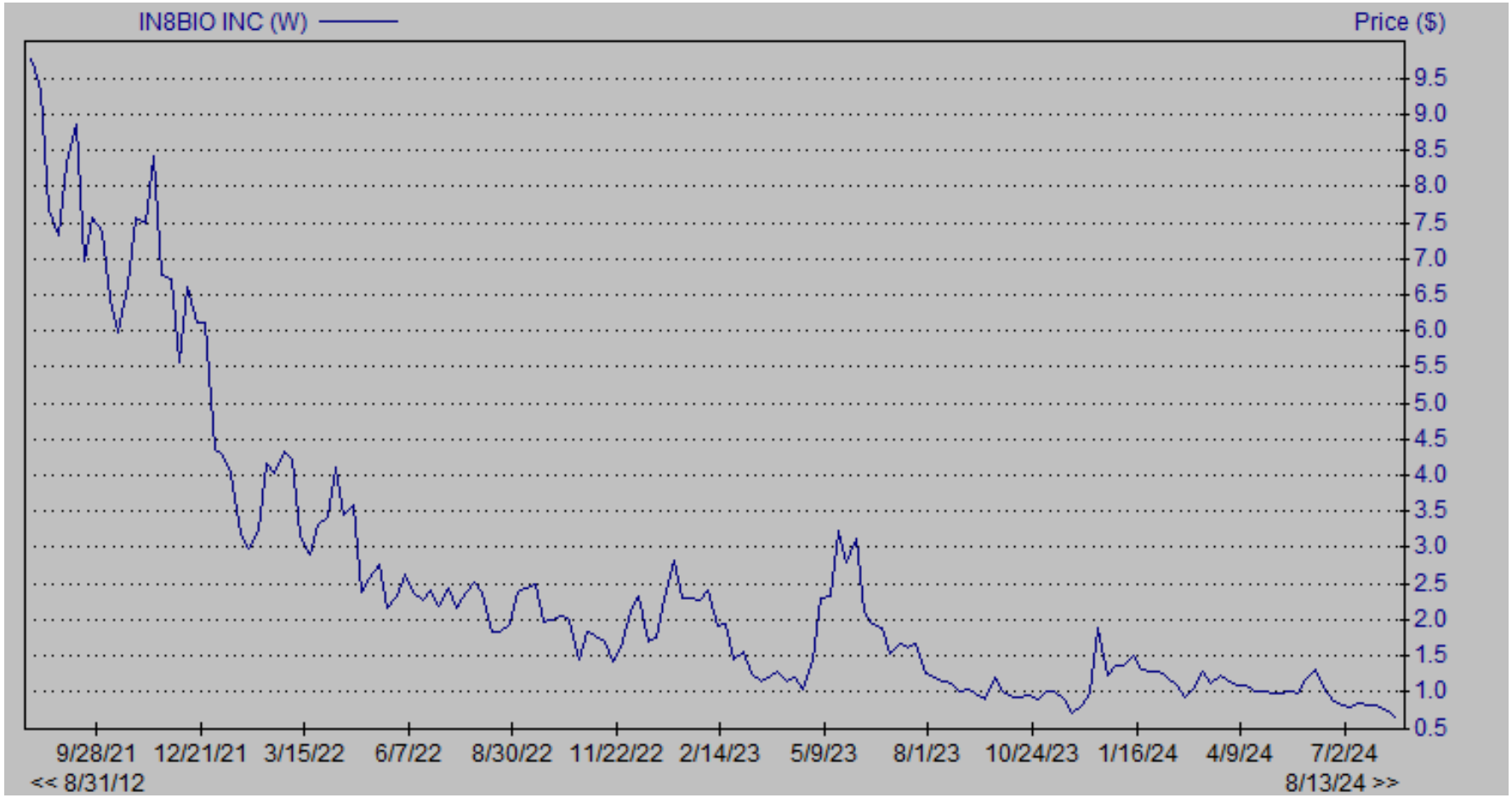
HISTORICAL STOCK PRICE

IN8bio, Inc. – Share Price Chart[8]



[8] Source: Zacks Research System

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