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IN8bio, Inc. (INAB: NASDAQ)

INAB: INB-200 Update at ASCO24

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 (5/17/2024)	$1.38
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	**2.68**
52-Week Low	**0.65**
One-Year Return (%)	**-49.5**
Beta	**0.0**
Average Daily Volume (sh)	**343,523**
Shares Outstanding (mil)	**44.7**
Market Capitalization ($mil)	**61.7**
Short Interest Ratio (days)	**0.6**
Institutional Ownership (%)	**39.9**
Insider Ownership (%)	**22.9**
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 E	$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	-$0.15 E	-$0.15 E	-$0.13 E	-$0.62 E
2025					-$0.63 E
2026					-$0.60 E

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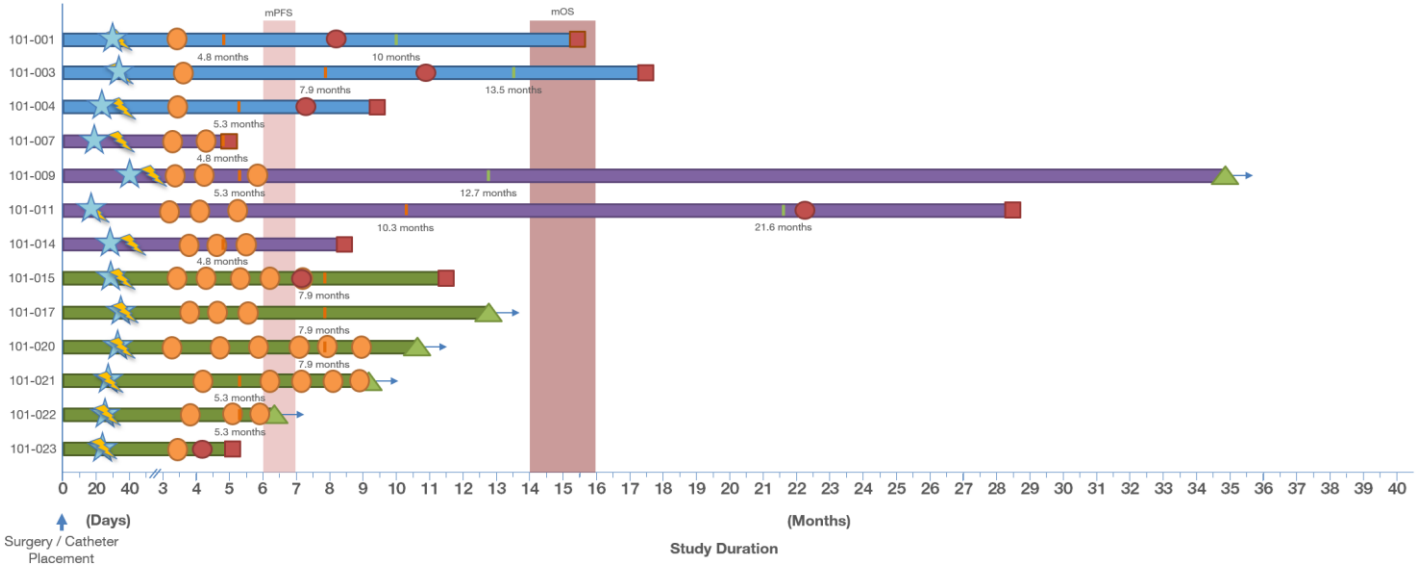
What's New?

IN8bio, Inc (NASDAQ: INAB) updated results from its Phase I INB-200 clinical trial at the American Society of Clinical Oncology (ASCO) 2024 meeting last Saturday. 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 30, 2024, 92% 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

Updated data from the poster were provided in a press release on June 3rd which extended the observation period for the patients an extra 30 days.

One patient remains progression free at 34.9 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 of the therapy.

Exhibit I – INB-200 Patient Survival



IN8bio ASCO Poster, June 2024. Data in exhibit is as of 1May24 while data discussed in text is from 30May24

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.

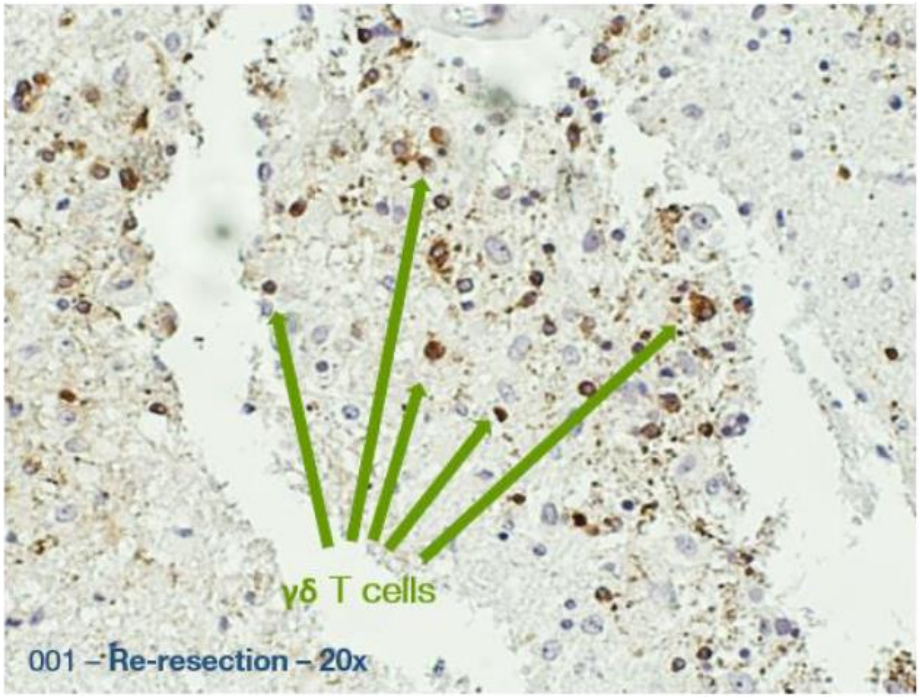
Our own review finds a range of reported survival of nine months to the upper twenty-month range depending upon specific characteristics. Most of the more recent resources we reviewed were 15 months or less. Factors associated with differing survival rates include age, further tumor treatment after surgery and MGMT promoter methylation among other contributors.[1,2,3,4,5,6]

[1] Brown, N.F. *et al*. Survival Outcomes and Prognostic Factors in Glioblastoma. Cancers. July 2022. (9.2 months)
[2] 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)
[3] 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)
[4] Stupp R. *et al*. Radiotherapy plus concomitant and adjuvant Temozolomide for glioblastoma. N Engl J Med. 2005. (14.6 months)
[5] Chang, K. *et al*. Multimodal imaging patterns predict survival in recurrent glioblastoma patients treated with bevacizumab. Neuro-Oncology. 2016. (15 months)
[6] 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).

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. 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 II – 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 started 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 under 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 relapsed 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.

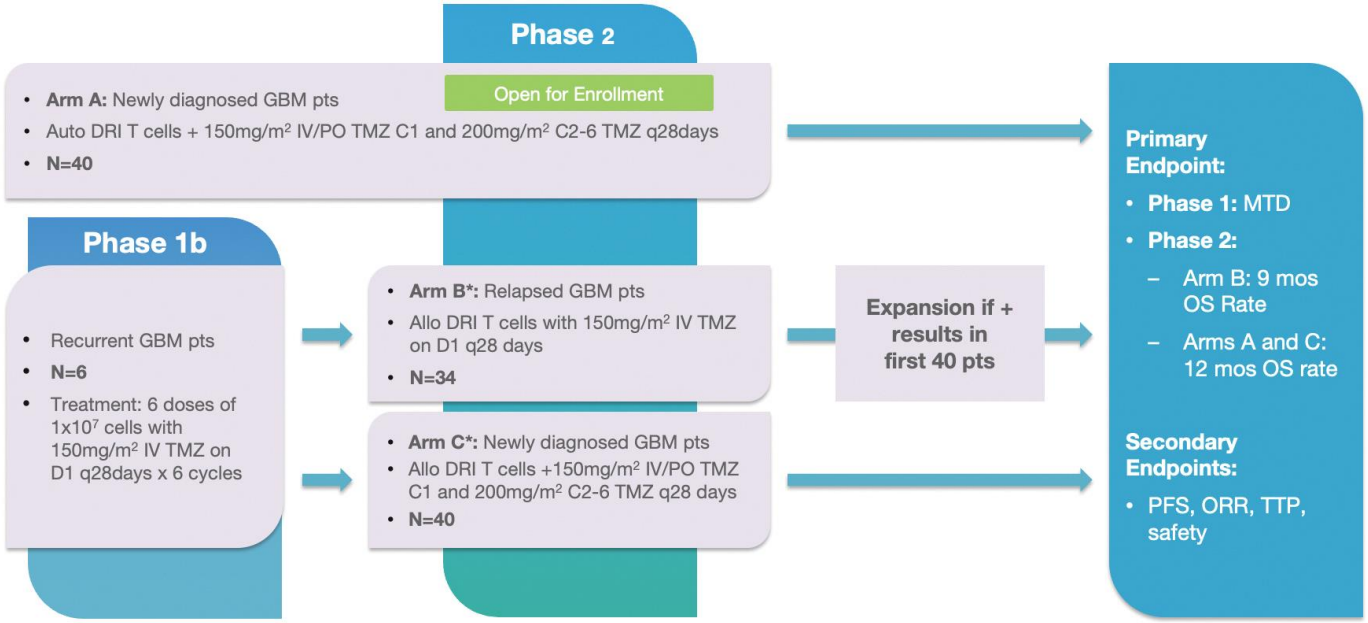
The Phase Ib portion of the trial will further develop the safety and efficacy profile for allogeneic cells (INB-400 DeltEx DRI allogeneic cells) administered to relapsed GBM patients. If determined safe, two cohorts of patients with either relapsed disease (Arm B) or newly diagnosed disease (Arm C)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

Exhibit III –Clinical Trial Design for INB-400



*Arm B and C subject to additional IND for allogeneic drug product (INB-400) as per FDA Guidance for Industry updated Nov. 2022 (https://clinicaltrials.gov/ct2/show/NCT05664243)

IN8bio 2023 Form 10-K filing

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.

INB-400 is actively enrolling and dosing subjects in the Phase II trial and should report initial data from the study in 2025.

Exhibit IV – IN8bio Pipeline



Source: IN8bio Website, Accessed May 2024

Milestones

- Future goals outlined for IN8bio – January 2024
- Present additional preclinical data for INB-300 (nsCAR) at AACR (poster) – 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
- IND filing for allogeneic arms of INB-400 – 2024
- Topline announcement for INB-100 expansion cohort – 2025

Summary

The ASCO poster that was recently presented and updated information in a press release have shown favorable results from the Phase I INB-200 trial which reported on 13 GBM patients at multiple doses of DRI modified γδ T cells. As of May 30th, 2024, 92% patients in the trial have exceeded the 7-month PFS standard set by the Stupp regimen. Overall survival data is not yet available; however, one patient is progression free at almost three years. With more supportive data coming from the INB-200 trial, attention turns to the INB-400 trial which has started and will also evaluate the DRI γδ T cells in GBM patients. We maintain our price target of $5.00 per share.

PROJECTED FINANCIALS

IN8bio, Inc. - Income Statement

IN8bio, Inc.	2023 A	Q1 A	Q2 E	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	$3,650	$3,601	$3,675	$15,829	$22,218	$22,150
General & Administrative	$13,510	$3,742	$2,950	$2,920	$3,000	$12,612	$12,990	$12,542
Income from Operations	($30,337)	($8,645)	($6,600)	($6,521)	($6,675)	($28,441)	($35,208)	($34,692)
Other Items	$330	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($30,007)	($8,562)	($6,600)	($6,521)	($6,675)	($28,358)	($35,208)	($34,692)
Net Income	**($30,007)**	**($8,562)**	**($6,600)**	**($6,521)**	**($6,675)**	**($28,358)**	**($35,208)**	**($34,692)**
Net Margin								
Reported EPS	**($1.00)**	**($0.20)**	**($0.15)**	**($0.15)**	**($0.13)**	**($0.62)**	**($0.63)**	**($0.60)**
YOY Growth								
Basic Shares Outstanding	29,865	43,287	43,850	44,110	52,225	45,868	56,000	58,000

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

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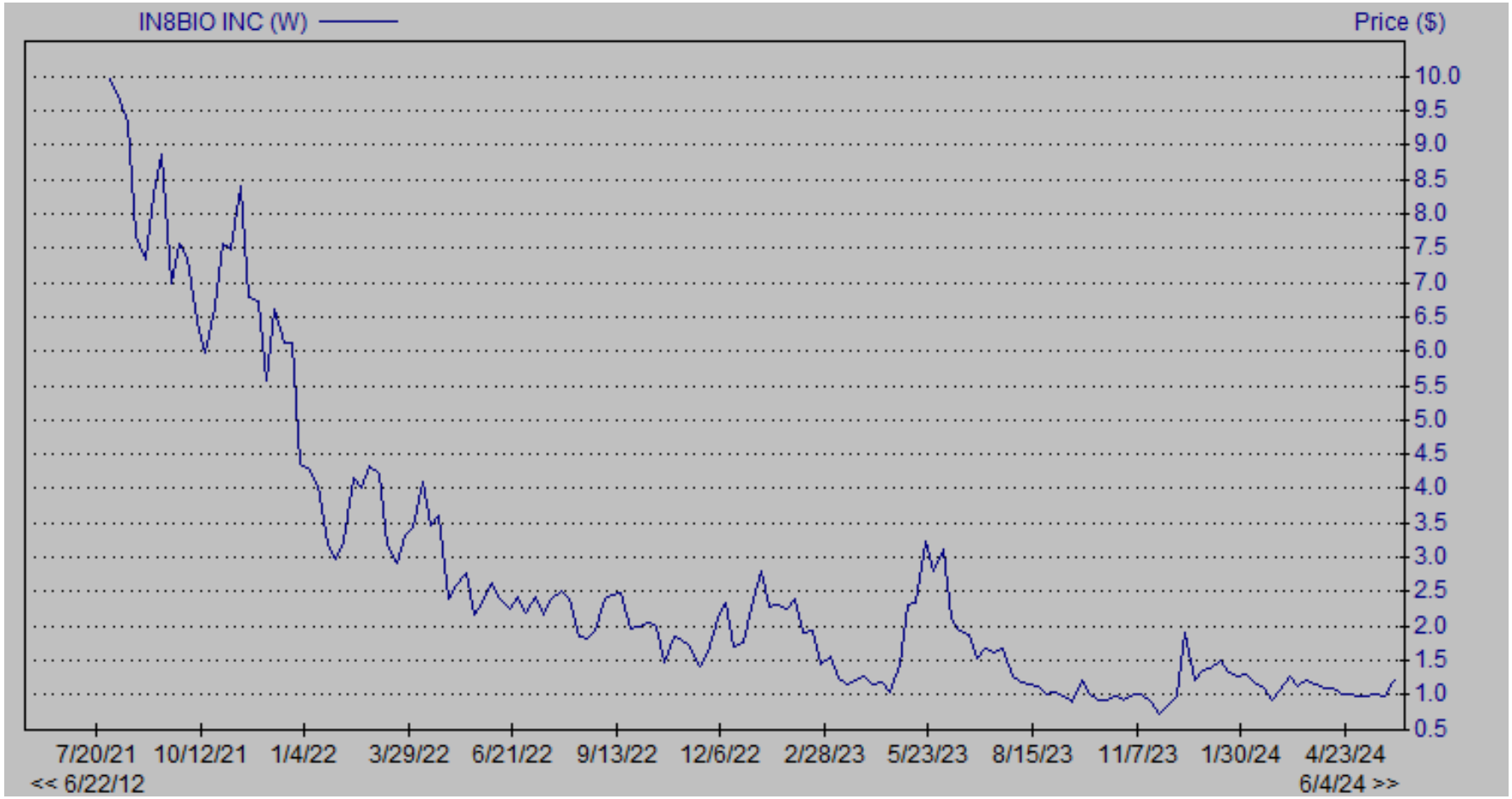
HISTORICAL STOCK PRICE

IN8bio, Inc. – Share Price Chart[7]



[7] Source: Zacks Research System

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