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IN8bio, Inc. (INAB: NASDAQ)

INAB: Restructuring Narrows Focus to AML

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 AML γδ T Cell programs in acute myeloid leukemia (AML). The probability of success adjustments recognize regulatory and commercialization risks. The model includes contributions from the United States and the developed world.

Current Price (10/1/2024)	$0.26
Valuation	**$1.50**

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. As of September 2024, the only active program is in AML.

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. The DRI genetic modification allows the cells to resist chemotherapy and persist in the tumor microenvironment.

While active clinical studies target leukemia, we see DeltEx DRI as a platform that can expand to additional 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 (%)	**-73.6**
Beta	**0.0**
Average Daily Volume (sh)	**243,350**
Shares Outstanding (mil)	**80.8**
Market Capitalization ($mil)	**21.0**
Short Interest Ratio (days)	**0.5**
Institutional Ownership (%)	**34.9**
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	-$0.07 E	-$0.58 E
2025					-$0.19 E
2026					-$0.20 E

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What's New?

IN8bio, Inc (NASDAQ: INAB) announced a restructuring in a September 4th press release indicating that the company will focus on the INB-100 program for acute myeloid leukemia (AML). Due to the difficult financing environment and investor lack of interest in pursuing a glioblastoma multiforme (GBM) program, IN8bio has decided to severely cut costs and focus its remaining resources on the very successful AML program which has observed 100% progression free survival. This narrowing of focus has allowed the company to execute a $12.4 million private placement led by a partner healthcare-focused institutional firm and other investors.

As a result of this decision to streamline the company, the company is cutting its workforce by half at both the New York and Birmingham offices along with reducing cash compensation for the executive management team and board. Restructuring costs will be cash expense of $0.3 million and incurred in the third quarter of 2022.

The GBM program was cut because it failed to receive investor credit and was also going to be more expensive than the AML program. The trial size that would have been necessary to convince investors and the FDA that INB-400 could generate pivotal data would have required a larger capital raise than is now feasible. The program has been paused, but management is optimistic that with the strong results either a partner will be found or investor interest resumes. With these changes, IN8bio will now be solely focused on the INB-100 program which provided its most recent update in mid-August.

Private Placement

On October 1st, IN8bio announced pricing for a private placement of $12.4 million, before fees and expenses. Capital providers for the deal include existing healthcare-focused institutional investors, a large mutual fund and other existing and new institutional investors. Net proceeds are expected to fund company operations into 2026.

Under the terms of the agreement, IN8bio will sell 25,759,595 shares of common stock and 5,646,853 pre-funded warrants as a unit combined with a warrant at a purchase price of $0.395 ($0.3949 for the pre-funded warrants). Each of the 31.4 million shares or prefunded warrants will have a warrant attached with an exercise price of $0.27 and a three-year duration. Along with the private placement, the terms of the series A common stock purchase warrants issued in conjunction with the December 2023 capital raise were modified. The exercise price moves from $1.25 to $0.45 and the expiration moves from June 2025 to October 2025.

The capital will support the further clinical development of INB-100 and the continued enrollment of patients in the expansion cohort. Total expected enrollment has been expanded to 25 patients at the anticipated Phase II dose. Enrollment is expected to extend until 1H:25 with long term follow up results anticipated in late 2025 and in 2026.

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.

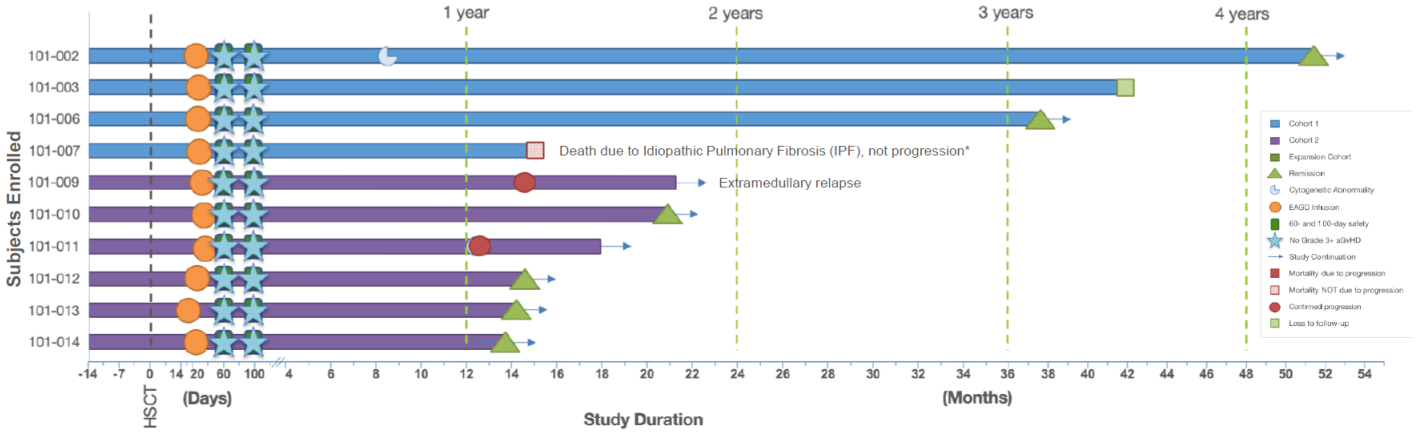
The achievement is even more impressive when subject risk profiles are considered. The average age of the 10-patient group was approximately 68 years[1] and over half had mutations or unfavorable cytogenetics associated with worse performance. Complete remission at one year is an excellent result that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

[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)

IN8bio will expand the trial to enroll another 25 patients at the recommended Phase II dose which is a single dose of 3 x 10^6 γδ T cells/kg. An additional ten patients will be monitored in parallel with the trial to establish a control. This arm will prospectively assess leukemia patients and enable comparison between patients receiving INB-100 to those who only receive standard haplotransplantation. Enrollment of the expansion population is expected to be complete in 1H:25 and further updates from the trial are expected in 2025 and 2026.

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.

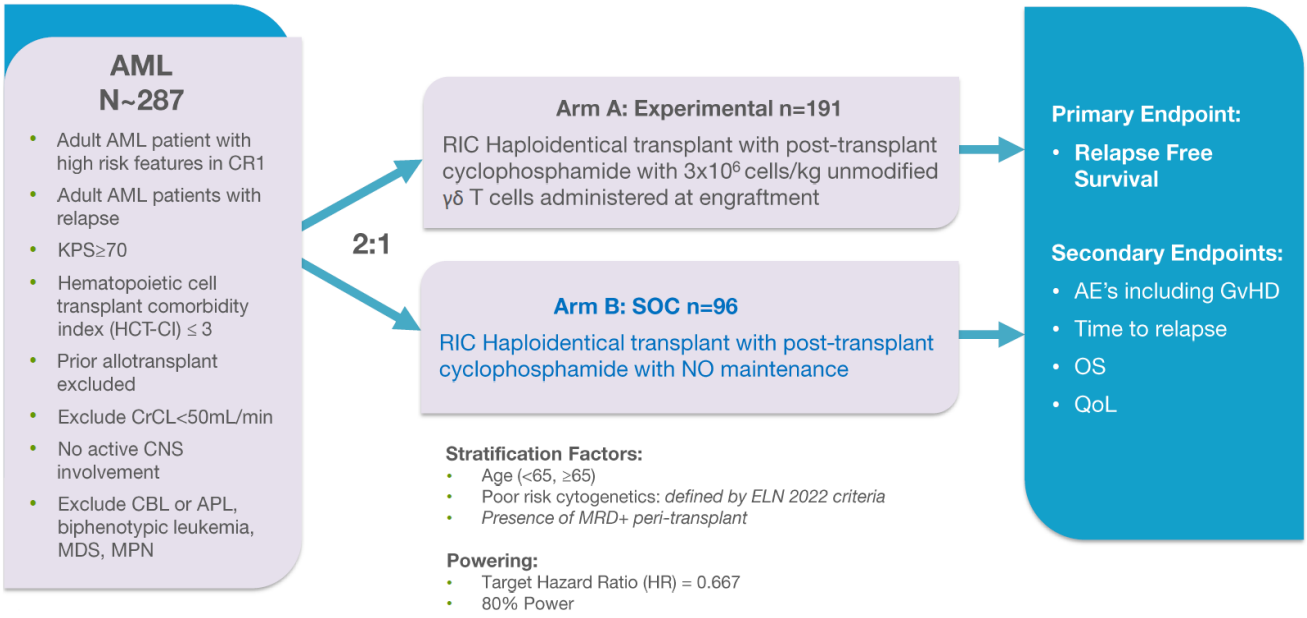
Exhibit I – INB-100 Patient Progression



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

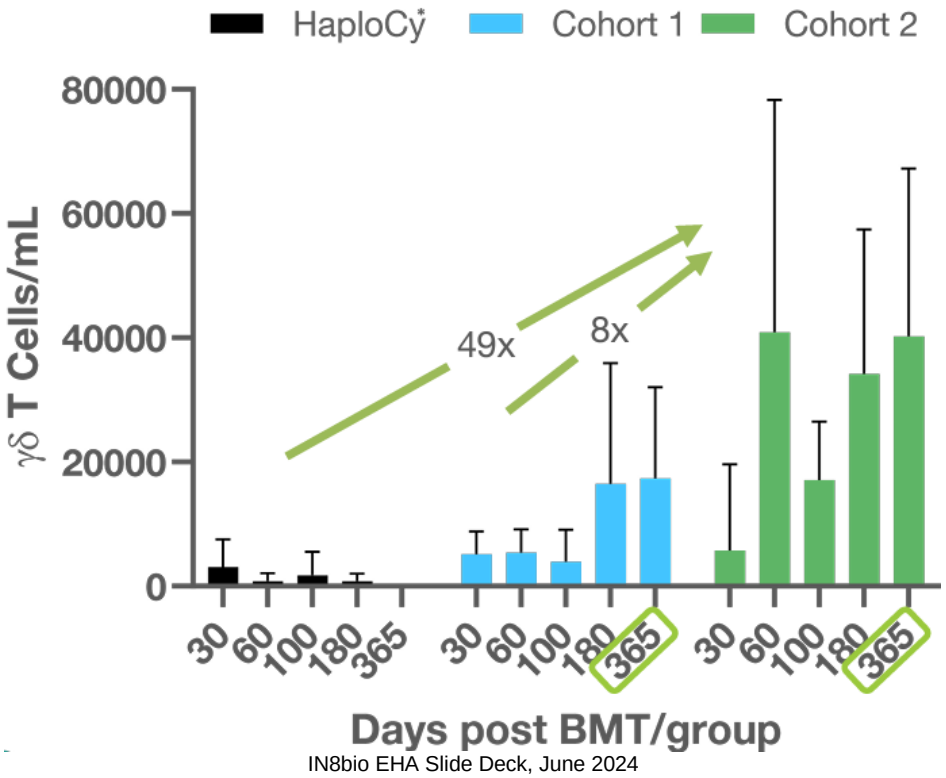


Source: IN8bio August 2024 Program Update Slide Deck

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.

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.

Valuation

We update our valuation to reflect the termination of the GBM program and the reduction in spend over INB-100's development period. New cost estimates are about half previous levels as shown in the model at the end of our report. We also modify the shares and warrants outstanding to reflect the new claims on equity. We continue to see a biologic license application (BLA) submission in 2029 and first sales of INB-100 in 2030 in the United States. Ex-US developed world regulatory submissions are expected to begin in 2030 with first international sales in 2031. The result of our adjustments generates a valuation of $1.50 per share.

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
- Restructuring and narrowing of focus to INB-100 AML program – September 2024
- $12.4 million capital raise – October 2024
- Topline announcement for INB-100 expansion cohort – 2025
- Submission of IND Phase II in AML – 1H:25

Summary

IN8bio had to make some tough decisions on its programs given the difficult funding environment and lack of value recognition for its GBM program. We expect to see costs cut by more than half and all resources directed towards the INB-100 program, which has shown impressive results. This restructuring was followed by a capital raise that will support an expansion of the Phase I trial from ten subjects to 25 and the addition of ten AML patients who will serve as a control. Successful results in this endeavor could support a much stronger capital raise in 2026 that will allow a proof-of-concept trial to be run. With successful Phase II results, INB-100 could receive expedited treatment by the FDA. The change in the pipeline, reduction in expenses and addition of new claims on equity require us to update our valuation which is now $1.50 per share and represents a return of over 5x. We believe that INB-100 is a safe and effective treatment but do recognize that the small number of patients that have responded so far may be insufficient to support moving into Phase II trials. We adjust our valuation to $1.50 per share.

PROJECTED FINANCIALS

IN8bio, Inc. - Income Statement

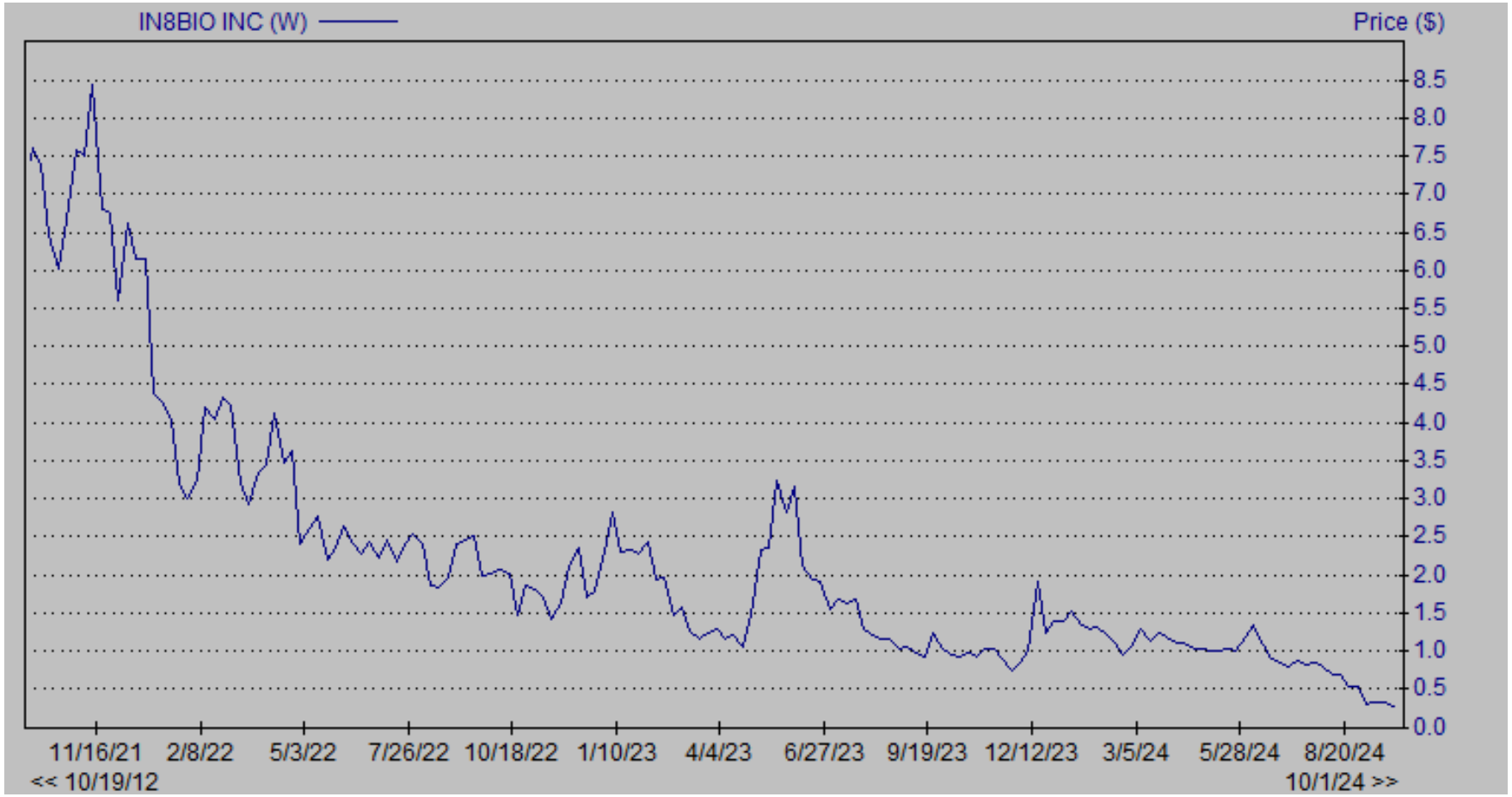
IN8bio, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Research & Development	$16,827	$4,903	$5,156	$3,601	$2,000	$15,660	$9,214	$10,100
General & Administrative	$13,510	$3,742	$3,533	$2,920	$1,650	$11,845	$5,400	$6,142
Income from Operations	($30,337)	($8,645)	($8,689)	($6,521)	($3,650)	($27,505)	($14,614)	($16,242)
Other Items	$330	$0	$60	$0	$0	$60	$0	$0
Pre-Tax Income	($30,007)	($8,562)	($8,629)	($6,521)	($3,650)	($27,362)	($14,614)	($16,242)
Net Income	**($30,007)**	**($8,562)**	**($8,629)**	**($6,521)**	**($3,650)**	**($27,362)**	**($14,614)**	**($16,242)**
Net Margin								
Reported EPS	**($1.00)**	**($0.20)**	**($0.19)**	**($0.14)**	**($0.05)**	**($0.52)**	**($0.19)**	**($0.20)**
YOY Growth								
Basic Shares Outstanding	29,865	43,287	45,126	46,810	74,500	52,431	76,250	81,955

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

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HISTORICAL STOCK PRICE

IN8bio, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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