UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2026

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number: 001-39692

IN8BIO, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-5462585**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
350 5th Avenue, Suite 5330 New York, New York	**10118**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (646) 600-6438

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	INAB	The Nasdaq Stock Market LLC

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The number of shares of Registrant's Common Stock outstanding as of November 2, 2026 was 10,808,292.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements.

IN8BIO, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2026 (unaudited)	December 31, 2025 (Note 2)
Assets		
Current assets		
Cash	$ 13,973	$ 27,092
Prepaid expenses and other current assets	1,221	788
Total Current Assets	15,194	27,880
Non-current assets		
Property and equipment, net	1,342	1,858
Restricted cash	177	220
Right-of-use assets - finance leases	64	296
Right-of-use assets - operating leases	1,816	1,882
Other non-current assets	102	146
Total Non-Current Assets	3,501	4,402
Total Assets	$ 18,695	$ 32,282
Liabilities and Stockholders' Equity		
Liabilities		
Current liabilities		
Accounts payable	$ 493	$ 309
Accrued expenses and other current liabilities	1,278	1,633
Short-term finance lease liability	64	295
Short-term operating lease liability	793	924
Total Current Liabilities	2,628	3,161
Long-term operating lease liability	1,893	1,563
Total Non-Current Liabilities	1,893	1,563
Total Liabilities	4,521	4,724
Stockholders' Equity		
Preferred stock, par value $0.0001 per share; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; no shares issued and outstanding	—	—
Common stock, par value $0.0001 per share; 490,000,000 shares authorized at September 30, 2026 and December 31, 2025; 9,858,383 and 9,766,132 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	10	10
Additional paid-in capital	169,723	168,644
Accumulated deficit	(155,559)	(141,096)
Total Stockholders' Equity	14,174	27,558
Total Liabilities and Stockholders' Equity	$ 18,695	$ 32,282

The accompanying notes are an integral part of these unaudited condensed financial statements.

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 2,599	$ 2,104	$ 7,705	$ 7,563
General and administrative	2,122	1,863	7,217	7,265
Total operating expenses	4,721	3,967	14,922	14,828
Interest income	129	113	459	330
Loss from operations	(4,592)	(3,854)	(14,463)	(14,498)
Net loss	$ (4,592)	$ (3,854)	$ (14,463)	$ (14,498)
Net loss per share – basic and diluted	$ (0.24)	$ (0.85)	$ (0.74)	$ (4.18)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	19,473,123	4,537,683	19,471,400	3,465,257

The accompanying notes are an integral part of these unaudited condensed financial statements.

IN8BIO INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock[1]		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2024	2,416,066	$ 7	$ 136,127	$ (121,656)	$ 14,478
Issuance of common stock, net of issuance costs	245,428	1	3,734	—	3,735
Issuance of common stock upon exercise of Series C warrants, net of issuance costs	47,088	—	383	—	383
Stock-based compensation expense	—	—	831	—	831
Net loss	—	—	—	(5,550)	(5,550)
Balance at March 31, 2025	2,708,582	8	141,075	(127,206)	13,877
Issuance of common stock, net of issuance costs	1,058,861	2	3,615	—	3,617
Issuance of common stock upon exercise of Series A & B warrants, net of issuance costs	310,696	—	1,884	—	1,884
Stock-based compensation expense	—	—	955	—	955
Net loss	—	—	—	(5,094)	(5,094)
Balance at June 30, 2025	4,078,139	10	147,529	(132,300)	15,239
Issuance of common stock, net of issuance costs	511,057	—	1,112	—	1,112
Stock-based compensation expense	—	—	692	—	692
Net loss	—	—	—	(3,854)	(3,854)
Balance at September 30, 2025	4,589,196	$ 10	$ 149,333	$ (136,154)	$ 13,189
Balance at December 31, 2025	9,766,132	$ 10	$ 168,644	$ (141,096)	$ 27,558
Payment of issuance costs from December 2025 issuance of common stock	—	—	(88)	—	(88)
Issuance of common stock upon exercise of prefunded warrants, net of issuance costs	80,957	—	—	—	—
Stock-based compensation expense	—	—	401	—	401
Net loss	—	—	—	(5,090)	(5,090)
Balance at March 31, 2026	9,847,089	10	168,957	(146,186)	22,781
Issuance of common stock, net of issuance costs	6,032	—	11	—	11
Stock-based compensation expense	—	—	352	—	352
Net loss	—	—	—	(4,781)	(4,781)
Balance at June 30, 2026	9,853,121	10	169,320	(150,967)	18,363
Issuance of common stock, net of issuance costs	5,262	—	6	—	6
Stock-based compensation expense	—	—	397	—	397
Net loss	—	—	—	(4,592)	(4,592)
Balance at September 30, 2026	9,858,383	$ 10	$ 169,723	$ (155,559)	$ 14,174

[1] All share amounts and per share amounts disclosed in this Quarterly Report on Form 10-Q have been restated to reflect a one-for-thirty reverse stock split effected in June 2025. See Note 1, Organization and Nature of Operations, for details.

The accompanying notes are an integral part of these unaudited condensed financial statements.

IN8BIO, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
Operating activities		
Net loss	$ (14,463)	$ (14,498)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	757	755
Non-cash stock-based compensation	1,150	2,478
Amortization of finance lease right-of-use assets	232	652
Amortization of operating lease right-of-use assets	403	573
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(433)	379
Other non-current assets	44	106
Accounts payable	184	(185)
Accrued expenses and other current liabilities	(355)	(629)
Short-term operating lease liabilities	522	426
Long-term operating lease liabilities	(660)	(630)
Net cash used in operating activities	(12,619)	(10,573)
Investing activities		
Purchases of property and equipment	(241)	—
Net cash used in investing activities	(241)	—
Financing activities		
Payment of issuance costs from December 2025 issuance of common stock	(71)	—
Proceeds from the issuance of common stock, net of issuance costs	—	8,464
Proceeds from the exercise of Series A & B warrants, net of issuance costs	—	1,884
Proceeds from the exercise of Series C warrants, net of issuance costs	—	383
Principal payments on finance leases	(231)	(582)
Net cash (used in) provided by financing activities	(302)	10,149
Net decrease in cash and restricted cash	(13,162)	(424)
Cash and restricted cash at beginning of period	27,312	11,386
Cash and restricted cash at end of period	$ 14,150	$ 10,962
Cash, end of period	$ 13,973	$ 10,689
Restricted cash, end of period	177	273
Cash and restricted cash, end of period	$ 14,150	$ 10,962
Supplemental disclosure of non-cash financing and investing activities:		
Lease modification of operating lease right-of-use assets and liabilities	$ 337	$ (1,287)

The accompanying notes are an integral part of these unaudited condensed financial statements.

IN8BIO, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. ORGANIZATION AND NATURE OF OPERATIONS

Organization and Business

IN8bio, Inc. (the "Company") is a leading clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta ("γδ") T cell product candidates and T cell engagers for cancer and autoimmune diseases. The Company's pipeline is anchored by INB-600, its proprietary, internally developed γδ T cell engager ("TCE") platform, which has potential applications across oncology and autoimmune indications. The Company's most advanced product candidates are INB-100, currently in an ongoing investigator-sponsored Phase 1 clinical trial of acute myeloid leukemia ("AML"), and INB-200/400, evaluating its DeltEx Drug Resistant Immunotherapy ("DRI") in patients with newly diagnosed glioblastoma ("GBM"). In addition, the Company's DeltEx platform has yielded a broad portfolio of preclinical programs, including INB-300 and INB-500, focused on addressing a range of potential applications, from solid tumors and hematological cancers to autoimmune diseases.

Incysus, Inc. ("Incysus") was a corporation formed in the State of Delaware on November 23, 2015 and Incysus, Ltd. was incorporated in Bermuda on February 8, 2016. Incysus was the wholly owned United States subsidiary of Incysus, Ltd. On May 7, 2018, Incysus, Ltd. reincorporated in the United States in a domestication transaction (the "Domestication") in which Incysus, Ltd. converted into a newly formed Delaware corporation, Incysus Therapeutics, Inc. ("Incysus Therapeutics"). On July 24, 2019, Incysus Therapeutics merged with Incysus. Incysus Therapeutics subsequently changed its name to IN8bio, Inc. in August 2020. Following the Domestication in May 2018 and the merging of Incysus Therapeutics and Incysus in July 2019, the Company does not have any subsidiaries to consolidate. The Company is headquartered in New York, New York.

Reverse Stock Split

On June 5, 2025, the Company effected a reverse stock split at a ratio of one-for-thirty (the "Reverse Stock Split"). Pursuant to their terms, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise or vesting of all outstanding stock options and warrants, and the number of shares of the Company's common stock authorized for issuance pursuant to the Company's equity incentive plans was reduced proportionally. The Reverse Stock Split did not reduce the number of authorized shares of common stock and did not alter the par value.

No fractional shares were issued as a result of the Reverse Stock Split. Stockholders of record who would have otherwise been entitled to receive a fractional share received a cash payment in lieu thereof. The Reverse Stock Split affected all stockholders proportionately and did not affect any stockholder's percentage ownership of the Company's common stock (except to the extent that the Reverse Stock Split resulted in any stockholder owning only a fractional share).

Liquidity and Going Concern

To date, the Company has funded its operations primarily with proceeds from various public and private offerings of its common stock, preferred stock and warrants. The Company has incurred recurring losses and negative operating cash flows since its inception, including net losses of $14.5 million and $14.5 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, the Company had an accumulated deficit of $155.6 million. The Company continues to deploy cash preservation measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact the Company's ability and the timing to execute its strategy. This includes the Company's ability to achieve the anticipated milestones and the timing of data releases and/or regulatory filings for its preclinical and clinical programs.

The Company has not yet generated product sales and as a result has experienced operating losses since inception. The Company expects to incur additional losses in the future as it advances its product candidates through clinical trials, grows its clinical, regulatory and quality capabilities, and incurs costs associated with operating as a public company. The actual amount of cash that the Company will need to operate is subject to many factors. Based on the Company's business strategy, its existing cash of $14.0 million as of September 30, 2026 is not anticipated to fund the Company's projected operating expenses and capital expenditure requirements for a period of at least 12 months from the date of issuance of these condensed financial statements, and accordingly, there is substantial doubt about the Company's ability to continue to operate as a going concern.

The Company continues to maintain cash preservation measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. To continue to fund the operations of the Company beyond this time period, management has developed plans, which primarily consist of pipeline prioritization, raising additional capital through some combination of equity and/or debt offerings, including through ATM offerings and private placements of securities, and identifying strategic collaborations, licensing or other arrangements to support development of the Company's product candidates.

In connection with the Company's private placement completed in December 2025, the Company may also be eligible to receive up to approximately $20.1 million in additional gross proceeds in exchange for up to 14,579,706 shares of common stock (or, for certain investors, pre-funded warrants in lieu of common stock), subject to the achievement of certain milestone-driven conditions related to preclinical data for the Company's CD19 targeting INB-619 product candidate. In addition, the Company may receive up to an aggregate of $2.3 million of proceeds from the exercise of its outstanding Series B ordinary warrants ("Series B warrants") if not otherwise redeemed by the Company and up to $6.7 million from the exercise of its outstanding Series C common stock purchase warrants ("Series C warrants"). See Note 7, Warrants, for additional information. There is no assurance, however, that the Company will receive any additional proceeds or that any additional financing or any revenue-generating collaboration will be available when needed, that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company, or that any additional financing or revenue generated through third-party collaborations will be sufficient to fund the Company's operations through this time period. If additional capital is not available on a timely basis, or at all, the Company will have to significantly delay, scale back or discontinue its research and development programs. If the Company becomes unable to continue as a going concern, it may have to terminate its operations and dispose of its assets and might realize significantly less than the values at which they are carried on its financial statements. These actions may cause the Company's stockholders to lose all or part of their investment in the Company's common stock. The accompanying condensed financial statements have been prepared on the basis that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

The Company's significant accounting policies, which are disclosed in the audited financial statements for the year ended December 31, 2025 and the notes thereto, are included in the Company's Annual Report on Form 10-K (the "Annual Report") that was filed with the Securities and Exchange Commission ("SEC") on March 12, 2026. Since the date of that filing, there have been no material changes to the Company's significant accounting policies.

Basis of Presentation

The Company has prepared the accompanying condensed financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP").

Unaudited Interim Financial Information

The condensed financial statements of the Company included herein have been prepared pursuant to the rules and regulations of the SEC. Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from these condensed financial statements, as is permitted by such rules and regulations. Accordingly, these condensed financial statements should be read in conjunction with the financial statements and notes thereto in the Annual Report. The results for any interim period are not necessarily indicative of results for any future period. In the opinion of the Company's management, all adjustments (consisting of normal and recurring adjustments) considered necessary for a fair statement of the results for the interim periods presented have been included.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting periods presented. Such estimates and assumptions are used for, but are not limited to, the accrual of research and development expenses, deferred tax assets and liabilities and the related valuation allowance, stock-based compensation, the useful lives of property and equipment and the valuation of warrants. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to significant concentrations of credit risk consist primarily of cash and restricted cash. All of the Company's cash and restricted cash is deposited in accounts with major financial institutions. Such deposits are in excess of the federally insured limits.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation and amortization of property and equipment is calculated using the straight-line method over the estimated useful lives of the assets. Significant replacements and improvements are capitalized, while maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. The estimated useful lives of the Company's respective assets are as follows:

	Estimated Useful Life
Furniture	5 years
Machinery and equipment	3-5 years
Software	3 years
Leasehold improvements	The shorter of the useful life of the leasehold improvement or the remaining term of the lease

Costs for capital assets not yet placed into service are capitalized as construction in progress and depreciated and amortized in accordance with the above guidelines once placed into service. Upon retirement or disposal of property and equipment, the cost and related accumulated depreciation and amortization are removed from the condensed balance sheets and any gain or loss is reflected in the condensed statements of operations.

Capitalized Software

The Company capitalizes the application development phase costs of internal use software in accordance with Accounting Standard Codification ("ASC") Topic 350-40, *Intangibles-Goodwill and Other-Internal Use Software*. Capitalized costs will be amortized on a straight-line basis over the estimated useful life of the asset upon completion.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM") in deciding how to allocate resources and assess performance. The Company has one operating segment, which is the business focused on the discovery, development and commercialization of gamma-delta T cell product candidates and TCEs for cancer and autoimmune diseases. The CODM is the Company's Chief Executive Officer ("CEO"). The CEO manages the Company's operations, assesses performance for the operating segment and decides how to allocate resources based on net loss, which is reported on the condensed statements of operations. All of the Company's long-lived assets are held in the United States. For additional segment information, see Note 13, Segments.

Recently Issued Accounting Standards Updates

The Company has evaluated all issued and unadopted Accounting Standards Updates issued by the Financial Accounting Standards Board, and believes the adoption of these standards will not have a material impact on the condensed financial statements.

3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Prepaid insurance	$ 726	$ 529
Other	495	259
Prepaid expenses and other current assets	$ 1,221	$ 788

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Machinery and equipment	$ 626	$ 385
Furniture and fixtures	402	402
Software	346	346
Leasehold improvements	3,924	3,924
Less accumulated depreciation and amortization	(3,956)	(3,199)
Property and equipment, net	$ 1,342	$ 1,858

Depreciation and amortization expense was $0.5 million and $0.2 million for the three months ended September 30, 2026 and 2025, respectively, and was $0.8 million and $0.8 million for the nine months ended September 30, 2026 and 2025, respectively.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued clinical trials	$ 18	$ 46
Accrued research and development	—	12
Accrued compensation	1,091	1,305
Accrued legal	39	207
Accrued other	130	63
Accrued expenses and other current liabilities	$ 1,278	$ 1,633

6. STOCKHOLDERS' EQUITY

The Company’s authorized capital stock consists of 500,000,000 shares, all with a par value of $0.0001 per share, of which 490,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock.

ATM Facility

In November 2022, the Company entered into a Controlled Equity Offering℠ sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") and Truist Securities, Inc. ("Truist") under which Cantor Fitzgerald and Truist agreed to act as sales agents to sell shares of the Company’s common stock, from time to time, in an at-the-market offering program. In March 2024, the Company delivered a termination notice to Truist, removing them as sales agent under the sales agreement, and on May 29, 2026, the Company and Cantor Fitzgerald mutually agreed to terminate the sales agreement effective at the close of business on May 29, 2026.

In November 2025, the Company filed a shelf registration statement on Form S-3 (File No. 333-291393) (the "Shelf Registration Statement") with the SEC, which became effective on May 20, 2026, which permits the issuance and sale by the Company of up to a maximum aggregate offering price of $200.0 million of its common stock, preferred stock, various series of debt securities, warrants to purchase common stock, preferred stock or debt securities, rights to purchase equity or debt securities, and/or units to purchase any combination of such securities. On June 1, 2026, the Company entered into a Capital on Demand™ Sales Agreement, (the "Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") with respect to an at-the-market offering program under which the Company may issue and sell, from time to time at its sole discretion, shares of its common stock, through or to JonesTrading (the "ATM Program") pursuant to the Shelf Registration Statement.

Under current SEC regulations, if at any time the Company's public float is less than $75.0 million, and for so long as the Company's public float remains less than $75.0 million, the amount the Company can raise through primary public offerings of securities in any 12-month period using shelf registration statements is limited to an aggregate of one-third of the Company's public float, which is referred to as the baby shelf rules. As of September 30, 2026, the Company's calculated public float was less than $75.0 million. During the year ended December 31, 2025, the Company sold an aggregate of 1,865,253 shares of its common stock under the ATM Program, resulting in net proceeds of $8.6 million, after deducting underwriting discounts. For the nine months ended September 30, 2026, the Company sold an aggregate of 11,294 shares of its common stock under the ATM Program, resulting in net proceeds of approximately $17,000 after deducting sales agent fees and other offering expenses. As of September 30, 2026, $2.8 million remained available for the sale of common stock under the ATM Program.

7. WARRANTS

In December 2023, the Company issued pre-funded warrants to purchase up to an aggregate of 19,141 shares of common stock ("2023 Pre-Funded Warrants"), 394,118 Series A warrants and 394,118 Series B warrants in a private placement. The 2023 Pre-Funded Warrants have an exercise price of $0.003 per share, are exercisable immediately and are exercisable until the 2023 Pre-Funded Warrant is exercised in full. In lieu of making the cash payment otherwise contemplated to be made to the Company upon exercise of a 2023 Pre-Funded Warrant in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the 2023 Pre-Funded Warrants terms. The 2023 Pre-Funded Warrants meet the criteria for permanent equity classification. As of September 30, 2026, there were no 2023 Pre-Funded warrants issued and outstanding.

The Series A warrants were issued with an exercise price of $37.50 per share. The Series A warrants were exercisable immediately. The Series A warrants meet the criteria for permanent equity classification.

In connection with the closing of the Company's private placement in October 2024, the Company amended certain of the Company’s outstanding Series A warrants, representing 390,462 shares of the Company’s common stock, to reduce the exercise price from $37.50 to $13.50 per share and (ii) extend the termination date of such Series A warrants to October 4, 2025. As of September 30, 2026, all Series A warrants have expired and there are no Series A warrants outstanding.

The Series B warrants have an exercise price of $45.00 per share. The Series B warrants are exercisable immediately and will expire on December 13, 2028. The Series B warrants allow the Company to redeem such warrants at a price of $0.30 per Series B warrant upon the Company’s public announcement of its INB-100 data for all enrolled patients covering a period of at least 22 months, along with certain stock price and trading volume requirements. Holders of Series B warrants may choose to exercise such warrants at a purchase price of $45.00 per share prior to such redemption. The Series B warrants meet the criteria for permanent equity classification. In April 2025, the Company entered into Amendment No. 1 to Securities Purchase Agreement (the "SPA Amendment") to amend the restrictions on certain equity sales by the Company set forth in the Securities Purchase Agreement, dated September 30, 2024, by and among the Company and the investors party thereto. In consideration for the SPA Amendment, the Company amended the Company's outstanding Series B warrants, representing 303,574 shares of the Company's common stock, to (i) reduce the exercise price from $45.00 to $13.50 per share. As of September 30, 2026, 166,964 Series B warrants were issued and outstanding.

In October 2024, the Company issued pre-funded warrants to purchase up to an aggregate of 188,227 ("2024 Pre-Funded Warrants") and 1,044,726 Series C warrants in a private placement. The 2024 Pre-Funded Warrants have an exercise price of $0.003 per share, were exercisable immediately and are exercisable until the 2024 Pre-Funded Warrant is exercised in full. In lieu of making the cash payment otherwise contemplated to be made to the Company upon exercise of a 2024 Pre-Funded Warrant in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the 2024 Pre-Funded Warrants terms. The 2024 Pre-Funded Warrants meet the criteria for permanent equity classification. As of September 30, 2026, 164,593 2024 Pre-Funded Warrants were outstanding.

The Series C warrants have an exercise price of $8.10 per share. The Series C warrants are exercisable immediately and will expire on October 4, 2027. The Series C warrants meet the criteria for permanent equity classification. As of September 30, 2026, 828,863 Series C warrants were outstanding.

In April 2025, the Company entered into privately negotiated letter agreements with certain holders of outstanding Series A warrants and Series B warrants (the "Participating Holders") to (i) exercise, for cash, 239,293 Series A warrants and 71,403 Series B warrants for the purchase of an aggregate of 310,696 shares of common stock, in each case at a reduced exercise price of (a) $5.53 per share for Participating Holders who are directors or executive officers of the Company and (b) $5.35 per share for all other Participating Holders and (ii) exchange certain Series A warrants and Series B warrants for 41,014 pre-funded warrants (the "Exchanged Pre-Funded Warrants"), in each case for a cash payment of (a) $5.53 per warrant share for Participating Holders who are directors or executive officers of the Company and (b) $5.35 per warrant share for all other Participating Holders (the "Warrant Exchanges"), for aggregate net proceeds of $1.9 million.

The Exchanged Pre-Funded Warrants issued in connection with the Warrant Exchanges have an exercise price of $0.003 per share. Each Exchanged Pre-Funded Warrant is exercisable immediately and will be exercisable until such Exchanged Pre-Funded Warrant is exercised in full. In lieu of a cash payment to the Company in payment of the aggregate exercise price upon exercise of an Exchanged Pre-Funded Warrant, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Exchanged Pre-Funded Warrants. Under the terms of the Exchanged Pre-Funded Warrants, the Company shall not effect the exercise of any portion of any Exchanged Pre-Funded Warrant, and a holder shall not have the right to exercise any portion of any Exchanged Pre-Funded Warrant, to the extent that after giving effect to such exercise, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates) would beneficially own in excess of 4.99% or 9.99%, as applicable, of the number of shares of common stock outstanding immediately after giving effect to such exercise. However, a holder may, upon written notice to the Company, increase or decrease such percentage to any other percentage not in excess of 19.99%; provided that any increase or decrease in such percentage will not be effective until 61

days after such notice is delivered to the Company. The Exchanged Pre-Funded Warrants meet the criteria for permanent equity classification. As of September 30, 2026, 2,732 of these Exchanged Pre-Funded Warrants were outstanding.

In December 2025, the Company issued pre-funded warrants to purchase up to an aggregate of 9,452,677 shares of common stock (the "2025 Pre-Funded Warrants") in a private placement. The 2025 Pre-Funded Warrants have an exercise price of $0.0001 per share, were exercisable immediately and are exercisable until the 2025 Pre-Funded Warrant is exercised in full. In lieu of making the cash payment otherwise contemplated to be made to the Company upon exercise of a 2025 Pre-Funded Warrant in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the 2025 Pre-Funded Warrants terms. The 2025 Pre-Funded Warrants meet the criteria for permanent equity classification. As of September 30, 2026, 9,452,677 2025 Pre-Funded Warrants were outstanding.

As of September 30, 2026, we had 9,620,002 pre-funded warrants, 166,964 Series B warrants, and 828,863 Series C warrants outstanding. Of these, 9,452,677 pre-funded warrants have an exercise price of $0.0001 per share and 167,325 pre-funded warrants have an exercise price of $0.003 per share. The Series B warrants have an exercise price of $13.50 per share and will expire on December 13, 2028. The Series C warrants have an exercise price of $8.10 per share and will expire on October 4, 2027.

8. STOCK-BASED COMPENSATION

2018 Equity Incentive Plan

On May 7, 2018, the Company established and adopted the 2018 Equity Incentive Plan (the "2018 Plan") providing for the granting of stock awards for employees, directors and consultants to purchase shares of the Company’s common stock. Upon the effectiveness of the 2020 Plan (as defined below), the 2018 Plan was terminated and no further issuances were made under the 2018 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2018 Plan.

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the "2020 Plan") was approved by the Company's Board of Directors and the Company’s stockholders and became effective on July 29, 2021. Upon the effectiveness of the 2023 Plan (as defined below), the 2020 Plan was terminated and no further issuances were made under the 2020 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2020 Plan.

Amended and Restated 2023 Equity Incentive Plan

The Amended and Restated 2023 Equity Incentive Plan (the "2023 Plan") was approved by the Company's Board of Directors and the Company’s stockholders and became effective on June 15, 2023. Upon the effectiveness of the 2026 Plan (as defined below), the 2023 Plan was terminated and no further issuances were made under the 2023 Plan, although it continues to govern the terms of any equity grants that remain outstanding under the 2023 Plan.

Amended and Restated 2026 Equity Incentive Plan

The Amended and Restated 2026 Equity Incentive Plan (the "2026 Plan") was approved by the Company's Board of Directors and the Company’s stockholders and became effective on May 7, 2026. The Board of Directors, or a committee thereof, is authorized to administer the 2026 Plan. The 2026 Plan provides for the grant of Incentive Stock Options ("ISO") within the meaning of Section 422 of the Internal Revenue Code of 1986 as amended, to employees, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to the Company’s employees, directors and consultants and any Company affiliates’ employees and consultants. The number of shares initially reserved for issuance under the 2026 Plan was 4,054,937, which automatically increases on January 1 of each year for a period of 10 years commencing on January 1, 2027 and ending on (and including) January 1, 2037, in an amount equal to 5% of the total number of shares of common stock, plus the total number of shares of common stock issuable upon settlement of pre-funded warrants (if any), in each case, outstanding on December 31 of the preceding year, or a lesser number of shares determined by the Board of Directors no later than the last day of the immediately preceding year. The maximum number of shares of common stock that may be issued upon the exercise of ISOs under the 2026 Plan is 20,000,000 shares. As of September 30, 2026, 2,491,148 shares were available for grant pursuant to the 2026 Plan.

Inducement Equity Awards

The 2026 Inducement Plan (the "2026 Inducement Plan") was approved by the Company's Board of Directors and became effective on July 31, 2026. The Board of Directors, or a committee thereof, is authorized to administer the 2026 Inducement Plan. The 2026 Inducement Plan was adopted by the Company’s Board of Directors without stockholder approval pursuant to Nasdaq Marketplace Rule 5635(c)(4), or Rule 5635(c)(4). In accordance with Rule 5635(c)(4), awards made under the 2026 Inducement Plan may only be granted to newly hired employees as an inducement material to the employees entering into employment with the Company. Awards granted under the 2026 Inducement Plan expire no later than ten years from the date of grant. An aggregate of 511,800 shares of common stock were reserved for issuance under the 2026 Inducement Plan. As of September 30, 2026, there were 489,600 shares of common

stock available for issuance under the 2026 Inducement Plan and together with the 2026 Plan (the "Plans"), there were 2,980,748 shares of common stock available for issuance.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") was approved by the Board of Directors and the Company's stockholders and became effective on July 29, 2021. A total of 6,666 shares of common stock were initially reserved for issuance under this plan, which automatically increases on January 1 of each year by the lesser of (i) 1% of the outstanding number of shares of common stock on the immediately preceding December 31; and (ii) 13,333, or such lesser number of shares as determined by the Board of Directors. As of September 30, 2026, no shares of common stock had been issued under the ESPP and 26,260 shares remained available for future issuance under the ESPP. The Board of Directors or designated committee has not set an offering period and the Board of Directors elected not to increase the number of shares of common stock reserved for future issuance under the ESPP as of January 1, 2026.

Stock Option Activity

The following is a summary of the stock option award activity under the Plans during the nine months ended September 30, 2026:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	502,027	$ 50.42	8.05	$ 41
Granted	1,094,058	1.74		
Exercised	—	—		
Forfeited	(10,096)	5.81		
Outstanding at September 30, 2026	1,585,989	$ 17.13	8.60	$ —
Exercisable at September 30, 2026	454,677	$ 52.35	6.68	$ —
Options expected to vest as of September 30, 2026	1,131,312	$ 2.97	9.37	$ —

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2026 and 2025 was $1.41 and $6.70, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the market price of the Company's common stock at September 30, 2026 and December 31, 2025.

Stock-Based Compensation Expense

For the nine months ended September 30, 2026 and 2025, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	September 30, 2026	September 30, 2025
Volatility	101.73% - 102.98%	96.66% - 99.24%
Expected life (years)	5.27 - 6.08	5.27 - 6.08
Risk-free interest rate	3.83% - 4.61%	4.00% - 4.24%
Dividend rate	—	—

- Volatility—The Company estimates the expected volatility of its common stock at the date of grant based on the historical volatility of comparable public companies over the expected term.
- Expected life—The expected term represents the period that the Company's stock option grants are expected to be outstanding. The expected term of the options granted to employees and non-employee directors by the Company has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

- Risk-free interest rate—The risk-free rate for periods within the estimated life of the stock award is based on the U.S. Treasury yield curve in effect at the time of grant.
- Dividend rate—The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

Stock-based compensation expense was recorded in the following line items in the condensed statements of operations for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 149	$ 278	$ 447	$ 862
General and administrative	248	414	703	1,616
Total stock-based compensation expense	$ 397	$ 692	$ 1,150	$ 2,478

No related tax benefits from stock-based compensation expense were recognized for the three and nine months ended September 30, 2026 and 2025. As of September 30, 2026, there was $2.3 million in unrecognized stock-based compensation expense, which is expected to be recognized over a weighted-average period of 2.08 years.

9. LICENSE AGREEMENTS

Emory University, Children's Healthcare of Atlanta, Inc. and UAB Research Foundation

In June 2016, the Company entered into an exclusive license agreement with Emory University, Children's Healthcare of Atlanta, Inc. and UAB Research Foundation ("UABRF"), as amended from time to time (the "Emory License Agreement"). The Emory License Agreement was amended in October 2017 and July 2020. Under the Emory License Agreement, the Company obtained an exclusive worldwide license under certain immunotherapy related patents and know-how related to gamma-delta T cells developed by Emory University, Children's Healthcare of Atlanta, Inc. and UABRF's affiliate, the University of Alabama at Birmingham, to develop, make, have made, use, sell, import and otherwise commercialize products that are covered by such patents or otherwise incorporate or use the licensed technology. Such exclusive license is subject to certain rights retained by these institutions and also the U.S. government.

In consideration of the license granted under the Emory License Agreement, the Company paid Emory University a nominal upfront payment. Between March 2017 and August 2020, the Company issued UABRF an additional 5,046 shares of common stock in satisfaction of these antidilution rights.

In addition, the Company is required to pay Emory University development milestones totaling up to an aggregate of $1.4 million, low-single-digit to mid-single-digit tiered running royalties on the net sales of the licensed products, including an annual minimum royalty beginning on a specified period after the first sale of a licensed product, and a share of certain payments that the Company may receive from sublicenses. In addition, in the event no milestone payments have been paid in certain years, the Company will be required to pay an annual license maintenance fee. The Emory License Agreement also requires the Company to reimburse Emory University for the cost of the prosecution and maintenance of the licensed patents. Pursuant to the Emory License Agreement, the Company is required to use its best efforts to develop, manufacture and commercialize the licensed product, and is obligated to meet certain specified deadlines in the development of the licensed products.

The term of the Emory License Agreement will continue until 15 years after the first commercial sale of the licensed product, or the expiration of the relevant licensed patents, whichever is later. The Company may terminate the Emory License Agreement at will at any time upon prior written notice to Emory University. Emory University has the right to terminate the Emory License Agreement if the Company materially breaches the agreement (including failure to meet diligence obligations) and fails to cure such breach within a specified cure period, if the Company becomes bankrupt or insolvent or decides to cease development and commercialization of the licensed product, or if the Company challenges the validity or enforceability of any licensed patents.

Exclusive License Agreement with UABRF

In March 2016, the Company entered into an exclusive license agreement with UABRF, as amended from time to time (the "UABRF License Agreement"). The Company amended the UABRF License Agreement in December 2016, January 2017, June 2017 and November 2018. Under the UABRF License Agreement, the Company obtained an exclusive worldwide license under certain immunotherapy-related patents related to the use of gamma-delta T cells, certain CAR-T cells and combination treatments for cellular therapies developed by the University of Alabama at Birmingham and owned by UABRF to develop, make, have made, use, sell, import and otherwise commercialize products that are covered by such patents. Such exclusive license is subject to certain rights retained by UABRF and also the U.S. government.

In consideration of the license granted under the UABRF License Agreement, the Company paid UABRF a nominal upfront payment and issued 3,041 shares of common stock to UABRF, which were subject to certain antidilution rights.

In addition, the Company is required to pay UABRF development milestones totaling up to an aggregate of $1.4 million, lump-sum royalties on cumulative net sales totaling up to an aggregate of $22.5 million, mid-single-digit running royalties on net sales of the licensed products, low-single-digit running royalties on net sales of the licensed products, and a share of certain non-royalty income that the Company may receive, including from any sublicenses. The UABRF License Agreement also requires the Company to reimburse UABRF for the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the UABRF License Agreement, the Company is required to use good faith reasonable commercial efforts to develop, manufacture and commercialize the licensed product.

The term of the UABRF License Agreement will continue until the expiration of the licensed patents. The Company may terminate the UABRF License Agreement at will at any time upon prior written notice to UABRF. UABRF has the right to terminate the UABRF License Agreement if the Company materially breaches the agreement and fails to cure such breach within a specified cure period, if the Company fails to diligently undertake development and commercialization activities as set forth in the development and commercialization plan, if the Company underreports its payment obligations or underpays by more than a specified threshold, if the Company challenges the validity or enforceability of any licensed patents, or if the Company becomes bankrupt or insolvent.

10. NET LOSS PER SHARE

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, including 9.6 million shares of pre-funded warrants to purchase shares of common stock. Diluted net loss per share is the same as basic net loss per share for the periods presented since the effects of potentially dilutive securities are antidilutive given the net loss of the Company.

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (4,592)	$ (3,854)	$ (14,463)	$ (14,498)
Net loss per share—basic and diluted	$ (0.24)	$ (0.85)	$ (0.74)	$ (4.18)
Weighted-average number of shares used in computing net loss per share—basic and diluted	19,473,123	4,537,683	19,471,400	3,465,257

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share, as their effect is antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options to purchase common stock	1,580,336	507,784	1,247,075	491,102
Series A warrants	—	129,296	—	245,879
Series B warrants	166,964	303,574	166,964	343,374
Series C warrants	828,863	997,638	828,863	1,004,710
Total	2,576,163	1,938,292	2,242,902	2,085,065

11. COMMITMENTS AND CONTINGENCIES

Intellectual Property

The Company has existing commitments to the licensors of the intellectual property which the Company has licensed. These commitments are based upon certain clinical research, regulatory, financial and sales milestones being achieved. Additionally, the Company is obligated to pay a single-digit royalty on commercial sales on a global basis of licensed products under the Emory License Agreement and the UABRF License Agreement. The royalty term is the later of 15 years from first commercial sale or expiration of the last-to-expire component of the licensed intellectual property.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred costs related to such legal proceedings.

12. EQUIPMENT AND FACILITY LEASES

The Company has historically entered into lease arrangements for its facilities. As of September 30, 2026, the Company had four operating leases with required future minimum payments. The Company determined the classification of these leases to be operating leases and recorded right-of-use assets and lease liabilities as of the effective date. The Company's leases generally do not include termination or purchase options.

Finance Leases

The Company entered into an agreement with an equipment leasing company in 2018, which provided up to $2.5 million for equipment purchases in the form of sale and leasebacks or direct leases. As of September 30, 2026, the Company had two active leases with the leasing company. The initial term of each lease is three years and afterwards provides for either annual extensions or an outright purchase of the equipment.

The Company entered into an agreement with another equipment leasing company in the second quarter of 2023. As of September 30, 2026, the Company had one active lease from this leasing company. In June 2024, the Company entered into two new finance lease agreements with another leasing company. The terms of these leases are each three years and afterwards provide for either annual extensions or an outright purchase of the equipment.

The equipment leases require three advance rental payments to be held as security deposits. The security deposits held amounted to approximately $0.1 million as of each of September 30, 2026 and December 31, 2025, and are included in other non-current assets on the condensed balance sheets.

Operating Leases

The Company has an operating lease for office space in Birmingham, Alabama, which was modified and extended in March 2024 for an additional 60-month term ending in March 2029, with an option to extend for five additional years, resulting in an increase to both the right-of-use assets and operating lease liabilities. Throughout the term of the lease, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the lease, including a proportionate share of applicable taxes, operating expenses and utilities. In April 2025, the Company terminated its operating lease for additional unutilized office space in Birmingham, Alabama. The Company paid a one-time termination fee of $0.1 million and paid five monthly payments of $20,000, beginning on June 1, 2025. As of October 1, 2026, there were no payments remaining.

The Company has an operating lease for office space in New York, New York, with a term that commenced on September 15, 2021, and continues through March 2027. This lease was modified and extended in August 2026 for an additional 60-month term ending in July 2032, resulting in an increase to both the right-of-use assets and operating lease liabilities. Throughout the term of the lease, the Company is responsible for paying certain costs and expenses, in addition to the rent, as specified in the lease, including a proportionate share of applicable taxes, operating expenses and utilities.

The Company has identified an embedded lease within the University of Louisville Manufacturing Services Agreement, as the Company has the exclusive use of, and control over, a portion of the manufacturing facility and equipment of the facility during the contractual term of the manufacturing arrangement. The commencement date of the embedded lease was August 4, 2022 and it continues through August 2028.

The operating leases required security deposits at the inception of each lease. The security deposits amounted to $0.2 million as of September 30, 2026 and December 31, 2025. As of September 30, 2026 and December 31, 2025, $0.2 million was included in restricted cash.

The following table contains a summary of the lease costs recognized and other information pertaining to the Company's finance and operating leases for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Lease Cost				
Amortization of finance lease right-of-use assets	$ 62	$ 196	$ 232	$ 721
Interest on finance lease liabilities	3	14	15	57
Operating lease cost	197	555	642	894
Short-term lease cost	6	131	41	314
Variable lease cost	33	60	88	92
Total lease cost	$ 301	$ 956	$ 1,018	$ 2,078

	September 30, 2026
Other Lease Information	
Cash paid for amounts included in the measurement of lease liability – finance leases	$ 15
Cash paid for amounts included in the measurement of lease liability – operating leases	$ 378
Weighted-average remaining lease term – finance leases (years)	0.25
Weighted-average remaining lease term – operating leases (years)	3.45
Weighted-average discount rate – finance leases	13.9%
Weighted-average discount rate – operating leases	16.3%

The following table reconciles the undiscounted cash flows to the operating and finance lease liabilities at September 30, 2026 (in thousands):

	Finance Leases	Operating Leases
Remainder of 2026	$ 65	$ 310
2027	—	1,160
2028	—	965
2029	—	357
2030	—	296
Thereafter	—	481
Total lease payment	65	3,569
Less: interest	1	883
Total lease liabilities	64	2,686
Less: short-term lease liability	64	793
Long-term lease liability	$ —	$ 1,893

13. SEGMENTS

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the CODM or decision making group in making decisions on how to allocate resources and assess performance. The Company has one operating segment focused on the discovery, development and commercialization of gamma-delta T cell product candidates and TCEs for cancer and autoimmune disease. The CODM is the Company's CEO. The CEO manages the Company's operations, assesses performance for the operating segment and decides how to allocate resources based on net loss, which is reported on the condensed statements of operations. Depreciation expense, amortization expense, stock-based compensation expense, and non-cash lease expense are significant noncash items included in net loss reviewed by the CFO and CEO and are reported on the condensed statements of cash flows. The measure of segment assets is reported on the condensed balance sheets as total consolidated assets.

The following table presents certain financial data for the Company's reportable segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
INB-100 research and development expenses	$ 137	$ 171	$ 760	$ 625
INB-200 research and development expenses	1	-	58	15
INB-400 research and development expenses	32	41	100	667
Personnel-related indirect research and development expenses	1,336	1,150	3,913	3,651
Total general and administrative expenses	2,122	1,863	7,217	7,265
Other segment items[1]	964	629	2,415	2,275
Segment net loss	$ 4,592	$ 3,854	$ 14,463	$ 14,498

(1) Other segment items include preclinical expenses, interest income and other income.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains statements that may constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believes," "expects," "intends," "estimates," "projects," "anticipates," "will," "plan," "may," "should," or similar language are intended to identify forward-looking statements.

It is routine for our internal projections and expectations to change throughout the year, and any forward-looking statements based upon these projections or expectations may change prior to the end of the next quarter or year. Readers of this Quarterly Report are cautioned not to place undue reliance on any such forward-looking statements. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Risks and uncertainties are identified under "Risk Factors" in Item 1A herein and in our other filings with the Securities and Exchange Commission ("SEC"). All forward-looking statements included herein are made only as of the date hereof. Unless otherwise required by law, we do not undertake, and specifically disclaim, any obligation to update any forward-looking statement, whether as a result of new information, future events, or otherwise after the date of such statement.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and related notes included elsewhere in this Form 10-Q, and our audited financial statements and related notes for the year ended December 31, 2025 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (the "Annual Report"). Unless otherwise indicated, all information in this Quarterly Report on Form 10-Q gives effect to a 1-for-30 reverse stock split of our common stock that became effective on June 5, 2025, and all references to shares of common stock outstanding and per share amounts give effect to the reverse stock split.

Overview

We are a leading clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell product candidates and T cell engagers ("TCEs") for cancer and autoimmune diseases. We are the most clinically advanced gamma-delta T cell-focused company and are utilizing our suite of DeltEx platform technologies as we aspire to eliminate cancer cells to achieve our mission of what we refer to as Cancer Zero™ — the safe elimination of all cancer and target cells in every patient battling disease. We develop TCEs, along with *ex vivo* expanded and activated gamma-delta T cell candidates based upon our deep expertise in gamma-delta T cell biology, proprietary genetic engineering, and cell-type specific manufacturing capabilities, which we refer to collectively as our DeltEx platform. Our platform employs TCEs, allogeneic, autologous, induced pluripotent stem cell ("iPSC"), and genetically modified cell therapy approaches that are designed to effectively identify and eradicate tumor or target cells. To date, we have conducted two primary investigator-sponsored Phase 1 clinical trials evaluating our gamma-delta T cell technologies in cancer patients, which have both completed primary enrollment. INB-100 is assessing our DeltEx Allogeneic ("Allo") gamma-delta T cell therapy in adult patients with high-risk leukemias undergoing haploidentical stem cell transplantation ("HSCT"). INB-200 evaluated our DeltEx Drug Resistant Immunotherapy ("DRI") in patients with newly diagnosed glioblastoma ("GBM"). Both trials have demonstrated encouraging clinical activity, including long-term durable remissions, with patients remaining alive and in remission or progression-free for more than four years.

Most recently we introduced INB-600, our proprietary, internally developed TCE platform. We have demonstrated that INB-619, a CD19 targeted gamma-delta TCE can efficiently and completely eliminate targeted B cells in a dose-dependent manner. Data presented at The American College of Rheumatology Convergence 2025 meeting ("ACR Convergence 2025") highlighted the potential of INB-619 in B cell-driven autoimmune diseases such as systemic lupus erythematosus ("SLE") and demonstrated deep B cell depletion through selective activation and expansion of gamma-delta T cells. We expect to report initial *in vivo* data for INB-619 by year-end 2026.

INB-100, our first DeltEx allogeneic product candidate, was developed to assess the safety and tolerability of donor-derived manufactured expanded and activated gamma-delta T cells that do not undergo additional genetic modification. The Phase 1 trial of INB-100 has completed primary enrollment and a recommended Phase 2 dose ("RP2D") has been determined. We are currently enrolling an expansion cohort at the RP2D, with a target of up to an additional 15 patients (for a minimum of 25 total patients in the INB-100 Phase 1 trial), to confirm the improvements in relapse free and OS observed to date. We expect to complete the treatment of all patients and present a clinical update at the American Society of Hematology (ASH) Annual Meeting in December 2026.

Our DeltEx DRI product candidate, INB-200, is being developed for newly diagnosed GBM. Patient dosing in the investigator-sponsored Phase 1 trial of INB-200 (NCT04165941) has been completed and we continue to follow patients for progression-free survival ("PFS") and overall survival ("OS"). In July 2026 we announced the publication of peer-reviewed clinical data from our Phase 1 trial of INB-200 in The Journal of Clinical Oncology ("JCO"), titled: "Intracranial injection of ex vivo expanded and activated gamma-delta T cells engineered with a MGMT-expressing lentivector in patients with primary glioblastoma."

INB-400 is our corporate-sponsored investigational new drug application ("IND") for the Phase 2, multi-center clinical trial evaluating our DeltEx DRI technology in newly diagnosed GBM. Treatment of any enrolled patients has been completed and the IND remains open. In September 2024, following a pipeline prioritization review, we suspended further enrollment in the Phase 2 trial of INB-400 to conserve capital. The trial was designed to further evaluate genetically modified, DRI gamma-delta T cells in newly diagnosed GBM patients across multiple centers in the United States. In June 2026, we presented longer-term follow-up data at the American Society of Clinical Oncology ("ASCO") Annual Meeting.

This data was updated through May 15, 2026, and patients who received repeated doses (three or six) of DeltEx DRI gamma-delta T cells reported a median progression-free survival ("mPFS") of 13.0 months and an OS exceeding 19.5 months, with median overall survival ("mOS") continuing to grow. Our DeltEx DRI approach has the potential to address this significant unmet need and demonstrates the activity of gamma-delta T cells. We expect to provide further clinical updates, including additional mOS data from the total data set, in an oral session at the Society for Neuro-Oncology Annual Meeting in November 2026.

In April 2023, we received Orphan Drug Designation ("ODD") from the FDA for both the autologous and allogeneic DeltEx DRI INB-400 product candidates, covering a broad range of malignant glioma indications, including relapsed and newly diagnosed GBM. We have sought further guidance from the FDA regarding potential development and regulatory pathways and expect to evaluate any potential funding sources and alternative strategic opportunities to derive value from this program.

We also have a portfolio of preclinical programs within our DeltEx pipeline which remain suspended in development due to current market interest and prioritization. These include INB-300, a targeted non-signaling gamma-delta T cell based chimeric antigen receptor ("nsCAR") construct which is applicable to both solid and liquid tumors, and INB-500, which encompasses our ability to produce gamma-delta T cells from iPSCs.

Our Pipeline



* DRI = Drug Resistant Immunotherapy, or a chemotherapy resistant cell therapy
** 1L = First line therapy
^ Timing of next anticipated milestones are estimates based on the successful raise of additional capital to fund our programs and are subject to change
# Please refer to the Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2026, for additional details about IN8bio's pipeline efforts

Going Concern

Since inception in 2016, our operations have focused on identifying and developing potential product candidates, conducting clinical trials, organizing and staffing, business planning, establishing our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations primarily through the sale of equity and equity-linked securities, including through our initial public offering ("IPO"), follow-on offering, at-the-market ("ATM") programs, and multiple private placements.

We expect to incur additional losses in the future as we advance our product candidates through clinical trials, grow our clinical, regulatory and quality capabilities, and incur costs associated with operating as a public company. Based on our business strategy, our existing cash of $14.0 million as of September 30, 2026 is not anticipated to fund our projected operating expenses and capital expenditure requirements for a period of at least 12 months from the date of issuance of the accompanying condensed financial statements, and accordingly, there is substantial doubt about our ability to continue to operate as a going concern.

We continue to maintain cash preservation measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility given the ongoing market environment for biotechnology stocks. These cash preservation measures may impact our ability and the timing to execute our strategy, including our ability to achieve the anticipated milestones and the timing of regulatory filings for our preclinical and clinical programs. To continue to fund our operations, management has developed plans, which primarily consist of the pipeline prioritization, raising additional capital through some combination of equity and/or debt offerings, including through our ATM program, and identifying strategic collaborations, licensing or other arrangements to support development of our product candidates.

In connection with our private placement completed in December 2025, we may also be eligible to receive up to approximately $20.1 million in additional gross proceeds in exchange for up to 14,579,706 shares of common stock (or, for certain investors, pre-funded warrants in lieu of common stock), subject to the achievement of certain milestone-driven conditions related to preclinical data for our CD19 targeting INB-619 product candidate. In addition, we may receive an additional $6.7 million in aggregate proceeds if the holders of our Series C warrants exercise their warrants in full. Further, if not otherwise redeemed by us, we may also receive aggregate proceeds of up to $2.3 million from the exercise of our outstanding Series B warrants in full. There is no assurance, however, that we will receive any additional proceeds from the second closing of the 2025 private placement or the exercise of outstanding warrants or pre-funded warrants, that any additional financing or any revenue-generating collaboration will be available when needed, that management will be able to obtain financing or enter into a collaboration on terms acceptable to us, or that any additional financing or revenue generated through third-party collaborations will be sufficient to fund our operations. If additional capital is not available to us on a timely basis, or at all, we will be required to take additional actions beyond the cost preservation measures initiated to date to address our liquidity needs, including exploring other strategic options, continuing to further reduce operating expense or delaying, reducing the scope of, discontinuing or altering our research and development activities. For additional information, see "—Liquidity and Capital Resources" below.

The actual amount of cash that we will need to operate is subject to many factors, including those described in the section titled "Risk Factors." The condensed financial statements have been prepared on the basis that we will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty.

Components of Our Results of Operations

Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for one or more of our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- employee-related expenses, including salaries, related benefits, severance payments and stock-based compensation expense for employees engaged in research and development functions;
- fees paid to consultants for services directly related to our product development and regulatory efforts;
- expenses associated with conducting preclinical studies performed by ourselves, outside vendors or academic collaborators;

- expenses incurred in connection with conducting clinical trials including investigator grants and site payments for time and pass-through expenses and expenses incurred under agreements with contract research organizations ("CROs") as well as contract manufacturing organizations ("CMOs") and consultants that conduct and provide supplies for our preclinical studies and clinical trials;
- costs to manufacture drug product candidates for use in our preclinical studies and clinical trials;
- costs associated with preclinical activities and development activities;
- costs associated with our intellectual property portfolio; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our condensed financial statements as prepaid or accrued research and development expenses. We allocate our direct external research and development costs across each product candidate. Preclinical expenses consist of external research and development costs associated with activities to support our current and future clinical programs but are not allocated by product candidate due to the overlap of the potential benefit of those efforts across multiple product candidates.

Research and development activities are central to our business. We expect that our research and development expenses will increase in the future as we continue clinical development for our product candidates and continue to discover and develop additional product candidates. If any of our product candidates enter into later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, auditing, tax and consulting services; travel expenses; director and officer insurance expenses as a publicly traded company; and facility-related expenses, which include shared expenses for rent and maintenance of facilities and other operating costs not included in research and development.

We expect that our general and administrative expenses will increase in the future, contingent on additional funding as our organization and headcount needed in the future grow to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to building a team to support our administrative, accounting and finance, communications, legal and business development efforts. In addition, we expect increased expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Interest Income

Interest income includes interest earned from certain bank accounts.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table sets forth our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 2,599	$ 2,104	$ 495
General and administrative	2,122	1,863	259
Total operating expenses	4,721	3,967	754
Interest income	129	113	16
Loss from operations	(4,592)	(3,854)	(738)
Net loss	$ (4,592)	$ (3,854)	$ (738)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Direct research and development expenses:			
INB-100	$ 137	$ 171	$ (34)
INB-200	1	-	1
INB-400	32	41	(9)
Unallocated expenses			
Preclinical expenses	621	99	522
Personnel expenses (including stock-based compensation)	1,336	1,150	186
Facility-related and other expenses	472	643	(171)
Total research and development expenses	$ 2,599	$ 2,104	$ 495

Research and development expenses were $2.6 million for the three months ended September 30, 2026, compared to $2.1 million for the comparable prior year period. This includes non-cash items such as stock-based compensation ("SBC") and depreciation of $0.4 million for the three months ended September 30, 2026. The increase of $0.5 million was primarily due to increases in direct preclinical costs of $0.5 million for INB-600 and $0.2 million personnel related expenses, partially offset by a $0.2 million decrease in facility-related expenses.

General and Administrative Expenses

General and administrative expenses were $2.1 million for the three months ended September 30, 2026, compared to $1.9 million for the comparable prior year period. This includes non-cash items such as SBC and depreciation of $0.3 million for the three months ended September 30, 2026. The increase of $0.2 million was primarily due to an increase in professional services.

Interest Income

Interest income was $0.1 million for the three months ended September 30, 2026 and 2025.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table sets forth our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 7,705	$ 7,563	$ 142
General and administrative	7,217	7,265	(48)
Total operating expenses	14,922	14,828	94
Interest income	459	330	129
Loss from operations	(14,463)	(14,498)	35
Net loss	$ (14,463)	$ (14,498)	$ 35

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Direct research and development expenses:			
INB-100	$ 760	$ 625	$ 135
INB-200	58	15	43
INB-400	100	667	(567)
Unallocated expenses			
Preclinical expenses	1,123	158	965
Personnel expenses (including stock-based compensation)	3,913	3,651	262
Facility-related and other expenses	1,751	2,447	(696)
Total research and development expenses	$ 7,705	$ 7,563	$ 142

Research and development expenses were $7.7 million for the nine months ended September 30, 2026, compared to $7.6 million for the comparable prior year period. This includes non-cash items such as SBC and depreciation of $1.2 million for the nine months ended September 30, 2026. This was primarily due to increases of $1.0 million in preclinical costs related to the TCE program, $0.3 million personnel related expenses, and $0.1 million for direct clinical costs related to INB-100, partially offset by decreases in direct clinical costs of $0.6 million for INB-400 and facility related costs of $0.7 million.

General and Administrative Expenses

General and administrative expenses were $7.2 million for the nine months ended September 30, 2026, compared to $7.3 million for the comparable prior year period. This includes non-cash items such as SBC and depreciation of $0.7 million for the nine months ended September 30, 2026. The decrease of $0.1 million was primarily due to a decrease in personnel-related costs, including SBC and a reduction in professional services.

Interest Income

Interest income was $0.5 million and $0.3 million for the nine months ended September 30, 2026 and 2025, respectively.

Liquidity and Capital Resources

Overview

We have funded our operations primarily through the sale of equity and equity-linked securities, including through our IPO, follow-on offering, ATM programs and multiple private placements. Through September 30, 2026, we have raised an aggregate of $163.3 million of gross proceeds from the sale of our securities.

As of September 30, 2026, we had cash of $14.0 million, which is only expected to fund our projected operating expenses and capital expenditure requirements through April 2027. We continue to deploy cash preservation measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy, including our ability to achieve the anticipated milestones and the timing of regulatory filings for our preclinical and clinical programs. To continue to fund our operations, management has developed plans, which primarily consist of the pipeline prioritization, raising additional capital through some combination of equity and/or debt offerings, including through our ATM program, and identifying strategic collaborations, licensing or other arrangements to support development of our product candidates.

In connection with the private placement completed in December 2025, we may also be eligible to receive up to approximately $20.1 million in additional gross proceeds in exchange for up to 14,579,706 shares of common stock (or, for certain investors, pre-funded warrants in lieu of common stock), subject to the achievement of certain milestone-driven conditions related to preclinical data for our CD19 targeting INB-619 product candidate. In addition, we may receive aggregate proceeds of up to $6.7 million from the exercise of our outstanding pre-funded warrants and Series C warrants, assuming the exercise in full of all of such warrants for cash. Further, if not otherwise redeemed by us, we may also receive aggregate proceeds of up to $2.3 million from the exercise in full of our outstanding Series B warrants. See Note 7, Warrants, in our unaudited condensed financial statements contained elsewhere in this Quarterly Report for additional information on our outstanding warrants. There is no assurance, however, that we will receive any additional proceeds from these warrants or that any additional financing or any revenue-generating collaboration will be available, when

needed. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or explore other strategic options for our research and development programs or other opportunities, or even terminate our operations.

ATM Program

In November 2022, we entered into a Controlled Equity Offering℠ sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") and Truist Securities, Inc. ("Truist") under which Cantor Fitzgerald and Truist agreed to act as our sales agents to sell shares of our common stock, from time to time, in an ATM program. In March 2024, we delivered a termination notice to Truist, removing them as sales agent under the sales agreement, and on May 29, 2026, we and Cantor Fitzgerald mutually agreed to terminate the sales agreement effective at the close of business on May 29, 2026.

In November 2025, we filed a shelf registration statement on Form S-3 (File No. 333-291393) (the "Shelf Registration Statement") with the SEC, which became effective on May 20, 2026, which permits the issuance and sale of up to a maximum aggregate offering price of $200.0 million of our common stock, preferred stock, various series of debt securities, warrants to purchase common stock, preferred stock or debt securities, rights to purchase equity or debt securities, and/or units to purchase any combination of such securities. On June 1, 2026, we entered into a Capital on Demand™ Sales Agreement (the "Sales Agreement") with JonesTrading Institutional Services LLC ("JonesTrading") with respect to an at-the-market offering program under which we may issue and sell, from time to time at our sole discretion, shares of our common stock, through or to JonesTrading (the “ATM Program”) pursuant to the Shelf Registration Statement. As of November 2, 2026, $2.8 million remained available for the sale of our common stock under the ATM Program.

As of the date of this Form 10-Q, our public float was less than $75 million. As a result, we are subject to the limitations of General Instruction I.B.6 to Form S-3 until such time as our public float exceeds $75 million, which means we only have the capacity to sell shares up to one-third of our public float under shelf registration statements in any 12-month period. We will remain constrained by the limitations of General Instruction I.B.6 to Form S-3 until such time as our public float exceeds $75 million, at which time the number of securities we may sell under a Form S-3 registration statement will no longer be limited by limitations of General Instruction I.B.6 to Form S-3.

Funding Requirements

We expect our expenses to increase substantially contingent on additional funding in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, the costs of manufacturing our clinical and preclinical product candidates, clinical costs, legal and other regulatory expenses and general overhead costs.

Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current and future product candidates;
- the cost and timing of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;

- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third party and government payers;
- addressing any potential interruptions, delays and/or cost increases resulting from public health crises, increased interest rates and geopolitical tensions, such as wars and terrorism;
- economic weakness, including inflation, or political instability in particular economies and markets;
- the effect of competing medical, scientific, technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

Additionally, inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates, tariffs and overhead costs may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increased operating costs in the near future (especially if inflation rates rise). Such increases may impact our labor costs and research and development costs, due to supply chain constraints, consequences associated with geopolitical tensions and any future tariffs enacted by the U.S. government and employee availability and wage increases, which may result in additional stress on our working capital resources.

Since inception, we have not generated any product revenue and have incurred net losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all. It is likely that we will seek third-party collaborators for the future commercialization of our product candidates that are approved for marketing. However, we may seek to commercialize our products at our own expense, which would require us to incur significant additional expenses for marketing, sales, manufacturing and distribution.

Until such time as we can generate significant revenue from product sales, if ever, we expect to continue to finance our operations from the sale of additional equity or debt financings, or other capital which comes in the form of strategic collaborations, licensing, or other arrangements. In the event that additional financing is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, it may result in dilution to our existing stockholders.

If we raise funds through strategic collaboration, licensing or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions, including as a result of increases in inflation and interest rates, disruptions to, and volatility in, the credit and financial markets in the United States, tariffs and trade wars, and other geopolitical tensions, such as wars and terrorism and future U.S. government shutdowns. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or explore other strategic options for our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Material Cash Requirements

Our material cash requirements as of September 30, 2026 included operating lease commitments, including the lease of our current headquarters office in New York, New York, laboratory and office space in Birmingham, Alabama and a manufacturing service agreement with a third party to engage in research of cell therapy products. See Note 12, Equipment and Facility Leases, in our unaudited condensed financial statements contained elsewhere in this Quarterly Report for additional information. As of September 30, 2026, we had fixed lease payment obligations of $3.6 million, with $1.3 million payable within 12 months.

Except as disclosed above, we have no long-term debt and no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase-order basis. We enter into contracts in the normal course of business with equipment and reagent vendors, CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not determinable.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods below (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (12,619)	$ (10,573)
Net cash used in investing activities	(241)	—
Net cash (used in) provided by financing activities	(302)	10,149
Net (decrease) increase in cash and restricted cash	$ (13,162)	$ (424)

Operating Activities

Cash used in operating activities was $12.6 million during the nine months ended September 30, 2026, primarily due to our net loss of $14.5 million and changes in operating assets and liabilities of $0.8 million, partially offset by non-cash charges of $2.5 million. Increases in our operating assets and liabilities consisted primarily of $0.5 million in accrued expenses and other current liabilities relating primarily to accrued compensation, accrued clinical and preclinical, and accrued legal, and $0.1 million in net operating lease liabilities, partially offset by $0.4 million in prepaid expenses and other current assets and a decrease of $0.2 million in accounts payable. Non-cash charges consisted primarily of $1.1 million in stock-based compensation, $0.8 million of depreciation, and $0.6 million in amortization of right-of-use assets associated with our operating and finance leases for the period.

Cash used in operating activities was $10.6 million during the nine months ended September 30, 2025, primarily due to our net loss of $14.5 million and changes in operating assets and liabilities of $0.5 million, partially offset by non-cash charges of $4.4 million. Increases in our operating assets and liabilities consisted primarily of $0.4 million in prepaid expenses and other current assets and $0.1 million in non-current assets, partially offset by decreases of $0.6 million in accrued expenses and other current liabilities relating primarily to accrued compensation, accrued clinical trials, and accrued legal, $0.2 million in accounts payable and $0.2 million in net operating lease liabilities. Non-cash charges consisted primarily of $2.5 million in stock-based compensation, $1.2 million in amortization of right-of-use assets associated with our operating and finance leases for the period and $0.8 million of depreciation.

Investing Activities

Cash used in investing activities was $(0.2) million during the nine months ended September 30, 2026, primarily due to the purchase of property and equipment.

Cash used in investing activities was nil during the nine months ended September 30, 2025.

Financing Activities

Cash used in financing activities was $(0.3) million during the nine months ended September 30, 2026, primarily due to $0.3 million in principal payments of finance leases.

Cash provided by financing activities was $10.1 million during the nine months ended September 30, 2025, primarily due to $8.4 million in net proceeds received from our ATM Program, $2.3 million in warrants exercised, partially offset by $0.6 million in principal payments of finance leases.

Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our condensed financial statements, which are prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience, known trends and other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. In making estimates and judgments, management employs critical accounting policies.

We have listed below our critical accounting policies that we believe to have the greatest potential impact on our financial statements. Historically, our assumptions, judgments and estimates relative to our critical accounting estimates have not differed materially from actual results.

Critical Accounting Policies

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. Our significant accounting policies are more fully described in Note 2 to our financial statements located elsewhere in this Quarterly Report on Form 10-Q. We have listed below our critical accounting estimates and accounting policies that we believe to have the greatest potential impact on our financial statements. Historically, our assumptions, judgments and estimates relative to our critical accounting estimates have not differed materially from actual results.

Research and Development Costs

We expense all costs incurred in performing research and development activities. Research and development expenses include salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to nonemployees and entities that conduct certain research and development activities on our behalf and expenses incurred in connection with license agreements. Non-refundable advance payments for goods or services that will be used for rendered or future research and development activities are deferred and amortized over the period that the goods are delivered, or the related services are performed, subject to an assessment of recoverability.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. We make estimates of our accrued expenses as of each condensed balance sheet date in the condensed financial statements based on facts and circumstances known to us at that time. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure all stock-based awards granted to employees, nonemployees and directors based on the fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We account for our stock-based compensation as an expense in the condensed statements of operations based on the awards' grant date fair values. We account for forfeitures as they occur by reversing any expense recognized for unvested awards. We estimate the fair value of options granted using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to us, including stage of product development and life science industry focus. We use the simplified method as allowed by the SEC Staff Accounting Bulletin (SAB) No. 107, Share-Based Payment, to calculate the expected term for options granted to employees, as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Recent Accounting Pronouncements

During the nine months ended September 30, 2026, we did not adopt any new Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board.

We have evaluated recently issued and unadopted ASUs, and believe the adoption of these standards will not have a material impact on our condensed financial statements.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an emerging growth company ("EGC") as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until December 31, 2026, or such earlier time that we are no longer an emerging growth company. We would cease to be an EGC earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates or we issue more than $1.0 billion of non-convertible debt securities over a three-year period. For so long as we remain an EGC, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. We may choose to take advantage of some, but not all, of the available exemptions.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company," and we may continue to be a smaller reporting company so long as either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2026, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the nine months ended September 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings that we believe could have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment.

Summary of Selected Risk Factors Associated with Our Business

The following is a summary of the principal risks associated with an investment in our common stock:

- There is substantial doubt regarding our ability to continue as a going concern. We will require substantial additional funding to finance our operations through regulatory approval, and if we are unable to raise capital, we could be forced to delay, reduce or explore other strategic options for certain of our development programs, or even terminate our operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.
- A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.
- Our outstanding warrants may not be exercised and we may not receive any cash proceeds from any exercise of warrants.
- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- Our ability to raise capital may be limited by applicable laws and regulations.
- We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We are dependent on the successful clinical development, regulatory approval and commercialization of our gamma-delta T cell and T cell engager product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.
- Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Our DeltEx product candidates utilize novel approaches to cell therapies, including cancer treatment, which presents significant challenges to successfully develop, manufacture and commercialize our product candidates.
- The clinical and commercial utility of our DeltEx platform is uncertain and may never be realized. Additionally, certain aspects of the function and production of gamma-delta T cells and TCEs are poorly understood or currently unknown and may only become known through further preclinical and clinical testing.
- Clinical product candidate development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We may not be able to file investigational new drug ("IND") applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or any other regulatory agency may not permit us to proceed.
- Development of a product candidate intended for use in combination with an already approved therapy may present increased complexity and more or different challenges than development of a product candidate for use as a single agent or monotherapy.

- Public opinion and scrutiny of our competitors, cell-based immunotherapy, T cell engagers, and genetic modification approaches may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business, raise additional capital and our business plans.
- We face significant competition, and many of our competitors have substantially greater experience and resources than we have.
- Our manufacturing processes are complex, and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for future clinical trials or commercialization, if approved.
- We may rely on third-party contractors or contract development manufacturing organization for the manufacturing of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.
- We currently store our gamma-delta T cells, TCEs and biologic correlative and research specimens from clinical trials and development programs and clinical lentivectors at our research and development facilities and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise would cause delays in replacement, and our business could suffer.
- We are currently dependent on a single third-party supplier for manufacture of our automated manufacturing device and our lentiviral vectors for our cellular therapies. These are critical products required for the manufacturing of our product candidates, including INB-100, INB-200 and INB-400. Any damage or loss to the ability of our suppliers to deliver supplies in a timely manner could cause delays in manufacturing or our clinical trials and our business could suffer.
- We rely on third-party healthcare professionals to administer gamma-delta T cells to patients, and our business could be harmed if these third parties administer these cells incorrectly.
- Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our license agreements with the University of Alabama at Birmingham Research Foundation, Children's Healthcare of Atlanta, Inc. and Emory University, or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.
- Our ability to compete in the pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on the services of our co-founders, William Ho, our Chief Executive Officer ("CEO"), and Dr. Larry Lamb, our Chief Scientific Officer ("CSO"), and of our President and Chief Operating Officer ("COO"), Dr. Kate Rochlin, and the loss of these members of our management team or other key employees could impede, delay or prevent the successful development of our product pipeline, the completion of our current and planned clinical trials, and the commercialization of our products or in-licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan.
- Our (or the third parties with whom we work) actual or perceived failures to comply with applicable data privacy and security obligations, including laws, regulations, contractual obligations, industry standards and other obligations could lead to regulatory investigations or actions, litigation (including class claims), fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.
- Unstable market and economic conditions, including as a result of increases in inflation, the price of oil, and interest rates, tariffs and trade wars, elections, public health crises or geopolitical tensions, such as wars and terrorism, and future U.S. government shutdowns, may have serious adverse consequences on our business, ability to raise capital, financial condition and share price.

Risks Related to Our Financial Position and Capital Needs

There is substantial doubt regarding our ability to continue as a going concern. We will require substantial additional funding to finance our operations, and if we are unable to raise capital, we could be forced to delay, reduce or explore other strategic options for certain of our development programs, or even terminate our operations.

As of September 30, 2026, we had cash of $14.0 million, which is only expected to fund our projected operating expenses and capital expenditure requirements through April 2027. We continue to maintain cash preservation measures to defer or reduce costs in the near term in order to preserve capital and increase financial flexibility. These cash preservation measures may impact our ability and the timing to execute our strategy. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. We continue to analyze various alternatives, including additional debt or equity financings or other arrangements. Due to the uncertainty of our ability to meet our current operating and capital expenses, in their report on our audited annual financial statements as of and for the years ended December 31, 2025 and 2024, our independent auditors included an explanatory paragraph regarding our ability to continue as going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and we may have a more difficult time obtaining financing. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations.

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, our product candidates and advance our other programs. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Other unanticipated costs may also arise. Because the design and outcome of our ongoing and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Moreover, we will need to obtain substantial additional funding in connection with our continuing operations and planned research and clinical development activities. Our future capital requirements will depend on many factors, including:

- the timing, progress, costs and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, reimbursement and distribution, for any of our product candidates for which we may receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we may receive marketing approval;
- the cost of any milestone and royalty payments with respect to any approved product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

We may never generate the necessary data or results required to obtain regulatory approval in order to generate revenue from product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, including as a result of increases in inflation and interest rates, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, tariffs and trade wars, elections, public health crises or geopolitical tensions, such as wars and terrorism and future U.S. government shutdowns. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or explore other strategic options for our research and development programs or other opportunities, or even terminate our operations. If we do not obtain additional financing and are required to terminate our operations, our stockholders will lose all or a part of their investment.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we will need to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital, if available, through the sale of equity or convertible debt securities, including through our ATM program, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. For example, in recent years we have issued a substantial number of shares of common stock and warrants to purchase shares of common stock to raise additional capital, including most recently our sale and issuance of 5,127,029 shares of common stock and pre-funded warrants to purchase up to 9,452,677 shares of common stock in a private placement in December 2025. In addition, we may also be eligible to receive up to approximately $20.1 million in additional gross proceeds in exchange for up to 14,579,706 shares of common stock (or, for certain investors, pre-funded warrants in lieu of common stock), subject to the achievement of certain milestone-driven conditions related to preclinical data for our CD19 targeting INB-619 product candidate.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us, if at all. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or explore other strategic options for our product candidate development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, including as a result of exercises of the outstanding warrants. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Our outstanding warrants may not be exercised and we may not receive any cash proceeds from any exercise of warrants.

As of September 30, 2026, we had 9,620,002 pre-funded warrants, 166,964 Series B warrants, and 828,863 Series C warrants outstanding. Of these, 9,452,677 pre-funded warrants have an exercise price of $0.0001 per share and 167,325 pre-funded warrants have an exercise price of $0.003 per share. The Series B warrants have an exercise price of $13.50 per share and will expire on December 13, 2028. The Series C warrants have an exercise price of $8.10 per share and will expire on October 4, 2027.

We may receive up to an aggregate of $9.0 million from the exercise of the Series B and Series C warrants, assuming the exercise in full of all of the warrants for cash. However, we will only receive proceeds to the extent the holders of warrants elect to exercise. We can provide no assurances as to the amount of proceeds we will receive from the exercise of warrants or whether we will receive any proceeds at all. Additionally, the warrants may, in certain circumstances, be exercised by way of cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the applicable warrant. Accordingly, we may not receive any additional funds, or any significant additional funds, upon any exercise of the warrants.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred significant operating losses since inception. Our net loss was $14.5 million and $14.5 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $155.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, organizing and

staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. To date, we have never obtained regulatory approval for, or commercialized, any product candidates. It could be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- conduct our current and future clinical trials for our product candidates;
- continue to develop and advance our preclinical product candidates;
- seek regulatory and marketing approvals for any of our current and future product candidates that successfully complete clinical trials;
- establish our manufacturing capability, including developing our contract development and manufacturing relationships, and building our internal manufacturing facilities;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing and commercialization efforts;
- establish a sales, marketing and distribution infrastructure in the future to commercialize any current or future product candidate for which we may obtain marketing approval;
- seek to identify, discover, develop and commercialize additional product candidates; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our current and future product candidates, obtaining regulatory approval, establishing and validating commercial-scale current good manufacturing practices ("cGMP") facilities, marketing and selling any products for which we obtain regulatory approval (including through third parties), as well as discovering or acquiring and developing additional product candidates. We are only in the preliminary stages of some of these activities. As inflation expectations remain uncertain in the United States and globally, we expect the costs of certain activities will increase. Should suppliers and consultants increase prices to cover increased wages and materials costs, we expect our expenses and cash utilization could increase substantially. We may never succeed in these activities and, even if we do, may never generate revenues that are sufficient to offset our expenses and achieve profitability.

Because of the numerous risks and uncertainties associated with product candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our ability to raise capital may be limited by applicable laws and regulations.

Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than $75.0 million, then the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. As our public float is currently less than $75.0 million, we are currently subject to this limitation. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities continues to be limited to one-third of our public float, we may need to conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, which would increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an early clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. Our operations to date have been limited to financing and staffing our company, developing our technology, identifying and developing our product candidates, undertaking preclinical studies, initiating and conducting clinical trials for our product candidates, business planning and raising capital. Other than INB-400, INB-200 and INB-100, all of our ongoing research programs are still in the preclinical or research stage of development, and the risk of failure in the biopharmaceutical industry for programs or products candidates at such stage of development is even higher than those in the clinical stage of development. We have not yet demonstrated an ability to successfully conduct or complete any clinical trials, including large-scale, multi-center pivotal clinical trials, obtain marketing approval, manufacture a clinical or commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes about six to ten years to develop a new drug from the time it enters Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing genetic medicine product candidates.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research and clinical focus to a company, if any of our product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to the Development of Our Product Candidates

We are dependent on the successful clinical development, regulatory approval and commercialization of our gamma-delta T cell and TCE product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate product revenue will be adversely affected.

Our business is dependent on our ability to successfully complete development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We may face unforeseen challenges in our product candidate development strategy, and we can provide no assurances that our product candidate or clinical trial design will prove to be effective, that we will be able to take advantage of abbreviated regulatory pathways for any of our product candidates, or that we will ultimately be successful in our future clinical trials. We expect that a substantial portion of our efforts and expenses over the next several years will be devoted to the development of our lead product candidates, in ongoing clinical trials. Our product candidates are in early stages of development and may never be commercialized. Additionally, we announced in September 2024 that we have suspended patient enrollment in the INB-400 Phase 2 clinical trial for newly diagnosed GBM while we explore additional funding, potential regulatory pathways and/or partnership opportunities, if any, for the program. We would require substantial additional funds to recommence and advance this trial through data and BLA submission.

We currently anticipate seeking initial regulatory approvals in the United States and the European Union but may in the future submit applications for the regulatory approval of one or more of our product candidates to additional foreign regulatory authorities, such as Australia. We have not applied or obtained regulatory approval for any product candidate in the United States or abroad, and it is possible that neither our current product candidates nor any product candidates we may seek to develop in the future will obtain regulatory approval. Neither we nor any of our partners are permitted to market any of our product candidates in the United States or abroad until we receive regulatory approval from the FDA or the applicable foreign regulatory agency.

All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies, assay development or clinical trials for our product candidates either pre- or post-approval, or it may object to elements of our clinical development program, requiring their alteration. We may also decide to modify clinical protocols or procedures in future clinical trials based on clinical and experimental data.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval or marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval or marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including, among others:

- disagreement with the design or conduct of any of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory agencies that our product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

Additionally, any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue.

Even if we eventually complete clinical testing and receive approval of a BLA, or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

Moreover, because all of our product candidates are based on the same core gamma-delta T cell technology, if any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems including the failure to demonstrate comparability or equivalence, these could impact the development plans for our other product candidates. Our failure to timely complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates could adversely affect our business, financial condition and results of operations.

Our product candidates are in early stages of development, and therefore they will require extensive additional preclinical and clinical testing. Success in preclinical studies or early-stage clinical trials may not be indicative of results in future clinical trials and we cannot assure you that any ongoing, planned or future clinical trials will lead to results sufficient for the necessary regulatory approvals.

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. INB-100 is our only product candidate currently in active clinical trials. While the IND remains open, in September 2024, we announced that we have suspended patient enrollment in the INB-400 Phase 2 clinical trial for newly diagnosed GBM while we explore additional funding, potential regulatory pathways and/or partnership opportunities for the program, if any. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials and/or product candidate will generate the same results or otherwise provide adequate data to demonstrate the efficacy, safety and equivalency of a product candidate. Preclinical studies and Phase 1 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical studies and earlier clinical trials does not ensure that later efficacy trials will be successful, nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or even if they successfully advance through earlier clinical trials.

Our novel approaches to immune cell therapies are unproven and as such, the cost and time needed to develop our product candidates is difficult to predict and our efforts may not be successful. If we do not observe favorable results in clinical trials of our product candidates, we may decide to delay or abandon clinical development of any such product candidate. Any such delay or abandonment could harm our business, financial condition, results of operations and prospects.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks, including failure in late-stage clinical trials even after achieving promising results in preclinical testing and earlier clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval.

Further, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Our gamma-delta T cell engager ("γδ TCE") programs, INB-600, INB-633 and INB-619, which are currently in preclinical development, are subject to significant risks and uncertainties that could materially impact development of this platform and impact our results, timelines, financing or business objectives. The development of these product candidates is in early stages and remains preclinical; the work required to bring a γδ TCE through IND-enabling development and into clinical development encompasses many critical processes including cloning into optimized GMP compliant vector and cell systems, scale-up, generation of transient or stable cell lines for production, GMP manufacturing and large-scale production. These processes present complex scientific and technical challenges and are subject to numerous risks and uncertainties, including the risk that the TCE's properties, such as the stimulatory/expansion domain, binding affinity or specificity, or targeting domains may not function as anticipated when transitioning from preclinical systems to a larger-scale production system. Additionally, achieving sufficient purity during the manufacturing scale up and purification process to meet stringent regulatory standards for clinical trials poses a significant risk, as difficulties in removing impurities or ensuring product stability could lead to manufacturing delays or failures. Furthermore, in IND-enabling animal models, there is a risk that the TCE may not demonstrate the anticipated efficacy or may exhibit toxicity not previously identified in *in vitro* or early *in vivo* testing, potentially due to differences in biological systems or unforeseen off-target effects. Advancing to clinical trials introduces additional uncertainties, including challenges in obtaining regulatory approvals, potential safety or efficacy issues, difficulties in patient recruitment, and the complexities of trial execution. Failure to successfully address these risks could delay or prevent the progression of our T cell engager into clinical development.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "topline" or preliminary data from our clinical trials. Interim, "topline" or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, "topline" and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, "topline," and preliminary data should be viewed with caution until the final data are available. Differences between interim, "topline" and preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, "topline," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Our DeltEx product candidates utilize novel approaches to cell therapies, including cancer treatment, which presents significant challenges to successfully develop, manufacture and commercialize our product candidates.

We believe that our product candidates represent a novel approach to immunotherapy, including cancer treatment, and we have concentrated significant research and development efforts to date developing our INB-100, INB-200 and INB-400 product candidates, as well as our additional drug-resistant immunotherapy ("DRI") gamma-delta T cell and gamma-delta T cell engager preclinical product candidates. Gamma-delta T cell immunotherapy is a newly emerging field and our approaches, including genetic modification and DeltEx DRI gamma-delta T cells, have not been extensively tested over any significant period. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in clinical trials or in obtaining marketing approval thereafter.

For example, INB-100, our novel allogeneic gamma-delta T cell product candidate that we are initially developing for the treatment of patients with acute leukemia undergoing hematopoietic stem cell transplantation, is manufactured from healthy donor T cells using our proprietary manufacturing process. Allogeneic versions of cell therapy and gamma-delta T cell product candidates is an unproven field of development and is subject to particular risks that are difficult to quantify, including understanding and addressing variability in the quality and quantity of a donor's T cells and the patient's potential immune reaction to the foreign donor cells, which could ultimately affect safety, efficacy and our ability to produce product in a reliable and consistent manner. As such, we may be faced with unforeseen results, delays and setbacks, in addition to the other foreseeable risks and uncertainties associated with developing immune cell therapies.

Additionally, we are the first company to advance a genetically modified gamma-delta T cell product candidate, INB-200, which we are currently developing for the treatment of certain solid tumors, into the clinic. The manufacture of our cell therapies involves complex processes, including, for INB-100, where blood cells are isolated from an allogeneic donor via leukapheresis, gamma-delta T cells are expanded and activated, and other cells are removed through magnetic separation and then cryopreserved. For INB-200, blood cells are isolated from the patient via leukapheresis, the gamma-delta T cells are transduced, expanded and activated, and, if required, other cells are removed through magnetic separation prior to cryopreservation.

Any delay or difficulties in manufacturing lentiviral vector and/or clinical supply of INB-100, INB-200 and INB-400 or any of our other current or future product candidates would adversely affect our business and operations. For additional details surrounding risks related to our manufacturing processes, see the risks highlighted in "Risks Related to Manufacturing and our Dependence on Third Parties," including "Our manufacturing processes are complex and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for future clinical trials or commercialization, if approved."

Advancing product candidates utilizing such novel approaches to immunotherapy creates significant challenges for us, including, among others:

- manufacturing our product candidate to our specifications and in a timely manner to support our clinical trials, and, if approved, commercialization;
- sourcing clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;
- understanding and addressing variability in the quality of a donor and/or patient's T cells, which could ultimately affect our ability to produce our product candidates in a reliable and consistent manner;
- conditioning patients with chemotherapy or other lymphodepletion agents in advance of administering our product candidates, which may increase the risk of adverse side effects;
- educating medical personnel regarding how to properly isolate cells, perform apheresis, administer our cells and the potential side effect profile of our product candidates, such as cytokine release syndrome, neurotoxicity, tumor inflammation-associated neurotoxicities, graft versus host disease, prolonged cytopenia, infections, hygromas and neutropenic sepsis, among others;
- enrolling sufficient numbers of patients in clinical trials;
- training a sufficient number of technicians in how to properly manufacture our cells;
- developing a reliable, safe, effective and cost-effective means of consistently expanding and manufacturing our cells;
- understanding and addressing variability in demand for manufacturing and its impact on capacity utilization of available infrastructure and costs;
- developing a reliable, safe and effective means of genetically modifying our cells;
- submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of immunotherapies for cancer and viral associated infectious diseases; and
- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges in order for us to successfully develop, commercialize and manufacture our product candidates utilizing our novel approaches to gamma-delta T cell therapies.

The clinical and commercial utility of our DeltEx platform is uncertain and may never be realized. Additionally, certain aspects of the function and production of gamma-delta T cells are poorly understood or currently unknown and may only become known through further preclinical and clinical testing.

To date, gamma-delta T cells have only been evaluated in early clinical trials. These clinical trials were primarily designed to evaluate safety and tolerability, and not designed to produce statistically significant results as to efficacy. Most of the data to date regarding gamma-delta T cells were derived from clinical trials not conducted by us, including physician-sponsored clinical trials, and utilizing gamma-delta T cells not manufactured by us. We currently have two ongoing clinical trials to evaluate gamma-delta T cells in investigator-sponsored clinical trials, which have enrolled and dosed only a limited number of patients to date. Success in early clinical trials does not ensure that large-scale clinical trials will be successful, nor does it predict final results. Even after the completion of our ongoing Phase 1 clinical trials, our gamma-delta T cell product candidates will have only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our product candidates as we expand into larger clinical trials.

We may not ultimately be able to provide the FDA with substantial clinical evidence to support a claim of safety, efficacy, equivalency, purity and potency sufficient to enable the FDA to approve our DeltEx platform product candidates for any indication. This may be because early clinical trials do not meet their endpoints, because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the results of such trials are not statistically significant, because the FDA disagrees with how we interpret the data from these clinical trials, or because the FDA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. For example, we are developing INB-100 for the treatment of patients undergoing hematopoietic stem cell transplantation for the treatment of AML, and our manufacturing processes are predominantly based on cells received from healthy haploidentical related donors with at least half of the major human leukocyte antigen ("HLA") types matched. Our clinical development plan for INB-100 will seek to determine the safety of HLA mismatched, donor-derived gamma-delta T cells and establish the risk of graft versus host disease ("GvHD") if any. While mismatched gamma-delta T cells are not known to initiate GvHD, we observed grade 1 and/or 2 GvHD in approximately 60% of patients treated with INB-100 as of January 17, 2025. We will also seek to better understand the persistence of mismatched gamma-delta T cells and their potential impact on immune reconstitution, clinical activity and duration of response. The grade 1/2 GvHD that we have observed has been responsive to steroid treatment, and we believe that a high degree of HLA matching will not be required to prevent or reduce the risks of GvHD or for clinically meaningful activity and durability of response. Competitor data presented at ASCO 2024 demonstrated that persistence of donor derived cells are correlated with levels of HLA matching and they are now advancing their programs to be haploidentical matched as we have in our INB-100 program. If it becomes apparent through preclinical testing or additional clinical trials that such HLA matching is always required, a future "off-the-shelf" product may not be attainable, which could prevent or delay the further advancement of "off-the-shelf" product candidates and adversely affect our business and future development plans. We will also need to demonstrate that our DeltEx platform product candidates are safe. Unexpected adverse events reported by ourselves or competitors can negatively impact the market and perception of the viability of cellular therapies broadly. In recent years a newly defined severe adverse event termed tumor inflammation-associated neurotoxicity ("TIAN") has been identified that can lead to severe neurological adverse events leading to patient death. While we have not identified or observed such toxicities in our clinical trials to date, unexpected adverse events can present significant risks. We do not have data on possible harmful long-term effects of our DeltEx platform product candidates and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and efficacy data sufficient to support submission of a marketing application or commercialization of our DeltEx platform product candidates is uncertain and is subject to significant risk.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may impose specific post-market requirements, such as establishment of a Risk Evaluation and Mitigation Strategy ("REMS") and request additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Clinical product candidate development involves a lengthy and expensive process with uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.

We may not commercialize, market, promote or sell any product candidate without obtaining marketing approval from the FDA or other comparable regulatory authority, and we may never receive such approvals. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.

A failure of one or more clinical trials can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our ongoing trials for INB-100 and INB-200 involve studying a relatively small patient population, which makes it difficult to predict whether the favorable results observed in such clinical trial will be repeated in larger and more advanced clinical trials.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the following (among other unforeseen events included in this "—Risks Related to the Development of our Product Candidates" subsection):

- delays in reaching a consensus with regulatory authorities on the design, location or implementation of our clinical trials;
- delays or setbacks in patient enrollment;
- clinical trials of our product candidates may produce negative or inconclusive results;
- the number of patients required for clinical trials for our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or may be lower than we anticipate due to challenges in recruiting and enrolling suitable patients that meet the study criteria, participants may drop out of these clinical trials at a higher rate than we anticipate or the duration of these clinical trials may be longer than we anticipate;
- the impact of future public health crises, which may slow potential enrollment, impact hospital clinical and/or administrative support staff, reduce the number of eligible patients for clinical trials, or reduce the number of patients that remain in our trials;
- imposition of a clinical hold by regulatory authorities as a result of, among other reasons, a serious adverse event, a failure in the chemistry manufacturing and controls requirements, or a failed inspection of our clinical trial operations, trial sites or manufacturing facilities;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; and
- need to conduct additional clinical trials or abandon product development programs.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

In addition, the clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. Regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the commercialization of resulting products.

Further, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may be delayed in obtaining marketing approval, or not obtain marketing approval at all, obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, and/or have regulatory authorities withdraw or suspend their approval or impose restrictions on distribution in the form of a modified REMS, among other results. We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Additionally, the FDA or an independent institutional review board ("IRB") may also suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA’s current Good Clinical Practice ("GCP") regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our INDs or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed.

Development of a product candidate intended for use in combination with an already approved therapy may present increased complexity and more or different challenges than development of a product candidate for use as a single agent or monotherapy.

We are developing certain of our product candidates, including INB-400 and INB-200, to be used in combination with approved therapies, such as chemotherapy, which may present additional challenges. For example, the FDA may require us to use more complex clinical trial designs, to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that most or any positive results are attributable to the already approved product. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross labeled. To the extent that we do not have rights to already approved products, this may require us to work with another company to satisfy such a requirement. Moreover, developments related to the already approved therapies may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the approved therapy's safety or efficacy profile, changes to the availability of the approved therapy, and changes to the standard-of-care.

If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in part depends on patient enrollment, and as such identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter difficulties in enrolling a sufficient number of eligible patients to participate in our clinical trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Because our focus includes rare disorders, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. Additionally, some of the initial indications for which we are developing our current product candidates, including glioblastoma and AML, primarily affect an elderly population over the age of 65, who might suffer from other age-related and unknown and/or pre-existing ailments or health concerns. If any such patient enrolled in our smaller-scale Phase 1 trials has to drop out due to pre-existing health issues or due to a serious adverse effect, or otherwise dies, and we are not able to recruit additional patients in a timely manner, or at all, our clinical trials could be delayed or otherwise halted. As such, despite diligent planning of our clinical trials and analysis of their feasibility regarding patient recruitment, we may experience difficulties, delays or inability in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the severity and incidence of the disease under investigation;
- the design of the trial and the complexity for patients and clinical sites;
- the general health condition of the patient and their gamma-delta T cells and immune cells broadly;
- the risk that patients' general health conditions do not allow the conduct of study/screening procedures (such as leukapheresis) the manufacture of therapeutic product or application of the appropriate standard-of-care treatment or application of the Stupp regimen;
- the ability to consistently manufacture gamma-delta T cell product candidates in sufficient quantities at sufficient activity and/or transduction efficiency to provide a suitable therapeutic dose of gamma-delta T cells;
- competing clinical trials for similar therapies, other new therapeutics, new combination treatments, new medicinal products;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved or become standard-of-care for the indications we are investigating;
- differences in clinician treatment practices and/or protocols from center to center;
- the ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients' unwillingness to participate due to public health crises;
- the risk that enrolled subjects will drop out, develop complications or die before completion of the trial;
- the ability to develop and provide appropriate screening, product characterization and release assays;
- patients failing to complete a clinical trial or returning for post-treatment follow-up;
- our ability to manufacture the requisite materials for a patient and clinical trial; and
- inability of clinical sites to enroll patients as health care capacities are required to cope with natural disasters, epidemics or other health system emergencies.

Our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. Any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we may rely on clinical research organizations ("CROs") and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to ensure their actual performance.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. Many times, side effects are only detectable after investigational drugs are tested in large-scale pivotal trials or, in some cases, after they are made available to patients on a commercial scale after approval. For example, in January 2024, FDA required approved CAR-T products to add boxed warning information to their labeling concerning the risk of developing secondary T cell malignancies. If additional clinical experience indicates that any of our product candidates or the use of lentiviral vectors have side effects or cause serious or life-threatening side effects, the development of the product candidate may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Undesirable side effects caused by our product candidates, implanted devices, gene-editing methods, delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may be placed on clinical hold and not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our studies could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

To date, we have not tested our TCE product candidates in human patients and we have only tested INB-100, INB-200 and INB-400 in a limited number of patients with cancer and these clinical trial participants have only been observed for a limited period of time after dosing at a limited number of sites. To date, our clinical trials have been run at academic/tertiary care centers. As we continue developing our lead product candidates and initiate multi-center clinical trials of our product candidates, including potentially at community hospitals, SAEs, undesirable or potentially fatal side effects, cytokine release syndrome, viral or bacterial infections, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Should we observe SAEs in our clinical trials or identify undesirable side effects or other unexpected findings, our trials could be delayed or even terminated, and our development programs may be halted entirely.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

We may not be able to file IND applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We have previously announced our goals for potentially submitting additional INDs for INB-100, INB-400 and INB-619. We have suspended enrollment for INB-400 as we explore additional funding, potential regulatory pathways, partnerships and/or strategic alternatives for this program. We may not be able to make additional filings on the timelines we expect, which may cause delays in commencing additional clinical trials. Even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. Moreover, we cannot be sure that submission of an IND for any of our other product candidates will result in the FDA allowing trials to begin, or that, once begun, issues will not arise that result in a decision by us, by IRBs, or independent ethics committees, or by the FDA or other regulatory authorities to suspend or terminate clinical trials. For example, we may experience manufacturing delays or other delays with IND-enabling studies or the FDA or other regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we cannot be assured that submission of an IND will result in the FDA or any other regulatory authority allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by IRBs, or independent ethics committees or by the FDA or other regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. The inability to initiate clinical trials any of our product candidates on the timeline currently anticipated or at all could have a material adverse effect on our business, results of operations and prospects.

We may seek Breakthrough Therapy, RMAT or Fast Track designations and may pursue accelerated approval for some or all of our current product candidates, but we may be unable to obtain such designations or, where obtained, we may be unable to maintain Breakthrough Therapy or RMAT designation or obtain or maintain the benefits associated with such designations.

We may seek Breakthrough Therapy, RMAT or Fast Track designations and may pursue accelerated approval for INB-100, INB-200, INB-400 and some or all of our other and future product candidates. Breakthrough Therapy designation is intended to expedite the development and review of products that treat serious or life-threatening diseases when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation of a product candidate as a Breakthrough Therapy provides potential benefits that include intensive guidance on an efficient drug development program, beginning as early as Phase 1, organizational commitment involving senior managers; and eligibility for rolling review and priority review. Breakthrough Therapy designation does not change the standards for product approval. There can be no assurance that we will receive Breakthrough Therapy designation for any product candidate or any particular indication.

We may also seek Fast Track designation. If a drug or biologic candidate is intended for the treatment of a serious or life-threatening condition or disease and the drug demonstrates the potential to address unmet medical needs for the condition, the sponsor may apply for Fast Track designation. Even if we do apply for and receive Fast Track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may rescind Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Additionally, we may also seek accelerated approval under the FDA's accelerated approval programs. The FDA may approve a drug or biologic for a serious or life-threatening disease or condition that generally provides meaningful advantages over available treatments and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and comparable foreign regulatory agencies have broad discretion whether or not to grant any of these or similar designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional procedures, as applicable. The FDA or other regulatory agencies may also rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program.

Although we have received orphan drug designation for INB-400 in the past and may continue to seek orphan drug designation for some or all of our current or future product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for supplemental market exclusivity.

In April 2023, we received orphan drug designation for the autologous and allogeneic IND-400 product candidate, covering a broad range of malignant glioma treatments, including newly diagnosed glioblastoma. We may continue to seek orphan drug designation for one or more of our current or future product candidates, including INB-100 or its successor. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the identity of the biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the particular active ingredient in the product treating the disease for which it has such orphan drug designation, that product is entitled to orphan product exclusivity. This means that the FDA may not approve any other applications, including a BLA, to market the same product for the same indication for seven years. However, that exclusivity may be nullified in limited circumstances in which another product shows clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other products that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for INB-100 and some or all of our other or future product candidates in additional orphan indications in which there is a medically plausible basis for the use of these product candidates. Even when we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive these designations. For example, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the Federal Food, Drug and Cosmetic Act, and regulations promulgated thereunder, in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our product candidates are approved, for our targeted indications.

We may not be able to identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our efforts to identify and develop, additional product candidates will require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. We may also broaden the reach of our DeltEx platform by selectively in-licensing technologies or product candidates. Our efforts may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development, approved products or commercial revenues for many reasons, including the following:

- the methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render any product candidates we develop obsolete;
- any product candidates we develop may be covered by third parties' patents or other exclusive rights;
- a product candidate may demonstrate harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians, patients, the medical community or third-party payors.

We have limited financial and management resources and, as a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products, including attractive or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in circumstances under which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, we may not be successful in replicating our approach to product candidate development for other disease indications. If we are unsuccessful in identifying and developing additional product candidates or are unable to do so, our business may be harmed.

Public opinion and scrutiny of our competitors, cell-based immunotherapy, T cell engagers, and genetic modification approaches may impact public perception of our company and product candidates, or may adversely affect our ability to raise capital, conduct our business and our business plans.

Our DeltEx platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals, and our TCE program involves engineering antibodies that bind on T cells and a tumor-associated antigen on cancer cells. Public perception may be influenced by negative claims about our DeltEx platform, CAR-T therapies or T cell engagers, or that of competitor's products and/or programs such as claims that gamma-delta T cell and/or other cell-based immunotherapy is unsafe, unethical, inefficacious, expensive or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general and a recent increase in patient deaths and clinical holds by other companies could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Negative public attitudes may adversely impact our ability to enroll patients in clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion could have an adverse effect on our business, ability to raise additional capital and/or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

We face significant competition, and many of our competitors have substantially greater experience and resources than we have.

The clinical and commercial landscape in the indications we are targeting, as well as in the field of immuno-oncology, is highly competitive. We may face potential competition with respect to our current product candidates and may face competition with respect to any other product candidates that we may seek to develop or commercialize in the future from pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research institutions.

Many of our current or potential competitors have greater financial and other resources, larger research and development staffs, and more experienced capabilities in researching, developing and testing products than we do. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Smaller or clinical-stage companies like us may successfully compete by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of cancer and other diseases, which could give such products significant regulatory and market timing advantages over any of our product candidates. In addition, large pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo therapy opportunities that would have otherwise been complementary to our product development and collaboration plans. Our competitors may succeed in developing, obtaining patent protection for, or commercializing their products more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market. A competing company developing or acquiring rights to a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment could render our products noncompetitive or obsolete. We may not be successful in marketing any product candidates we may develop against competitors.

We expect the product candidates we develop will be regulated as biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Risks Related to Manufacturing and Our Dependence on Third Parties

Our manufacturing processes are complex, and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for future clinical trials or commercialization, if approved.

The manufacture of biotechnology products is complex and requires significant expertise and capital investment. We and our contract manufacturers must comply with cGMP regulations and guidelines for clinical trial product manufacture and for commercial product manufacture. We may encounter difficulties in production of INB-619 or future product candidates, particularly in scaling up, addressing product quality, product comparability, validating production processes and mitigating potential sources of contamination. These difficulties include:

- challenges procuring raw materials;
- maintaining quality control for our products, including stability of products, quality assurance testing, issues arising from operator error;
- retaining qualified personnel for manufacturing processes;
- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- reliance on third-party suppliers and manufacturers;
- compliance with cGMP requirements and other inspections by the FDA, EMA or other comparable regulatory authorities.
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- inability to manufacture, or obtain from third parties, sufficient quantities of qualified materials under cGMPs, for the completion in pre-clinical and clinical studies; and
- problems with biopharmaceutical product candidate storage, stability and distribution resulting from global supply chain disruptions.

In addition, if microbial, viral or other contaminations are discovered in therapeutic products or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

Any adverse developments affecting manufacturing operations for INB-619 and future product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals, recalls or other interruptions in the supply of our drug product, which could prevent the administration to patients and delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation

efforts, or seek more costly manufacturing alternatives. In such event, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

We may rely on third-party contractors or contract development manufacturing organization for the manufacturing of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.

Although we endeavor to build and operate a manufacturing facility in the future, we do not currently own any facility that may be used as our clinical or commercial-scale manufacturing and processing facility and expect that we will rely on outside vendors for at least a portion of the manufacturing of our cell therapy product candidates that we develop. The facilities used by our partners and contract manufacturers must be submitted and disclosed to the FDA or other foreign regulatory agencies and may be selected for inspection or audit following the submission of an application to the FDA or other foreign regulatory agencies. To the extent that we engage third parties for manufacturing services, we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with confidentiality agreements and the cGMP requirements for the manufacture of our product candidates. We have not yet had any product candidates to be manufactured or processed on a commercial scale and may not be able to do so. We will make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will result in products that meet specifications are capable or safe and effective. If such contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of third parties to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not agree that these facilities for the manufacture of our product candidates are acceptable or if it withdraws any such approval or acceptance in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Moreover, the process of manufacturing lentiviral vector and cell therapies is susceptible to product loss due to contamination, equipment failure or improper installation, maintenance or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, increased costs, impact to key product quality attributes, and other supply disruptions. Such minor deviations did in fact occur in our previously contracted manufacturing facility due to operator error.

Product defects can also occur unexpectedly. If microbial, viral or other contaminations are discovered in our product candidates, manufacturing reagents, raw materials, or in the manufacturing facilities in which our product candidates and/or their precursors are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because some of our cell therapy product candidates are manufactured from the blood of third-party donors, the process of manufacturing is susceptible to the availability and variability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product and patients may not receive a dose. These types of contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Furthermore, the selection and distribution of the appropriate cell product for therapeutic use in a patient requires close coordination between the manufacturing facility, clinical operations, supply chain and quality assurance personnel.

We also intend to rely on third-party manufacturers to supply us with additional quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of product. If we are not able to meet market demand for any approved product, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;

- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP requirements and other inspections by the FDA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for reagents and components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

In addition, if we enter into a strategic collaboration with a third party for the commercialization of our current or any future product candidates, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of our current or any future product candidates, it could limit our potential revenues.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the supply of our drug product which could prevent the administration to patients and delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

We currently store our gamma-delta T cells and biologic correlative and research specimens from clinical trials and development programs and clinical lentivectors at our research and development facilities and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers and/or facilities from natural disasters or otherwise would cause delays in replacement, and our business could suffer.

Specimens are stored in our freezers at our research and development facilities. If these cells are damaged, including by the loss or malfunction of our freezers or our back-up power systems, as well as by damage from fire or other natural disasters, our development program could be delayed or terminated and our business could suffer. Loss of a significant supply would require manufacturing of additional vector which could cause us to incur significant additional expenses and liability.

We are currently dependent on a single third-party supplier for manufacture of our automated manufacturing device and our lentiviral vectors for our cellular therapies. These are critical products required for the manufacturing of our product candidates, including INB-100, INB-200 and INB-400. Any damage or loss to the ability of our suppliers to deliver supplies in a timely manner could cause delays in manufacturing, and our clinical trials and our business could suffer.

Our gamma-delta T cell products for INB-100 and INB-200, as well as our INB-400 program, are manufactured in a programmable, cell-manufacturing, closed system device. We have multiple devices, including backup devices in all facilities if the primary instrument breaks, however, if the devices are damaged and cannot be repaired or the supplier cannot deliver new devices in a timely manner, or at all, our ability to manufacture and supply sufficient quantities of our products for clinical or commercial usage could be delayed, or potentially hindered. Our current supply of vectors will cover approximately 189 patients after a large manufacturing run was completed in the first half of 2023. If our third-party contractor is unable to provide adequate lentiviral vectors for our cellular therapies in a timely manner, our ability to manufacture and supply sufficient quantities of our product candidates for clinical or commercial usage will be delayed or hindered, and our business could suffer.

We rely on third-party healthcare professionals to administer gamma-delta T cells to patients, and our business could be harmed if these third parties administer these cells incorrectly.

We rely on the expertise of physicians, nurses and other associated medical personnel to administer gamma-delta T cells to clinical trial patients. If these medical personnel are not properly trained to administer, or do not properly administer, gamma-delta T cells, the therapeutic effect of gamma-delta T cells may be diminished or the patient may suffer injury.

In addition, if we achieve the ability to freeze and thaw our gamma-delta T cells, third-party medical personnel will have to be trained on proper methodology for thawing gamma-delta T cells received from us. If this thawing is not performed correctly, the cells may become damaged and/or the patient may suffer injury. While we intend to provide training materials and other resources to these third-party medical personnel, the thawing of gamma-delta T cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that gamma-delta T cells are ineffective or harmful, the desire to use gamma-delta T cells may decline, which would negatively impact our business, reputation and prospects. We may also face significant liability even though we may not be responsible for the actions of these third parties.

We believe we may require an updated and validated protocol for commercial-scale expansion and manufacturing of gamma-delta T cells for conducting pivotal trials and for commercialization of our product candidates, if approved.

Future clinical trials that we conduct, as well as any potential commercialization of our product candidates when approved, will depend on the reliability, safety and efficacy of our protocols for expanding, transducing and manufacturing gamma-delta T cells at scale. Our efforts to scale up production of our gamma-delta T cells in anticipation of future clinical trials or commercialization may reveal, an inability to overcome biology or may otherwise encounter challenges, including scrutiny from regulatory authorities. To the extent we encounter any such difficulties, our ability to conduct additional clinical trials or to scale for commercialization will be hindered or prevented, which would have an adverse effect on our business.

We have not yet developed commercial-scale infrastructure for freezing and thawing large quantities of gamma-delta T cells, which we believe will be required for the storage and distribution of our gamma-delta T cell product candidates at commercial scale.

We have not demonstrated that gamma-delta T cells can be frozen and thawed in large commercial-scale quantities without damage, in a cost-efficient manner and without degradation over long periods of time. We may encounter difficulties not only in developing freezing and thawing, but also in obtaining the necessary regulatory approvals for using such in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze gamma-delta T cells for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw gamma-delta T cells in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish. For these and other reasons, we may not be able to commercialize gamma-delta T cells on a large scale or in a cost-effective manner.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict or interrupt our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our product candidates, such as genetically modified cells, and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

We intend to partner with third parties, such as academic institutions and CROs, to conduct, supervise and monitor some of our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business and delay or impair our ability to obtain regulatory approval or otherwise commercialize our product candidates.

Although we are conducting our current clinical trials through our direct contractual agreements with hospitals, we intend to rely on CROs and clinical trial sites to conduct our future preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of the activities of our third-party service providers, including investigators and CROs. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We are, and our future CROs will be, required to comply with the good laboratory practices ("GLPs") and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Council for Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our future CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our future CROs, or hospitals where we conduct our clinical trials, do not successfully carry out their contractual duties or obligations with us or regulatory agencies, fail to meet necessary safety measures and protocols, fail to meet expected deadlines, or fail to comply with regulatory and/or IRB requirements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

Additionally, the FDA or other regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by investigator-sponsored trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate further clinical trials and/or obtain any regulatory approvals.

If our relationships with any CROs or hospitals where we conduct our current clinical trials terminate, we may not be able to enter into arrangements with alternative CROs and other third parties or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, principal investigators, consultants, commercial partners and outside actors. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being advanced, developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products or regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events, such as public health crises, that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to cleared or approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years including in October 2025 and February 2026, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current administration has implemented substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could delay reviews and negatively impact our business.

Risks Related to Our Intellectual Property

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our license agreements with the University of Alabama at Birmingham Research Foundation, Children's Healthcare of Atlanta, Inc. and Emory University, or any of the other agreements under which we acquired, or will acquire, the intellectual property rights to our product candidates, we could lose the ability to continue the development and commercialization of the related product.

The licensing of intellectual property is of critical importance to our business and to our current and future product candidates, and we expect to enter into additional such agreements in the future. In particular, our product candidates, INB-100, INB-200, INB-300 and INB-400, are dependent on our license agreements with The UAB Research Foundation ("UABRF") Children's Healthcare of Atlanta, Inc. ("CHOA") and Emory University ("Emory" and, together with UABRF and CHOA, the "Licensors"), pursuant to which we have obtained exclusive worldwide licenses under certain immunotherapy related patents and know-how that are critically important for these product candidates.

Although we have been granted exclusive licenses under these license agreements, we do not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license from UABRF and Emory. Therefore, we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business. Although we have a right to have our comments considered in connection with the prosecution process, if the Licensors fail to prosecute and maintain such patents, or loses rights to those patents or patent applications as a result of its control of the prosecution activities, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

If we fail to meet our obligations under our license agreements in any material respect, and fail to cure such breach in a timely fashion, then the Licensors may terminate their applicable license agreement. If the license agreements are terminated, and we lose our intellectual property rights thereunder, this may result in a complete termination of our product development and any commercialization efforts for our product candidates. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the license agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all. For more information on our license agreements, see Note 9, License Agreements, in our unaudited condensed financial statements contained elsewhere in this Quarterly Report.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, the research resulting in certain of our in-licensed patent rights was funded in part by the U.S. federal or state governments. As a result, the government may have certain rights, including march-in rights, to such patent rights. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of the patent protection obtained is not sufficiently broad or robust, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates and technology may be adversely affected.

Our success depends, in large part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We and our licensors have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. As of September 30, 2026, we owned, co-owned or exclusively licensed six issued U.S. patents, nine issued European patents, 20 other issued foreign patents, ten pending U.S. applications, one pending PCT application and 13 other foreign national-stage applications, including three European regional-phase applications that are important to the development of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file a patent application relating to any particular aspect of a product candidate. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from infringing our patents in all countries outside the United States, or from selling or importing products that infringe our patents in and into the United States or other jurisdictions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, the research resulting in certain of our owned and in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent rights depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our service providers or our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. If we, our service providers or our licensors fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as or similar to our product candidates, which would have an adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for or otherwise fail to obtain applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of product candidates such as INB-100, INB-200, INB-300, INB-400, INB-500, and INB-600, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent. However, the extension cannot extend the total patent term beyond 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. Additionally, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights and/or trademark, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property, trademarks and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, names, including interference proceedings, post grant review and *inter partes* review before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in

the future. Other companies and research institutions have filed, and may file in the future, patent applications related to gamma-delta T cell immunotherapy. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have an adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time-consuming and would divert management's attention from our core business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring

claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counterclaims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as *ex parte* reexaminations, *inter partes* review, post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license, or if the license offered as a result is not on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent

applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Since we rely on third parties to help us discover, develop and manufacture our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. In addition, from time to time, we may hire scientists or other employees or consultants who originate from jurisdictions, including China, that have a history of engaging in misappropriation or theft of trade secrets or other acts of trade secret espionage; if any such individuals are found to be engaging in such illegal behavior, it could have a material adverse effect on our ability to protect our intellectual property and our business prospects more generally.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Further, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or other proprietary information. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our current or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

- others may be able to make cells, cell products, genetic modifications, compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our ability to compete in the pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on the services of our co-founders, William Ho, our Chief Executive Officer, Dr. Larry Lamb, our Chief Scientific Officer, and of our President and Chief Operating Officer, Dr. Kate Rochlin, and the loss of these members of our management team or other key employees could impede, delay or prevent the successful development of our product pipeline, the completion of our current and planned clinical trials, and the commercialization of our products or in-licensing or acquisition of new assets, and could negatively impact our ability to successfully implement our business plan.

We are highly dependent on our co-founders, our Chief Executive Officer, William Ho, our Chief Scientific Officer, Dr. Lawrence Lamb and on our President and Chief Operating Officer, Dr. Kate Rochlin. Each of them may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other senior executives, qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully lead, develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and our results of operations.

We plan to expand our organization in the future, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of September 30, 2026, we had 20 full-time employees. As the development of our product candidates continues to progress, we expect to require additional employees and expand the scope of our operations, particularly in the areas of research, drug development, manufacturing, clinical operations, regulatory affairs, business and development, finance and accounting and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such potential growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any expansion of our operations may lead to significant expenses, additional dilution and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may explore strategic collaborations that may not have the intended benefits or never materialize, or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.

We may enter into strategic partnerships, create joint ventures or collaborations or enter into licensing arrangements with third parties with respect to our product candidates that we believe will complement or augment our business. At the current time, however, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, if any at all. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing them, including:

- expenditure of substantial operational, financial and management resources;
- dilutive issuances of our securities;
- substantial actual or contingent liabilities; and
- termination or expiration of the arrangement, which would delay the development and may increase the cost of developing our product candidates.

Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite data and/or potential to demonstrate safety and efficacy. Strategic partners may also delay clinical trials, experience financial difficulties, provide insufficient funding, terminate a clinical trial or abandon a product candidate, which could negatively impact our development efforts. We cannot be certain that we would achieve the revenues or specific net income that justifies such strategic partnerships. Additionally, strategic partners may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation, any of which could adversely affect our business, financial position and operations.

If our information technology systems, or those of the third parties with whom we work, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to, a significant disruption of our product development programs and our ability to operate our business effectively, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, and other adverse consequences.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we and the third parties with whom we work process sensitive information, and as a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our sensitive information. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Our internal computer systems, cloud-based computing services and those of any third parties with whom we work are vulnerable to damage or interruption from a variety of sources, including cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities. These threats include, but are not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), data corruption, intentional or accidental actions or inactions by our employees or others with access to our network, supply chain attacks, ransomware attacks, denial-of-service attacks (such as credential stuffing), credential harvesting, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by A.I., natural disasters, terrorism, war and telecommunication and electrical failures, and other similar threats that affect service reliability and threaten the confidentiality, integrity, and availability of information. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, are increasingly difficult to detect, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us. We also face increased cybersecurity risks due to the number of our employees who are working remotely, which creates additional opportunities for cybercriminals to exploit vulnerabilities and data, as our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

If any of the previously identified or similar threats were to occur and cause a security incident or other interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, access to, or other similar disruptions to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and we expect such attempts will continue in the future. In addition, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Security incidents could lead to material adverse consequences, including but not limited to: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data and clinical trial data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of clinical trial data); financial loss; and other similar harms. Additionally, applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. In general, under Section 382 of the United States Internal Revenue Code of 1986, as amended ("Code") a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") to offset future taxable income. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent changes in our stock ownership (some of which are outside our control). As a result, if and to the extent that we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations.

Under current U.S. federal tax law, NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely, but the deductibility of these carryforwards is limited.

It is uncertain if and to what extent various states will conform to the federal law. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase the state taxes owed.

In order to realize the future tax benefits of our NOL carryforwards, we must generate taxable income, of which there is no assurance. Accordingly, we have provided a full valuation allowance for deferred tax assets as of December 31, 2025.

There are risks inherent in our business that may subject us to potential product liability suits and other claims, which may require us to engage in expensive and time-consuming litigation or pay substantial damages and may harm our reputation and reduce the demand for our product.

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of biopharmaceutical products. For example, we may be sued if any product we develop allegedly causes or is perceived to cause injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties and/or trademarks. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources.

Certain aspects of how gamma-delta T cells are processed and administered may increase our exposure to liability. Medical personnel administer gamma-delta T cells to patients in an outpatient procedure. This procedure poses risks to the patient similar to those occurring with infusions of other cell products, such as T cells and stem cells, including blood clots, infection and mild to severe allergic reactions. Additionally, gamma-delta T cells or components of our gamma-delta T cell therapy may cause unforeseen harmful side effects. For example, a patient receiving gamma-delta T cells could have a severe allergic reaction, severe graft versus host disease, cytokine release syndrome, or could develop an autoimmune condition to materials infused with gamma-delta T cells.

In addition, we have not conducted studies on the long-term effects associated with the media and/or expansion process that we use to grow our gamma-delta T cells. Similarly, we expect to use media in freezing our gamma-delta T cells for storage and shipment. These media and other reagents used in the manufacturing process could contain substances that have proved harmful if used in certain quantities. As we continue to develop our gamma-delta T cell therapy, we may encounter harmful side effects that we did not observe in our prior studies and clinical trials. Additionally, the discovery of unforeseen side effects of gamma-delta T cells could also lead to lawsuits against us.

Regardless of merit or eventual outcome, product liability or other claims may, among other things, result in:

- decreased demand for any approved products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue;
- a potential decrease in our stock price; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We obtained product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Commercialization and Regulatory Compliance

Even if we obtain regulatory approvals for our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approvals for our product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to a REMS, to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or may contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and for surveillance to monitor the quality, safety and efficacy of the product candidate. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

In addition, product candidate manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product candidate, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product candidate is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product candidate, a regulatory authority may impose restrictions relative to that product candidate, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the product candidate from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidates, a regulatory authority may, among other things, issue warning letters or untitled letters, mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products, require us

to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance, seek an injunction or impose administrative, civil or criminal penalties or monetary fines, suspend or modify any ongoing clinical trials, or suspend, modify withdraw regulatory approval or restrict the marketing or manufacturing of the product candidate.

Moreover, the FDA and other regulatory authorities strictly regulate the promotional claims that may be made about biologic products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

Even if any product candidate receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if any product candidate receives marketing approval, it may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. If any such product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the cost, efficacy, safety profile, convenience, ease of administration and other potential advantages compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our relationships with patient communities;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product candidate together with other medications.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business.

Furthermore, the attention to different types of prospective treatments and proposed cures for cancers has historically varied. In recent years, various forms of oncological immunotherapy have been prominent areas for academic and clinical advancement. While gamma-delta T cell therapy has not yet received prominent negative attention from the mainstream media or the scientific press, it is possible that it could, and it is possible that if immunotherapy generally falls out of favor with these key constituencies, whether due to the failure of one or more competitive products or technologies or otherwise, our business, including our ability to conduct our planned clinical trials and to raise capital, may in turn suffer.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing them, if and when they are approved.

To successfully commercialize any product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any product candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable

to generate sufficient revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

Even if we obtain and maintain approval for our product candidates from the FDA, we may never obtain approval outside the United States, which would limit our market opportunities.

Approval of a product candidate in the United States by the FDA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Sales of our product candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. Obtaining approval for our product candidates in the European Union from the European Commission following the opinion of the European Medicines Agency ("EMA") if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a product candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we commercialize our product candidates outside the United States, a variety of risks associated with international operations could harm our business.

While we have not taken any steps to obtain approval of our product candidates outside of the United States, and do not plan to seek approval in the near term, we may do so in the future. If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including:

- different regulatory requirements for approval of therapies in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty due to labor unrest;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including wars and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and public health emergencies.

We have no prior experience in these areas. In addition, there are complex regulatory, immigration, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, including the United States and, with which we will need to comply. Many biopharmaceutical companies have found the process of marketing their products in foreign countries to be challenging.

Our relationships with customers, physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, including anti-kickback and false claims laws, transparency laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws, health information privacy laws, transparency laws, and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and the regulations promulgated thereunder. For additional information on the healthcare laws and regulations that we may be subject to, see the section captioned "Business─Government Regulation" in our Annual Report.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians, some of whom are compensated with a stipend or stock options for services performed for us, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

Coverage and adequate reimbursement may not be available for our product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Therefore, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor’s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor’s list of covered products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Further, the U.S. Department of Health and Human Services ("HHS") imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Currently, in the allogeneic transplant setting, reimbursement is often made based on a capitated payment system, and obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Therefore, our product candidates may not be reimbursed separately but their cost

may instead be bundled as part of a capitated payment received by the provider for the procedure only. We cannot be sure that the clinical results of our trials will be sufficient or meaningful to educate hospitals and/or clinicians on the benefits of our product or to get third-party payors to change reimbursement to separate outside of the current bundle. A decision by a third-party payor not to cover or separately reimburse for our product candidates or procedures using our product candidates, could reduce physician utilization of our products once approved. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any product candidates that we develop. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private payors in the United States. Since its enactment, however, there have been executive, judicial and Congressional challenges and amendments to the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform ("TrumpRx") U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on demand for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. For additional information on healthcare reform, see the section captioned "Business─Government Regulation" in our Annual Report.

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry. In addition, the current administration has implemented substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could delay reviews and negatively impact our business.

Our (or the third parties with whom we work) actual or perceived failures to comply with applicable data privacy and security obligations, including laws, regulations, contractual obligations, industry standards and other obligations could lead to regulatory investigations or actions, litigation (including class claims), fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about participants in connection with clinical trials, and sensitive third-party data (collectively, sensitive information). Our data processing activities subject us to numerous data privacy and security obligations, such as various state, federal and foreign laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations relating to data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to process sensitive information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or the third parties with whom we work to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of sensitive information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

As our operations and business grow, we become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, federal, state, and local laws and regulations, including data breach notification laws, personal data privacy laws, state health information privacy laws, and federal and state consumer protection laws and regulations (i.e., Section 5 of the FTC Act), and other similar laws govern the collection, use, disclosure, and protection of health-related and other personal data. In addition, we obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to data privacy and security requirements under the Federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations promulgated thereunder (collectively, "HIPAA"). Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable data privacy and security laws and regulations, some of which may be more stringent than HIPAA. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, the "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents,

and requires business to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights related to their personal data. The CCPA allows for statutory fines for noncompliance and a private right of action for certain data breaches to recover significant statutory damages. Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase compliance costs and potential liability for us and the third parties with whom we work. Similar laws have been enacted or are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future, which could further complicate compliance efforts.

In addition, all 50 U.S. states and the District of Columbia have enacted breach notification laws that may require us to notify affected individuals or regulators in the event of unauthorized access to or disclosure of personal data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and can be costly. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. We are, and may in the future become, subject to certain industry standards, or we may elect to comply with such standards.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater. Further, classes of data subjects or consumer protection organizations authorized at law to represent their interests may initiate litigation related to processing of personal data. In Canada, the PIPEDA and various related provincial laws, may apply to our operations.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States or other countries. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future.

In addition, certain countries outside Europe have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, which increases the cost and complexity of doing business.

If we cannot implement a valid compliance mechanism for cross-border data transfers, or if the requirements for a legally compliant transfer are too onerous, we may face increased exposure to regulatory actions, substantial fines and penalties, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws, or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We also publish privacy policies, marketing materials, and other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Although we work to comply with applicable data privacy and security laws, regulations and standards, our contractual obligations and other legal obligations, these requirements (and individuals' data privacy expectations) are evolving, becoming increasingly stringent, and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties with whom we work. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties with who we work to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, or adversely affect our business, financial condition, and results of operations. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. For example, we may experience adverse consequences such as interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations; government enforcement actions (i.e., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

Our employees and personnel use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI technologies, it could make our business less efficient and result in competitive disadvantages.

Risks Related to the Ownership of Our Common Stock

An active trading market for our common stock may not be sustained, and you may not be able to sell your shares quickly or at the market price.

Although our common stock is traded on the Nasdaq Stock Market LLC ("Nasdaq"), the liquidity in our common stock on that stock market remains thin. If an active trading market for our common stock is not sustained, you may not be able to sell your shares quickly or at all at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

The market price of our common stock is volatile and may fluctuate substantially, and you could lose all or part of your investment.

The market price of our common stock is volatile. The stock market in general, and the market for biopharmaceutical and pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. In addition to the factors discussed in this "Risk Factors" section, the market price for our common stock may be influenced by, among other factors:

- the commencement, enrollment or results of our planned or future clinical trials of our product candidates or those of our competitors;
- the success and failures of competitive products or therapies or announcements, including patient deaths and clinical holds, by potential competitors of their product development efforts;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- coordinated buying or selling activity in our common stock, including market manipulation;
- unusual trading in our common stock or securities derivative thereof, including pursuant to naked, or uncovered, short positions or "short squeezes;"
- commentary by investors on the prospects for our business or our common stock on the internet, including blogs, articles and message board, and/or social media and resulting in trading of our common stock;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- stock price and volume fluctuations attributable to inconsistent trading volume levels and a wide bid-ask in our common stock;
- announcement or expectation of additional financing efforts or sales by our stockholders;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of increases in inflation and interest rates, tariffs and trade wars, public health crises and other geopolitical tensions, such as wars and terrorism, and future U.S. government shutdowns; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

In addition, some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- provide that our directors may be removed for cause only upon the vote of at least 66 2/3% of our outstanding shares of voting stock;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock; and
- require the approval of the holders of at least 66 2⁄3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL") which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. We have not elected to opt out of DGCL Section 203. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, with respect to any state actions or proceedings under Delaware statutory or common law, the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty;
- any action or proceeding asserting a claim against us or any of our directors, officers, employees or agents arising under the DGCL, our amended and restated certificate of incorporation or our second amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our second amended and restated bylaws; and
- any action or proceeding asserting a claim against us or any of our directors, officers, employees or agents that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find an exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our business.

General Risk Factors

Unstable market and economic conditions, including as a result of increases in inflation, the price of oil, and interest rates, tariffs, elections and trade wars, geopolitical tensions such as wars and terrorism and future U.S. government shutdowns, may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions. For example, the macroeconomic uncertainty and volatile business environment have resulted in ongoing inflation, elevated interest rates, volatility in the capital markets, significantly reduced liquidity and credit availability, decreases in consumer demand and confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Similarly, geopolitical tensions, such as wars and terrorism may have global economic consequences, including potential disruptions of the global supply chain, manufacturing and energy markets. Further, over the last several years the U.S. government has shut down several times. If a prolonged government shutdown occurs in the future, including as a result of any failure by the U.S. federal government to increase the debt ceiling or otherwise, it could significantly impact the ability of the FDA and the SEC to timely review and process our submissions, as well as cause interest rates and borrowing costs to further increase, which may negatively impact our ability to access the debt markets, including the corporate bond markets, on favorable terms, which could have a material adverse effect on our business.

Trade disputes, tariffs, and other geopolitical tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions, including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns, which may also limit our access to capital, or otherwise negatively impact our business and operations. Additionally, current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Additional and higher tariffs and sanctions may be imposed on goods imported from other countries which could increase the cost of goods needed to continue development of our product candidates. Further, such actions by the U.S. could result in retaliatory action by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business, operations and financial condition could be materially harmed.

The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report on Form 10-Q.

Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of increases in inflation and interest rates, political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition.

If we fail to satisfy all applicable requirements of Nasdaq and it determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

To maintain the listing of our common stock on Nasdaq, we are required to meet certain listing requirements, including having a minimum closing bid price of $1.00 per share, a minimum of 300 round lot holders, and a minimum of 500,000 publicly held shares. Further, if the market value of our publicly held common stock declines below $1 million, or the closing price of our common stock declines to $0.10 per share or less for 10 consecutive trading days, we would also be subject to Nasdaq delisting proceedings on that basis. Nasdaq's staff also maintains discretionary authority under its listing rules to delist companies whose capital structure or public offerings raise public interest and investor protection concerns, including as a result of highly dilutive issuances, and it is possible that Nasdaq could assert that offerings that we have consummated, or future offerings we may consummate, raise such concerns.

In addition, on July 22, 2026, the SEC's Division of Trading and Markets approved a new Nasdaq continued listing standard that would require us to maintain a market value of listed securities of at least $5 million. Unlike many other of Nasdaq's continued listing standards, this new listing standard provides no cure or compliance period, and requests for review by a Nasdaq Hearings Panel do not stay the suspension of trading. However, on July 29, 2026, the SEC stayed approval of this rule after two parties filed notices of intent to seek SEC review. As a result, we cannot predict whether or when the new listing standard will take effect.

We have previously received a Nasdaq deficiency notice for failing to maintain the minimum closing bid price required for continued listing, and we transferred our listing from the Nasdaq Global Market to the Nasdaq Capital Market in connection with obtaining an extension to regain compliance. Our market capitalization has been volatile and has at times been at levels that could place us at risk under the market value of listed securities standard if it is reinstated. As of November 2, 2026, we had 10,808,292 shares of common stock outstanding, and the closing bid price was $0.91 per share, resulting in a market value of listed securities of approximately $9.5 million. If the SEC ultimately reinstates approval of the new market value of listed securities rule, our common stock would be subject to immediate suspension and delisting if the market value of our common stock falls below $5 million for a period of 30 consecutive business days.

There can be no assurance that we will maintain compliance with the requirements for listing our common stock on Nasdaq. If we are unable to satisfy the Nasdaq criteria for continued listing, our common stock would be subject to delisting. A delisting of our common stock could negatively impact us by, among other things, (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) decreasing the amount of news and analyst coverage of us; (iv) limiting our ability to issue additional securities or obtain additional financing in the future; (v) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets; and (iv) impairing our ability to provide equity incentives to our employees. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business.

Social media platforms and artificial intelligence-based platforms present new risks and challenges to our business.

Social media is increasingly being used to communicate information about us, our programs and the diseases our therapeutics are being developed to treat. Social media practices in the pharmaceutical and biotechnology industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product or a product candidate, which could result in reporting obligations or other consequences. Further, the accidental or intentional disclosure of non-public information by our workforce or others through media channels could lead to information loss. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us, our products, or our product candidates on any social media platform. The nature of social media prevents us from having real-time control over postings about us on social media. We may not be able to reverse damage to our reputation from negative publicity or adverse information posted on social media platforms or similar mediums. If any of these events were to occur or we otherwise fail to comply with application regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business including quick and irreversible damage to our reputation, brand image and goodwill.

Additionally, AI-based platforms are increasingly being used in the pharmaceutical industry and we are expanding the use of AI-based platforms in our operations for data analysis, summarization and automation, which subjects us to a variety of risks, including potential cybersecurity vulnerabilities, breaches of data privacy and the potential for inadvertent or unauthorized disclosure of our confidential information and intellectual property. Our use, or the use by our vendors, suppliers and contractors with access to our proprietary and confidential information, including trade secrets, may lead to the release of our proprietary and confidential information, which may negatively impact our company, including our ability to realize the benefit of our intellectual property. Moreover, AI-based platforms may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor “poisons” the AI-based platform with bad inputs or logic), or if the logic of the AI-based platform is flawed (a so-called “hallucination”).

If research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or financial analysts publish about us or our business. We currently have research coverage by a few industry or financial analysts and may never obtain additional coverage. Equity research analysts may elect not to provide research coverage of our common stock or may drop coverage and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have additional equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares, reduce their price-targets, or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act ("Section 404") we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an EGC or a smaller reporting company with less than $100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We could be an EGC until the end of the fiscal year following the fifth anniversary of our initial public offering. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be

able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404.

In addition, our assessment of internal controls and procedures may not detect material weaknesses in our internal control over financial reporting. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock. These events could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering of Common Stock

Not applicable.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

None of our directors or executive officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule-10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K, during the fiscal quarter ended September 30, 2026.

Item 6. Exhibits.

(3) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on August 3, 2021).
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on June 4, 2025).
3.3	Second Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on December 7, 2023).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101.

* This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

IN8bio, Inc.

Date: November 5, 2026

By: /s/ William Ho
William Ho
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

By: /s/ Patrick McCall
Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, William Ho, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IN8bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

IN8bio, Inc.

Date: November 5, 2026

By: /s/ William Ho

William Ho
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Patrick McCall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of IN8bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

IN8bio, Inc.

Date: November 5, 2026

By: /s/ Patrick McCall

Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of IN8bio, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN8bio, Inc.

Date: November 5, 2026

By: /s/ William Ho
William Ho
Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

By: /s/ Patrick McCall
Patrick McCall
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)