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 June 30, 2021

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.)**
79 Madison Avenue New York, New York	**10016**
(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 September 7, 2021 was 18,754,553.

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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)

	June 30, 2021 (unaudited)	December 31, 2020
Assets		(Note 2)
Current assets		
Cash	$ 11,999	$ 17,994
Prepaid expenses and other current assets	168	150
Total Current Assets	12,167	18,144
Non-current assets		
Property and equipment, net	142	186
Deferred offering costs	3,362	2,439
Right of use assets - financing leases	990	—
Right of use assets - operating leases	762	—
Other non-current assets	141	141
Total Non-Current Assets	5,397	2,766
Total Assets	$ 17,564	$ 20,910
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Liabilities		
Current liabilities		
Accounts payable	$ 462	$ 620
Accrued expenses and other current liabilities	1,485	1,778
Short-term financing lease liability	517	—
Short-term operating lease liability	135	—
Loan payable, current	174	174
Total Current Liabilities	2,773	2,572
Deferred rent	—	17
Long-term financing lease liability	432	—
Long-term operating lease liability	698	—
Total Liabilities	3,903	2,589
Commitments and Contingencies		
Convertible preferred stock, Series A, par value $0.0001 per share; 27,564,260 shares authorized at June 30, 2021 and December 31, 2020; 9,993,727 shares, issued and outstanding at June 30, 2021 and December 31, 2020, and a liquidation preference of $39,390 and $37,969 at June 30, 2021 and December 31, 2020, respectively	34,900	34,900
Stockholders' Deficit		
Common stock, par value $0.0001 per share; 50,700,000 shares authorized at June 30, 2021 and December 31, 2020; 3,764,488 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital	2,211	1,458
Accumulated deficit	(23,451)	(18,038)
Total Stockholders' Deficit	(21,239)	(16,579)
Total Liabilities, Convertible Preferred Stock and Stockholders' Deficit	$ 17,564	$ 20,910

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 2,064	$ 1,784	$ 3,310	$ 2,836
General and administrative	986	1,090	2,103	1,729
Total operating expenses	3,050	2,874	5,413	4,565
Loss from operations	(3,050)	(2,874)	(5,413)	(4,565)
Net loss	$ (3,050)	$ (2,874)	$ (5,413)	$ (4,565)
Net loss attributable to common stockholders (Note 11)	$ (3,765)	$ (3,178)	$ (6,834)	$ (5,129)
Net loss per share attributable to common stockholders – basic and diluted	$ (1.00)	$ (0.92)	$ (1.82)	$ (1.52)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	3,764,488	3,462,182	3,764,488	3,383,774

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

IN8BIO INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, COMMON STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)
(Unaudited)

	Convertible Preferred Stock Series A		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019	2,713,980	$ 8,896	3,235,671	$ 1	$ 238	$ (9,481)	$ (9,242)
Issuance of common stock – Class A in relation to license agreement	—	—	44,011	—	—	—	—
Issuance of common stock – Class A	—	—	182,500	—	200	—	200
Issuance of convertible preferred stock – Series A, net of $16 issuance costs	1,533,947	5,480	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	18	—	18
Net loss	—	—	—	—	—	(1,691)	(1,691)
Balance at March 31, 2020	4,247,927	$ 14,376	3,462,182	$ 1	$ 456	$ (11,172)	$ (10,715)
Stock-based compensation expense	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	(2,874)	(2,874)
Balance at June 30, 2020	4,247,927	$ 14,376	3,462,182	$ 1	$ 476	$ (14,046)	$ (13,569)
Balance at December 31, 2020	9,993,727	$ 34,900	3,764,488	$ 1	$ 1,458	$ (18,038)	$ (16,579)
Stock-based compensation expense	—	—	—	—	361	—	361
Net loss	—	—	—	—	—	(2,363)	(2,363)
Balance at March 31, 2021	9,993,727	$ 34,900	3,764,488	$ 1	$ 1,819	$ (20,401)	$ (18,581)
Stock-based compensation expense	—	—	—	—	392	—	392
Net loss	—	—	—	—	—	(3,050)	(3,050)
Balance at June 30, 2021	9,993,727	$ 34,900	3,764,488	$ 1	$ 2,211	$ (23,451)	$ (21,239)

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

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

	Six Months Ended June 30,	
	2021	2020
Operating activities		
Net loss	$ (5,413)	$ (4,565)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	44	44
Non-cash stock-based compensation	753	38
Amortization of financing lease right-of-use assets	250	—
Amortization of operating lease right-of-use assets	61	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(62)	8
Other non-current assets	—	(1)
Accounts payable	(372)	1
Accrued expenses and other current liabilities	(221)	1,191
Short-term operating lease liabilities	62	—
Long-term operating lease liabilities	(70)	—
Net cash used in operating activities	(4,968)	(3,284)
Financing activities		
Proceeds from the issuance of common stock - Class A	—	200
Proceeds from issuance of preferred stock - Series A, net of $16 of issuance costs	—	5,480
Principal payments on financing leases	(248)	—
Proceeds from issuance of loan	—	174
Deferred offering costs paid	(779)	—
Net cash (used in) provided by financing activities	(1,027)	5,854
Net (decrease) increase in cash and restricted cash	(5,995)	2,570
Cash and restricted cash at beginning of period	17,994	610
Cash and restricted cash at end of period	$ 11,999	$ 3,180
Supplemental disclosure of non-cash financing and investing information:		
Deferred offering costs included in accounts payable and accrued expenses	$ 1,020	$ —
Initial measurement of operating lease right-of-use assets and liabilities	$ 3,483	$ —

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

1. ORGANIZATION AND NATURE OF OPERATIONS

Organization and Business

IN8bio, Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer. The Company's lead product candidates are currently in Phase 1 clinical trials: INB-200, for the treatment of newly diagnosed glioblastoma ("GBM"), and INB-100, for the treatment of patients with leukemia that are undergoing hematopoietic stem cell transplantation ("HSCT"). In addition, the Company's DeltEx platform has yielded a broad portfolio of preclinical programs, including INB-400 and INB-300, focused on addressing other solid tumor types.

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 did not have any subsidiaries to consolidate as of December 31, 2020. The Company is headquartered in New York, New York.

Coronavirus pandemic

The current COVID-19 (coronavirus) pandemic, which is impacting worldwide economic activity, poses risk that the Company or its employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to shutdowns that may be requested or mandated by governmental authorities. The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. COVID-19 may impact the timing of regulatory approval of the investigational new drug (INDs) for clinical trials, the enrollment of any clinical trials that are approved, the availability of clinical trial materials and regulatory approval and commercialization of our products. COVID-19 may also impact the Company's ability to access capital, which could negatively impact short-term and long-term liquidity.

Liquidity and Capital Resources

Through June 30, 2021, the Company funded its operations primarily with proceeds from the initial closing and additional closings of its Series A convertible preferred stock financing ("Series A Financing"). The Company has incurred recurring losses and negative operating cash flows from operations since its inception, including net losses of $5.4 million and $4.6 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the Company had an accumulated deficit of $23.5 million. The Company expects to continue to generate operating losses for the foreseeable future.

On August 3, 2021, the Company completed its initial public offering ("IPO") in which it issued and sold 4,000,000 shares of its common stock at a public offering price of $10.00 per share pursuant to its Registration Statement on Form S-1, as amended (File No. 333-249530). The Company received net proceeds from the initial public offering of $32.6 million, after deducting underwriters' discounts, commissions, and estimated offering-related costs of $7.4 million. B. Riley Securities Inc. acted as the sole book-running manager for the IPO.

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 to conduct research and development and will need to raise additional capital to fully implement management's business plan. The Company intends to raise such capital through the issuance of additional equity, and potentially through borrowings, strategic alliances with partner companies and other licensing transactions. However, if such financing is not available at adequate levels, the Company may need to reevaluate its operating plans. Management believes that its existing cash of $12.0 million as of June 30, 2021 and the net proceeds of $32.6 million from the IPO will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance of these condensed financial statements.

2. SUMMARY OF 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 ("US 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 Securities and Exchange Commission ("SEC"). Certain information and note disclosures normally included in financial statements prepared in accordance with US 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 for the years ended December 31, 2020 and 2019 included in the Company's final prospectus that forms part of the Company's Registration Statement on Form S-1 (File No. 333-249530), filed with the SEC pursuant to Rule 424(b)(4) on July 30, 2021 (the "Prospectus"). 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 condensed financial statements in conformity with US 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 condensed 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 related valuation allowance, fair value of common stock and stock-based compensation, and the useful lives of property and equipment. 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.

Leases

Effective January 1, 2021, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02" or "ASC 842"), using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidance under Accounting Standards Codification ("ASC") ASC 840, *Leases*. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only. On the adoption date, $1.7 million was recognized as total lease liabilities and $1.8 million was recognized as total right-of-use assets on the Company's condensed balance sheet.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process preferred stock or common stock financings as deferred offering costs until such financings are consummated. The deferred offering costs will be offset against the IPO proceeds during the quarter ending September 30, 2021 as a result of the consummation of the IPO. As of June 30, 2021 and December 31, 2020, the Company had deferred offering costs related to the IPO of $3.4 million and $2.4 million, respectively.

Recently Issued Accounting Standards Updates

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU) No. 2019-12, *Simplifying the Accounting for Income Taxes*. ASU No. 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This update is effective for entities other than public business entities, including emerging growth companies that elected to defer compliance with new or revised financial accounting standards until a company that is not an issuer is required to comply with such standards, for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. The Company is currently evaluating the impact, if any, that the adoption of this guidance will have on the condensed financial statements.

3. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2021	December 31, 2020
Machinery and equipment	$ 443	$ 443
Less accumulated depreciation	(301)	(257)
Property and equipment, net	$ 142	$ 186

Depreciation expense was $22,000 for the three months ended June 30, 2021 and 2020 and was $44,000 for the six months ended June 30, 2021 and 2020.

4. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 31, 2021	December 31, 2020
Accrued offering costs	$ 806	$ 876
Accrued clinical trials	300	376
Accrued compensation	340	400
Accrued other	39	126
Total accrued expenses and other current liabilities	$ 1,485	$ 1,778

5. DEBT

In April 2020, the Company was granted a loan (the "Loan") in an amount of $0.2 million, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act, which was enacted on March 27, 2020. The Loan, which was in the form of a Note dated April 16, 2020, matures on April 16, 2022 and bears interest at a rate of 1.0% per annum, payable monthly commencing on November 16, 2020. The Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

Funds from the Loan may only be used for payroll costs, costs used to continue group healthcare benefits, mortgage payments, rent, utilities, and interest on other debt obligations incurred before February 15, 2020. The Company used the entire Loan amount for

qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. In August 2021, the Company repaid the Loan in full.

Loan payable at June 30, 2021 and December 31, 2020 consists of the following (in thousands except years and percentage):

	Year of Maturity	Interest Rate	Outstanding Principal
Loan payable	2022	1.00%	$ 174

6. CONVERTIBLE PREFERRED STOCK

Convertible Series A Preferred Stock

From January through August 2020, the Company issued 7,048,351 shares of Series A convertible preferred stock ("Series A Preferred Stock") at $3.5833 per share for $25.3 million in gross proceeds related to the Series A Preferred Stock agreement from 2018.

At June 30, 2021, a total of $35.0 million, at $3.5833 per share, had been raised by the Company through the Series A preferred financing and the issuance of the Note Series 2018A convertible promissory note that converted into Series A Preferred Stock on May 7, 2018 following the Domestication. The Series A Preferred Stock includes 9,993,727 shares issued and outstanding on June 30, 2021 and December 31, 2020. In connection with the issuance of Series A Preferred Stock in 2018, the Company issued 231,396 warrants to purchase Series A Preferred Stock, accounted for as issuance costs and classified as a liability. In October 2020, the warrants were exercised and converted into Series A Preferred Stock.

In August 2020, the Company increased the authorized shares of Series A Preferred Stock, par value $0.0001 per share, to 27,564,260 shares.

Dividends

Dividends at the rate per annum of $0.2866 per share shall accrue on the Series A Preferred Stock, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock. Accruing dividends accrue from day to day, whether or not declared, and are cumulative; provided that such accruing dividends are payable only when, as and if declared by the Board of Directors and the Company is under no obligation to pay such accruing dividends.

Liquidation

The Series A Preferred Stock has a liquidation preference to the holders of common stock. The Series A Preferred Stock has a liquidation preference of $3.5833 per share plus any accrued but unpaid dividends.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, the holders of the shares of Series A Preferred Stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to its stockholders before any payments are made to the holders of common stock by reason of their ownership thereof, an amount per share equal to one times the Series A original issue price, plus any accruing dividends accrued but unpaid thereon, whether or not declared.

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, after payment in full of all Series A liquidation amounts required to be paid to the holders of shares of Series A Preferred Stock, the remaining assets of the Company available for distribution to its stockholders are required to be distributed among the holders of the shares of Series A Preferred Stock and common stock, pro-rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock, provided, that if the aggregate amount which the holders of Series A Preferred Stock are entitled to receive exceeds $3.92361 per share (the "Maximum Participation Amount"), each holder of Series A Preferred Stock is entitled to receive upon such liquidation, dissolution or winding up of the Company, the greater of (i) the Maximum Participation Amount and (ii) the amount such holder would have received if all shares of Series A Preferred Stock had been converted into common stock immediately prior to such liquidation, dissolution or winding up of the Company.

Voting Rights

Each holder of outstanding shares of Series A Preferred Stock is entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of the Series A Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter.

Protective Provisions

At any time when at least 131,400 shares of Series A Preferred Stock remain outstanding (subject to appropriate adjustments), the Company shall not take any of the following actions without (1) the vote or written consent of the holders of at least 60% of the then outstanding shares of Series A Preferred Stock separately as a class and (2) prior approval of at least 60% of the members of the Company's Board of Directors then in office: (i) liquidate, dissolve or wind-up the business and affairs of the Company, effect any merger or consolidation or any other Deemed Liquidation Event, or consent to any of the foregoing; (ii) amend, alter or repeal any provision of the Company's certificate of incorporation or bylaws in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock; (iii) create, or authorize the creation of, or issue shares of, or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends and rights of redemption; (iv) increase or decrease the authorized number of shares of Preferred Stock or of Series A Preferred Stock, or increase or decrease the authorized number of shares of any additional class or series of capital stock of the Company; (v) (a) reclassify, alter or amend any existing security of the Company that is pari passu with the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock in respect of any such right, preference, or privilege or (b) reclassify, alter or amend any existing security of the Company that is junior to the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Series A Preferred Stock in respect of any such right, preference or privilege; (vi) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Company other than (a) redemptions of or dividends or distributions on the Series A Preferred Stock as expressly authorized in the Certificate of Incorporation, (b) dividends or other distributions payable on the common stock solely in the form of additional shares of common stock and (c) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Company or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then current fair market value thereof; (vii) create, or authorize the creation of, or issue, or authorize the issuance of any debt security or permit any subsidiary to take any such action with respect to any debt security, if the aggregate indebtedness of the Company and its subsidiaries for borrowed money following such action would exceed $2,000,000 (other than equipment leases or bank lines of credit); (viii) create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Company, or permit any subsidiary to create, or authorize the creation of, or issue or obligate itself to issue, any shares of any class or series of capital stock, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Company, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary; or (ix) increase or decrease the authorized number of directors constituting the Board of Directors.

Optional and Mandatory Conversion Rights

Each share of Series A Preferred Stock is convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the Series A original issue price by the Series A conversion price in effect at the time of conversion. The Series A conversion price is initially equal to $3.5833. Such initial Series A conversion price, and the rate at which shares of Series A Preferred Stock may be converted into shares of common stock, is subject to adjustment.

In connection with the Series A Preferred Stock issuance in August 2020, the Series A conversion price was adjusted to $3.2583.

At the time of issuance, no beneficial conversion charge was recorded as the fair value of the Series A Preferred Stock was determined by management to be less than the stated conversion value. When the triggering event that forces conversion where both price and shares are known, the beneficial conversion charge will be recorded.

Redemption

The Series A Preferred Stock is redeemable upon the occurrence of a deemed liquidation event, which is not solely in control of the Company. Therefore, the Series A Preferred Stock has been classified as temporary equity.

Series A Preferred Stock Warrants

On May 7, 2018, in connection with the sale and issuance of the Series A Preferred Stock, the Company issued liability-classified warrants to purchase an aggregate of 231,396 shares of Series A Preferred Stock (the "2018 Warrants"), with an exercise price of $0.0003 per share of Series A Preferred Stock, subject to adjustment per the terms of the 2018 Warrants. The 2018 Warrants

were exercisable immediately on date of issuance and expire five years from issuance, in May 2023. These warrants were subject to an earlier expiration upon the closing of the Company's qualifying initial public offering of common stock. In October 2020, the warrants were exercised at the price of $0.0003 per share and the warrant liability was settled for its fair value of $0.8 million.

7. COMMON STOCK

The Company has 50,700,000 authorized shares of common stock, par value $0.0001 per share, of which 3,764,488 shares were issued and outstanding as of June 30, 2021 and December 31, 2021.

In October 2020, the Company entered into a common stock purchase agreement with a director of the Company to issue and sell 29,674 shares of its common stock for a total purchase price of $0.2 million.

In March 2020, the Company entered into a common stock purchase agreement with a director of the Company to issue and sell 182,500 shares of its common stock for a total purchase price of $0.2 million.

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. A total of 2,101,478 shares were authorized under the 2018 Plan and 476,840 and 854,320 shares are available for granting of stock awards as of June 30, 2021 and December 31, 2020, respectively. The 2018 Plan provides for the granting of the following types of stock awards: (i) incentive stock options, (ii) non-statutory stock options, (iii) stock appreciation rights, (iv) restricted stock awards, (v) restricted stock unit awards and (vi) other stock awards. Incentive stock options may be granted only to employees of the Company. Stock awards other than incentive stock options may be granted to employees, directors and consultants who are providing continuous service to the Company.

The following is a summary of the stock option award activity during the six months ended June 30, 2021:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	1,247,158	$ 5.16	9.34	$ 1,486
Granted	305,132	5.36		
Exercised	—	—		
Cancelled	—	—		
Outstanding at June 30, 2021	1,552,290	$ 5.20	9.15	$ 1,486
Exercisable at June 30, 2021	238,172	$ 2.77	8.13	$ 715
Options expected to vest as of June 30, 2021	1,314,118	$ 5.64	9.15	$ 771

Generally, options are granted with an exercise price at, or in excess of, the fair value of common stock at the date of issuance. Options typically vest over a one- to four-year period in equal increments. The original term of all options is 10 years.

The weighted-average grant date fair value of options granted during the six months ended June 30, 2021 and 2020 is $4.02 and $0.96, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company's common stock at the end of the reporting period.

Stock-Based Compensation Expense

For the six months ended June 30, 2021 and 2020, the Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options and common stock warrants granted. The following table presents the assumptions and the Company's methodology for developing each of the assumptions used:

	June 30, 2021	June 30, 2020
Volatility	88.78%	83.3%
Expected life (years)	6.08	6.08
Risk-free interest rate	0.67%	0.45%-1.4%
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 life is estimated as the contractual term.
- 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 six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 180	$ 17	$ 348	$ 33
General and administrative	212	3	405	5
Total stock-based compensation expense	$ 392	$ 20	$ 753	$ 38

No related tax benefits from stock-based compensation expense were recognized for the three and six months ended June 30, 2021 and 2020. As of June 30, 2021, there was $4.7 million in unrecognized stock-based compensation cost, which is expected to be recognized over a weighted-average period of 3.0 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, 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. 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 91,250 shares of common stock to UABRF, which were subject to certain anti-dilution 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.

Antidilution Provision

The antidilution provision required the Company to issue additional shares of common stock such that UABRF maintains a 2.5% ownership interest in the Company until it has raised at least $20.0 million through one or more rounds of investment. During the six months ended June 30, 2021 and 2020, the Company did not issue any additional shares common stock in connection with the antidilution provision. As of June 30, 2021, the Company had a total of 151,382 shares of common stock issued in satisfaction of this antidilution provision.

The Company assessed the antidilution right and determined that the right (i) meets the definition of a freestanding financial instrument that was not indexed to the Company's own stock and (ii) meets the definition of a derivative and did not qualify for equity classification. The initial fair value of the antidilution liability, and the value at June 30, 2020, was determined to be immaterial based on the remote probability of an additional financing and the immaterial value of the total number of shares that could be issued pursuant to the provision. The antidilution provision was settled in August 2020 when the Company raised an additional $19.8 million in gross proceeds through the issuance and sale of Series A Preferred Stock for a total of $35.0 million in gross proceeds related to the issuance and sale of Series A Preferred Stock.

10. INCOME TAXES

The Company recorded no provision for income taxes for the three and six months ended June 30, 2021 and 2020.

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax bases of assets and liabilities using statutory rates. Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance has been established against the Company's otherwise recognizable net deferred tax assets.

11. 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, without consideration for potentially dilutive securities. 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 attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (3,050)	$ (2,874)	$ (5,413)	$ (4,565)
Cumulative dividends on convertible preferred stock	(715)	(304)	(1,421)	(564)
Net loss attributable to common stockholders	$ (3,765)	$ (3,178)	$ (6,834)	$ (5,129)
Net loss per share—basic and diluted	$ (1.00)	$ (0.92)	$ (1.82)	$ (1.52)
Weighted-average number of shares used in computing net loss per share—basic and diluted	3,764,488	3,462,182	3,764,488	3,383,774

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

	For the Six Months Ended June	
	2021	2020
Convertible preferred stock	9,993,727	4,247,927
Stock options to purchase common stock	1,552,290	392,723
Warrants to purchase preferred stock	—	231,396

12. 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. The royalty term is the later of 10 years from first commercial sale or expiration of the last-to-expire component of the licensed intellectual property.

13. LEASES

The Company has historically entered into lease arrangements for its facilities. As of December 31, 2020, the Company had three operating leases with required future minimum payments. In applying the transition guidance under ASC 842, 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 dates. The Company's leases generally do not include termination or purchase options.

Equipment Leases

The Company entered into an agreement with an equipment leasing company in the fall of 2018, which provided up to $1.4 million for equipment purchases in the form of sale and leasebacks or direct leases. As of June 30, 2021, the Company had completed the sale and leaseback for four pieces of equipment and is leasing three other items directly from the leasing company. The terms of the leases are three years and afterwards provide for either annual extensions or an outright purchase of the equipment.

The equipment leases require two advance rental payments to be held as security deposits. The security deposits held amounted to approximately $0.1 million as of June 30, 2021 and December 31, 2020. They are included in other non-current assets on the condensed balance sheets.

Operating Leases

In December 2020, the Company entered into an operating lease for office space in Birmingham, Alabama, for a 63-month term, ending in March 2026, with an option to extend five years. 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 December 2020, the Company entered into an operating lease for laboratory space in Birmingham, Alabama, for a 63-month term, ending in March 2026, with an option to extend five years. 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 operating leases required security deposits at the inception of the lease. The security deposits amounted to approximately $17,000 for the six months ended June 30, 2021. They are included in non-current assets on the balance sheet.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's finance and operating leases for the three and six months ended June 30, 2021 (in thousands):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Lease Cost		
Amortization of finance right-of-use assets	$ 138	$ 250
Interest on finance lease liabilities	25	46
Operating lease cost	53	105
Short-term lease cost	134	249
Variable lease cost	—	—
Total lease cost	$ 350	$ 650

	June 30, 2021
Other Operating Lease Information	
Cash paid for amounts included in the measurement of lease liability – finance leases	$ 340
Cash paid for amounts included in the measurement of lease liability – operating leases	$ 52
Weighted-average remaining lease term – finance leases	2.0
Weighted-average remaining lease term – operating leases	4.67
Weighted-average discount rate – finance leases	10.2 %
Weighted-average discount rate – operating leases	10.4 %

The following table reconciles the undiscounted cash flows to the operating and financing lease liabilities at June 30, 2021 (in thousands):

	Financing Leases	Operating Leases
Remainder of 2021	$ 327	$ 105
2022	435	216
2023	253	223
2024	30	230
2025	—	237
Thereafter	—	41
Total lease payment	1,045	1,052
Less: interest	96	219
Total lease liability	$ 949	$ 833

14. SUBSEQUENT EVENTS

Subsequent events have been evaluated through the date of filing of the unaudited condensed financial statements. The Company has identified the following subsequent events that require disclosure.

Initial Public Offering

On August 3, 2021, the Company completed its IPO in which the Company issued and sold 4,000,000 shares of its common stock, at a public offering price of $10.00 per share, for aggregate gross proceeds of $40.0 million. The Company received approximately $32.6 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses. In connection with the IPO, all outstanding shares of Series A convertible preferred stock converted into 10,990,065 shares of the Company's common stock.

2020 Equity Incentive Plan

The 2020 Equity Incentive Plan (the “2020 Plan”) was approved by the Board of Directors and the Company’s stockholders and became effective on July 29, 2021. The 2020 Plan provides for the grant of incentive stock options ("ISOs") within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended, to employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants and any affiliates’ employees and consultants. The number of shares initially reserved for issuance under the 2020 Plan was 4,200,000, which will automatically increase on January 1 of each year for a period of 10 years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the total number of shares of common stock outstanding on the last day of the immediately 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 on the exercise of ISOs under the 2020 Plan will be 13,000,000 shares.

2020 Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the “2020 ESPP”) was approved by the Company’s Board of Directors and the Company’s stockholders and became effective on July 29, 2021. A total of 200,000 shares of common stock were initially reserved for issuance under this plan, which will automatically increase on January 1 of each year for a period of 10 years, beginning on January 1, 2021 and continuing through January 1, 2031, by the lesser of 1% of the total number of shares of common stock outstanding on the last day of the immediately preceding year; and 400,000 shares, except before the date of any such increase, the Board of Directors may determine that such increase will be less than the amount set forth above.

New York Operating Lease

In September 2021, the Company entered into a new operating lease for general office purposes in New York, New York, with a term commencing on September 15, 2021 and continuing through September 2026. The commitment under the new lease is approximately $0.3 million annually.

Alabama Build-to-Suit Lease

In September 2021, the Company entered into a build-to-suit lease agreement with ECBuild to build out the Company's labs in Birmingham Alabama. The agreement has a threshold of $4.0 million in total costs incurred.

Repayment Loan Payable

In August 2021, the Company repaid the PPP loan of $0.2 million received in April 2020 in full. Refer to Note 5 “Debt” for further details.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the years ended December 31, 2020 and 2019, which are included in the final prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-249530) for our initial public offering, or IPO, dated July 29, 2021, that was filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act, on July 30, 2021, which we refer to as the Prospectus.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of gamma-delta T cell therapies for the treatment of cancer. Gamma-delta T cells are naturally occurring immune cells that embody properties of both the innate and adaptive immune systems, and can intrinsically differentiate between healthy and diseased tissue. These cells serve as a functional bridge between innate and adaptive immunity to contribute to direct tumor killing, as well as immune cell recruitment and activation to drive deeper immune responses. The pivotal role of gamma-delta T cells in immune function and activation, against diseases such as cancer, underscores their therapeutic potential across a wide range of solid and hematologic malignancies. We develop *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 allogeneic, autologous and genetically modified approaches to develop novel cell therapies, which are designed to effectively identify and eradicate tumor cells. We are currently the most clinically advanced gamma-delta T cell company. Our lead product candidates are currently in Phase 1 clinical trials: INB-200, for the treatment of newly diagnosed glioblastoma, or GBM, and INB-100, for the treatment of patients with leukemia that are undergoing hematopoietic stem cell transplantation, or HSCT. For INB-200, we expect to report the initial results from the second and third cohorts in this Phase 1 trial in 2022. For INB-100, we expect to report initial results from the first cohort in our Phase 1 clinical trial in 2022, with additional results in 2023. In addition, our DeltEx platform has yielded a broad portfolio of preclinical programs, including INB-400 and INB-300, focused on addressing other solid tumor types. We expect to file three INDs for our pipeline product candidates through 2023 with a total of four planned INDs over the next three years, including one in an undisclosed indication.

Since inception in 2016, our operations have focused on identifying and developing potential product candidates, conducting clinical trials, organizing and staffing the Company, 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. Through June 30, 2021, we raised an aggregate of $35.6 million of gross proceeds from the sale of our securities.

We have incurred significant operating losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $5.4 million and $4.6 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $23.5 million.

We expect our expenses and operating losses will increase substantially for the foreseeable future as we advance INB-100 and INB-200 through clinical trials, seek to expand our product candidate portfolio through developing additional product candidates, grow our clinical, regulatory and quality capabilities, and incur additional costs associated with operating as a public company. It is likely that we will seek third-party collaborators for the future commercialization of INB-100, INB-200 or any other product candidate that is 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.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such

agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

As of June 30, 2021, we had cash of $12.0 million. In August 2021, we issued and sold 4,000,000 shares of our common stock at a price to the public of $10.00 per share for aggregate gross proceeds of $40.0 million in our IPO. We received approximately $32.6 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses. Based on our current operating plan, we expect that our cash of $12.0 million as of June 30, 2021, and net proceeds of $32.6 million from the IPO will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the condensed financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

Recent Business Highlights

- During the second quarter, we presented data demonstrating in vitro activity of INB-300, our DeltEx drug-resistant immunotherapy (DRI) CAR-T cells against GBM at the American Association of Cancer Research (AACR) Annual Meeting 2021. Gamma-delta T cells were engineered with a chlorotoxin CAR-T binding domain and a chemotherapy resistance gene, which enhances binding to tumor cells and survival of concomitant dosing with alkylating chemotherapies, such as temozolomide, or TMZ.
- During the second quarter, we presented data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting from the first cohort of a Phase 1 clinical trial of INB-200 in patients with newly diagnosed GBM. INB-200 was generally well tolerated with no observed infusion reactions, cytokine release syndrome, neurotoxicity or dose limiting toxicities (DLTs). Enrollment for the second cohort of this trial was initiated. All three treated patients exceeded their expected median progression-free survival based on their respective age and O-6-Methylguanine-DNA Methyltransferase (MGMT) status. We expect to report additional data from this Phase 1 trial by the end of 2021.
- In July 2021, we appointed Emily Fairbairn and Luba Greenwood as two independent members into our Board of Directors. Ms. Fairbairn is currently a principal of Transcend Partners and was co-founder and CEO of Ascend Capital. Ms. Greenwood serves as Managing Partner of Binney Street Capital LLC, a venture capital fund established by the Dana Farber Cancer Institute.
- In August 2021, we completed dosing of the first cohort of INB-100, a Phase 1 clinical trial of donor-derived allogeneic gamma-delta T cells in leukemia patients undergoing HSCT. No severe adverse infusion reactions or DLTs were observed. The first two patients continue in complete remission more than one year after treatment. We expect to report initial results from the first cohort in this Phase 1 trial in 2022, with topline results for all cohorts in 2023.

Our Pipeline

Impact of COVID-19

The ongoing COVID-19 pandemic has had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The COVID-19 pandemic has impacted and may continue to impact the clinical sites and startup activities for the Company's Phase 1/2 clinical trial, including third-party manufacturing and logistics providers, which have disrupted and may continue to disrupt its clinical supply chain and the availability or cost of materials, and it has affected and may continue to affect the Company's ability to timely initiate, enroll and complete its clinical trials, conduct regulatory activities and its operate its business more generally. The Company continues to monitor the potential impact of COVID-19 on its business and financial statements and cannot be certain what the overall impact of the COVID-19 pandemic will be. The extent to which the COVID-19 pandemic will directly or indirectly continue to impact its business, results of operations, financial condition and liquidity, including ongoing and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of evolving variants of COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

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 Expense

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 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;
- preclinical studies—expenses associated with conducting preclinical studies performed by ourselves, outside vendors or academic collaborators;
- expenses incurred under agreements with contract research organizations, or CROs, as well as contract manufacturing organizations, or CMOs, and consultants that conduct and provide supplies for 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 financial statements as prepaid or accrued research and development expenses. Beginning with fiscal year 2020, 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 continue to increase for the foreseeable 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 Expense

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; and facility-related expenses, which include allocated 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 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. Following the IPO, we expect to incur 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.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following sets forth our results of operations for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
(in thousands)	**2021**	**2020**	**Change**
Operating expenses:			
Research and development	$ 2,064	$ 1,784	$ 280
General and administrative	986	1,090	(104)
Total operating expenses	3,050	2,874	176
Loss from operations	(3,050)	(2,874)	(176)
Net loss	$ (3,050)	$ (2,874)	$ (176)

Research and Development Expenses

Research and development expenses were $2.1 million and $1.8 million for the three months ended June 30, 2021 and 2020, respectively. The increase of $0.3 million was primarily due to increased third-party costs for the ongoing clinical trial for INB-200 and increased personnel-related costs, including stock-based compensation.

General and Administrative Expenses

General and administrative expenses were $1.0 million and $1.1 million for the three months ended June 30, 2021 and 2020, respectively. The decrease of $0.1 million was primarily due to decreased legal and professional fees partially offset by increased personnel costs, including non-cash stock-based compensation, in anticipation of becoming a public company.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following sets forth our results of operations for the six months ended June 30, 2021 and 2020:

(in thousands)	Six Months Ended June 30, 2021	2020	Change
Operating expenses:			
Research and development	$ 3,310	$ 2,836	$ 474
General and administrative	2,103	1,729	374
Total operating expenses	5,413	4,565	848
Loss from operations	(5,413)	(4,565)	(848)
Net loss	$ (5,413)	$ (4,565)	$ (848)

Research and Development Expenses

Research and development expenses were $3.3 million and $2.8 million for the six months ended June 30, 2021 and 2020, respectively. The increase of $0.5 million was primarily due to increased third-party costs for the ongoing clinical trial for INB-200 and increased personnel related costs, including stock-based compensation.

General and Administrative Expenses

General and administrative expenses were $2.1 million and $1.7 million for the six months ended June 30, 2021 and 2020, respectively. The increase of $0.4 million was primarily due to increased personnel costs, including stock-based compensation, in anticipation of becoming a public company.

Liquidity and Capital Resources

Overview

To date we have funded our operations primarily through the sale of equity and equity-linked securities. Through June 30, 2021, we have raised an aggregate of $35.6 million of gross proceeds from private placements of our equity securities. In August 2021, we completed our IPO in which we issued and sold 4,000,000 shares of our common stock at a public offering price of $10.00 per share for aggregate gross proceeds of $40.0 million. We received approximately $32.6 million in net proceeds after deducting underwriting discounts, commissions and estimated offering expenses.

As of June 30, 2021, we had cash of $12.0 million, which excludes the net proceeds of $32.6 million received from the IPO. Our net loss was $5.5 million and $4.6 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $23.5 million. 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. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures.

Cash Flows

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

(in thousands)	Six Months Ended June 30, 2021	2020
Net cash used in operating activities	$ (4,968)	$ (3,284)
Net cash used in investing activities	—	—
Net cash (used in) provided by financing activities	(1,027)	5,854
Net (decrease) increase in cash	$ (5,995)	$ 2,570

Operating Activities

Cash used in operating activities was $5.0 million during the six months ended June 30, 2021, primarily due to our net loss of $5.4 million and decrease in our operating assets and liabilities of $0.7 million partially offset by increases in non-cash charges of $1.1 million. Decreases in our operating assets and liabilities consisted primarily of $0.4 million in accounts payable mainly due to deferred

offering costs payments related to the IPO, $0.2 million in accrued expenses and other current liabilities mainly due to lower legal accruals as a result of the completion of the IPO, and $0.1 million in prepaid expenses and other current assets mainly due to lower clinical prepaids for the quarter. Increases in our non-cash charges consisted primarily of $0.8 million in stock-based compensation due to higher employee headcount and $0.3 million in amortization of operating and finance leases for the quarter.

Cash used in operating activities was $3.3 million during the six months ended June 30, 2020, primarily due to our net loss of $4.6 million offset by increases in our operating assets and liabilities of $1.2 million and increases in non-cash charges of $0.1 million. Increases in our operating assets and liabilities consisted primarily of $1.2 million in accrued expenses and other current liabilities due to increased legal accruals related to preparing for the IPO. Increases in our non-cash charges consisted primarily of $0.1 million in stock-based compensation due to higher employee headcount.

Financing Activities

Cash used in financing activities was $1.0 million during the six months ended June 30, 2021, primarily due to paying deferred offering costs related to our IPO, which closed in August 2021.

Cash provided by financing activities was $5.9 million during the six months ended June 30, 2020, primarily due to the issuance of Series A convertible preferred stock.

Funding Requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of INB-100 and INB-200 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company following our IPO. It is likely that we will seek third-party collaborators for the future commercialization of INB-100, INB-200 or any other product candidate that is 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.

We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. 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 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 or delays resulting from factors related to the ongoing COVID-19 pandemic;

- the effect of competing 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.

Until such time as we can generate significant revenue from product sales, if ever, we expect 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. Debt financing or preferred equity financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations.

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 and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate 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.

Contractual Obligations and Commitments

Effective January 1, 2021, the Company early adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02" or "ASC 842"), using the modified retrospective method and utilized the effective date as its date of initial application, with prior periods presented in accordance with previous guidan ASC 840, *Leases*. On the adoption date, $1.7 million was recognized as total lease liabilities and $1.8 million was recognized as total right-of-use assets on the Company's balance sheet. For more information regarding the adoption, please see Note 2 and Note 13 included in this quarterly report. There were no material changes to our contractual obligations and commitments during the six months ended June 30, 2020 from those described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Prospectus.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the U.S. Securities and Exchange Commission.

Critical Accounting Policies and Significant Judgements and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which are prepared in accordance with US GAAP. 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 and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

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 unaudited condensed financial statements located in "Part I – Financial Information, Item 1. Financial Statements" in this Quarterly Report on Form 10-Q.

There have been no significant changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our final Prospectus dated July 29, 2021 and filed with the SEC pursuant to Rule 434(b)(4) under the Securities Act, on July 30, 2021.

Recent Accounting Pronouncements

See Note 2 in our condensed financial statements in "Part I – Financial Information, Item 1. Condensed Financial Statements" in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as an EGC, as defined in the 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 $1.07 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) 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," meaning that the market value of our stock held by non-affiliates was less than $700 million at the closing of the IPO and our annual revenue for 2020 was less than $100 million. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 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 on Form 10-K 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 Securities Exchange Act of 1934, as amended, or 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, has 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 Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Form 10-Q was (a) reported within the time periods specified by SEC rules and regulations, and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in Internal Control over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ending December 31, 2021. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in 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, and we are not aware of any pending or threatened legal proceeding against us 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:

- 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 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 will require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- We are dependent on the successful clinical development, regulatory approval and commercialization of our gamma-delta T cell 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 DeltEx products 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 are poorly understood or currently unknown, and may only become known through further preclinical and clinical testing.
- If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- The ongoing COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.
- Interim, "top-line" 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.
- We face significant competition, and many of our competitors have substantially greater experience and resources than we have.
- Our manufacturing process is 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.
- Clinical product candidate development involves a lengthy and expensive process and involve uncertain outcomes. We may incur additional costs and encounter substantial delays or difficulties in our clinical trials.
- If we encounter difficulties in enrolling patients with our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- We currently store our gamma-delta T cells at our research and development facility and at the facilities of our clinical and/or manufacturing partners, and any damage or loss to our storage freezers 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. These are critical products required for the manufacturing of our product candidates, including INB-200 and INB-100. Any damage or loss to the ability of our suppliers to deliver supplies in a timely manner could cause delays in manufacturing, and our business could suffer.
- 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 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.

Risks Related to Our Financial Position and Capital Needs

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 $8.6 million for the year ended December 31, 2020 and $5.4 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $23.5 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 with INB-100 and INB-200;
- continue to develop our preclinical product candidates, INB-300 and INB-400;
- 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, or 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. 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.

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 INB-200 and INB-100 and our other product candidates, undertaking preclinical studies, initiating and conducting clinical trials for INB-200 and INB-100, business planning and raising capital. Other than INB-200 and INB-100, all of our 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, 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 10 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.

We require substantial additional funding to finance our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses 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. 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, including accounting for any COVID-19-related delays or other related impacts on our development programs;
- 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.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and 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 and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether terminate our research and development programs or future commercialization efforts.

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 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, INB-200 and INB-100, in our ongoing clinical trials. Our DeltEx platform, including our INB-200 and INB-100 product candidates, are in early stages of development and may never be commercialized.

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. 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, or 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, 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-200 and INB-100 are our only product candidates in clinical trials. Success in preclinical testing and early-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety 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.

For example, although we have commenced Phase 1 clinical trials for INB-200 and INB-100, the FDA has not yet made any determination regarding safety and efficacy of either product candidate in the targeted indications. Further, 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 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 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 and INB-200 product candidates, as well as our additional drug-resistant immunotherapy, or DRI, gamma-delta T cell 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 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, that 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 clinical supply of INB-200, INB-100 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 process, see the risks highlighted in "Risks related to manufacturing and our dependence on third parties," including "*—Our manufacturing process is 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'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 administer our cells and the potential side effect profile of our product candidates, such as cytokine release syndrome, neurotoxicity, 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, 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 hematological malignancies, and our “point-of-care” manufacturing process is predominantly based on cells received from healthy haploidentical related donors with at least half of the major human leukocyte antigen, or 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, or GvHD, if any. 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. While we believe that a high degree of HLA matching will not be required to prevent GvHD or for clinically meaningful activity and durability of response, if it becomes apparent through preclinical testing or clinical trials that such matching is required, an allogeneic or an “off-the-shelf” product may not be attainable, which would prevent the further advancement of our INB-100 allogeneic product candidate and adversely affect our business and current development plans. We will also need to demonstrate that our DeltEx platform product candidates are safe. 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, or 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 and involve 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 Phase 1 trials for INB-200 and INB-100 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 the ongoing COVID-19 pandemic, 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 risk evaluation and mitigation strategy, or 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, or 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, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug applications, or 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-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, 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;

- the ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients' unwillingness to participate due to the ongoing COVID-19 pandemic;
- 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, such as the evolving and ongoing COVID-19 pandemic.

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, or 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. If additional clinical experience indicates that any of our product candidates 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, 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 only tested INB-200 and INB-100 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. As we continue developing our lead product candidates and initiate clinical trials of our additional product candidates, serious adverse events, or 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.

The ongoing COVID-19 pandemic could continue to adversely impact our business, including our clinical trials, supply chain and business development activities.

In connection with the ongoing COVID-19 pandemic, governments have implemented significant measures, including closures of businesses, quarantines, travel restrictions and other social distancing directives, intended to control the spread of the virus. Companies have also taken precautions, such as requiring employees to work remotely, imposing travel restrictions and temporarily closing businesses. In response to these public health directives and orders, we have implemented certain travel restrictions and work-from-home policies for our employees, and as a result we have experienced limitations on employee resources. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and slow down or delay our ongoing and future clinical trials, preclinical studies and research and development activities, may cause disruptions to our supply chain, to the administrative functions of clinical trial sites and/or to the operations of our other partners, and as a result may impair our ability to execute our programs and/or business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, including our laboratories and our operations may be further limited or curtailed.

Our clinical trials have been, and may in the future be, affected by the ongoing COVID-19 pandemic. If a patient in any of our clinical trials contracts COVID-19, it could cause a serious adverse event to occur, especially in light of the immunosuppressive conditioning to which such patients are subject. To date, the spread of COVID-19 in the states of Alabama and Kansas has impacted the intensive care unit capacity at the hospitals participating in our clinical trials, and has slowed the rate of patient enrollment. The hospitals also experienced shortages in personal protective equipment, or PPE, that could in the future result in significant delays to our clinical trials. In addition, due to the ongoing COVID-19 pandemic, there was an increasing risk that a patient could undergo a conditioning or myeloablative preparative process only to find that their donor has been infected with COVID-19, making donor HSCs unavailable to the patient. This would result in patient death. Accordingly, we have submitted to the FDA and the IRB a modified clinical protocol to allow the usage of previously frozen HSCs to mitigate such risks associated with COVID-19 exposure. This potentially could result in lower potency, but allows the leukapheresis and harvest of the HSCs from the donor and the confirmation of a negative COVID-19 result prior to initiating the conditioning and/or myeloablation of the patient. We may experience other disruptions due to the ongoing COVID-19 pandemic that could severely impact our business, preclinical studies and clinical trials, including:

- delays or difficulties in enrolling and maintaining patients in our clinical trials;
- delays or difficulties in shipping and delivering in a timely manner supplies, samples or products required for our clinical trials due to the impact of the ongoing COVID-19 pandemic on the United States Postal Service, FedEx, United Parcel Service and/or other commercial shipping organizations;
- delays or difficulties in clinical site initiation, including difficulties completing any required contracts, successfully completing IRB review in a timely manner, or in recruiting clinical site investigators and clinical site staff;
- disruptions in our supply chain that result in shortages of reagents or materials to conduct our laboratory experiments and/or clinical trials, including PPE, PCR reagents and/or pipette tips;
- changes in local regulations as part of a response to the ongoing COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or cause us to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- difficulties in recruiting and retaining principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19;

- interruption of key clinical trial activities, such as clinical trial site monitoring, manufacturing and equipment maintenance due to limitations on travel or access imposed or recommended by federal or state governments, hospitals, employers and others, or interruption of clinical trial subject visits and study procedures;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could result in the reporting of an SAE, potentially including patient deaths, and impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the ongoing COVID-19 pandemic may be difficult to assess or predict, there have recently been, and could in the future be, significant disruptions of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the ongoing COVID-19 pandemic. As a result, we may face difficulties raising capital or such capital raises may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the ongoing COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs.

In April 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was intended to provide economic relief to United States businesses affected by the ongoing COVID-19 pandemic, was signed into law. In April 2020, we received a $0.2 million loan, or the PPP Loan, under the small business Paycheck Protection Program, established under the CARES Act and administered by the Small Business Administration, or the SBA. The loan is forgivable subject to certain limitations, including that the loan proceeds be used to retain workers and for payroll, rent, mortgage payments and utility costs. In order to apply for the PPP Loan, we were required to certify that, among other things, the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are found to be in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, or it is otherwise determined that we were not eligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan in its entirety. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, a review or audit by the SBA or other government entity, or claims under the False Claims Act. Any of these events could have a material adverse effect on our business, results of operations and financial condition. As of August 2021, we have repaid our PPP Loan in its entirety including any interest outstanding, if any.

Interim, “top-line” 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, “top-line” or preliminary data from our clinical trials. Interim, “top-line” 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, “top-line” 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, “top-line,” and preliminary data should be viewed with caution until the final data are available. Differences between interim, “top-line” 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, "top-line," 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.

We may seek breakthrough therapy 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 designation or obtain or maintain the benefits associated with such designations.

We may seek breakthrough therapy or fast track designations and may pursue accelerated approval for INB-100, INB-200, INB-400 and some or all of our current 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.

We may 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.

We may seek orphan drug designation for one or more of our current or future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. 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 a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which 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, except in limited circumstances such as a showing of 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, INB-200, INB-400 and some or all of our other current 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 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 for 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 cell-based immunotherapy and genetic modification approaches may impact public perception of our company and product candidates, or may adversely affect our ability to 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. Public perception may be influenced by negative claims about our DeltEX platform, such as claims that cell-based immunotherapy is unsafe, unethical, 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 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 prescribing, 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 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 immune-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, or 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

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 process is 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.

Some of our product candidates, including INB-200, are genetically engineered human cells, and the process of manufacturing such product candidates, as well as the lentiviral vectors, is complex, highly regulated, variable and subject to numerous risks. Manufacturing our product candidates involves harvesting cells from a donor, isolating cells via leukapheresis, activating and expanding the gamma-delta T cells, cryopreservation, testing, storage and eventually shipment and infusion of the cell product into the patient's body.

Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product back to the recipient, preparing the product for administration, infusing the patient with the product, manufacturing issues or different product characteristics resulting from the inherent differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment and/or programs, vendor or operator error, inconsistency in cell growth and variability in product characteristics.

Even minor variations in starting reagents and materials, or deviations from normal manufacturing processes could result in reduced production yields, product defects, manufacturing failure and other supply disruptions. If, for any reason in our ongoing Phase 1 clinical trials, we lose the starting material for a manufactured product for one of our patients at any point in the process, or the expansion or transduction procedures in the manufacturing process should fail for any reason, such patient would no longer receive a dose of the therapy and may end participation in our clinical trial. For instance, operator errors impacting machine function, gas or airflow, or reagent addition can negatively impact the process. Manufacturing by a previously contracted facility has resulted in such operator errors; however, we identified these errors through our quality control procedures prior to patient administration.

If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and back to the clinical trial recipient. Maintaining a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed. Any failure in the foregoing processes could render a batch of product unusable, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates.

We may make changes to our manufacturing process for various reasons, such as to control costs, increase yield or dose, achieve commercial scale, decrease processing time, increase manufacturing success rate or for other reasons. We recently relocated clinical trial manufacturing for one of our clinical development programs to an academic GMP facility closer to our laboratory headquarters in Birmingham, Alabama to permit us contractual direct access as a means of preventing manufacturing errors. However, even with this contractual direct access and closer collaboration with the facility's manufacturing staff, there can be no guarantee that manufacturing errors will not occur.

Changes to our process made during the course of clinical development could require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects.

We may rely on third parties for the manufacturing process of our product candidates, and failure by those parties to adequately perform their obligations could harm our business.

Although we endeavor to build 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 process of our product candidates that we develop. The facilities used by our contract manufacturers must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application for approval 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 manufacture of our product candidates. We have not yet caused 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 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 approve these facilities for the manufacture of our product candidates or if it withdraws any such approval 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 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 or in the manufacturing facilities in which our product candidates 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 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. This type 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 line for therapeutic use in a patient requires close coordination between 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 biologic correlative and research specimens from clinical trials and development programs and clinical lentivectors at our research and development facility, and any damage or loss to our storage freezers would cause delays in replacement, and our business could suffer.

Specimens are stored in our freezers at our research and development facility. 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, power loss or other natural disasters, although clinical vectors are stored at more than one site, loss of a significant supply would require manufacturing of additional vector which could cause us to incur significant additional expenses and liability, our development programs could be delayed or terminated 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. These are critical products required for the manufacturing of our product candidates, including INB-200 and INB-100. Any damage or loss to the ability of our suppliers to deliver supplies in a timely manner could cause delays in manufacturing, and our business could suffer.

Our gamma-delta T cell products for INB-200 and INB-100 are manufactured in a programmable, closed system device at GMP standards. 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 will be delayed, or potentially hindered.

There is currently a significant backlog for lentiviral vector manufacturing due to increased demand. Our current supply of vectors will only cover approximately 30 patients. If our third-party contractor is unable to provide adequate lentiviral vectors 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 Phase 1 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, or 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-initiated trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-initiated 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 the ongoing COVID-19 pandemic, 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 for 35 days beginning on December 22, 2018, 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.

Separately, in response to the ongoing COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on 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 current product candidates INB-200 and INB-100 are dependent on our license agreements with the The UAB Research Foundation, or UABRF, Children's Healthcare of Atlanta, Inc., or CHOA, and Emory University, or Emory, 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 the UABRF, CHOA and Emory 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 the UABRF, CHOA or Emory 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 INB-200 and INB-100. 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 the UABRF, CHOA and Emory license agreements, see the section titled “Business—License Agreements.”

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 may have been 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 June 30, 2021, we owned, co-owned or exclusively licensed two issued U.S. patents, two issued European patents, one allowed patent application in Europe, one allowed patent application in Australia, one allowed patent application in Israel, eight pending U.S. applications, one pending PCT application and 47 other foreign national-stage applications, including four European regional-phase applications that are important to the development of our business. For more information relating to our patent portfolio, see the section titled “Business—Intellectual Property.”

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. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the U.S. Patent and Trademark Office, or USPTO, itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. 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-200 and INB-100, 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, or 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 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

We are highly dependent on the services of our co-founders, William Ho, our President and Chief Executive Officer, and Dr. Lawrence Lamb, our Chief Scientific Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical and scientific personnel, our business will be harmed.

We are highly dependent on our co-founders, President and Chief Executive Officer, William Ho, and our Chief Scientific Officer, Dr. Lawrence Lamb. Each of them may currently terminate their employment with us at any time. The loss of the services of either 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. Additionally, we currently only maintain “key person” life insurance for our President and Chief Executive Officer.

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

As of June 30, 2021, we had 13 full-time employees. As the clinical development of our product candidates progresses, we also expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, drug development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated 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 anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs 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 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.

Our business strategy includes broadening our DeltEx platform by exploring strategic partnerships that maximize the potential of our gamma-delta T cell programs. As a result, we intend to periodically explore a variety of possible strategic partnerships in an effort to gain access to additional product candidates or resources. These strategic partnerships may include partnerships with large strategic partners. 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 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.

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. 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.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively, and adversely affect our business and operating results.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. 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 confidential information.

Our internal computer systems, cloud-based computing services and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage or interruption from a variety of sources, including computer viruses, data corruption, cyber-based attacks, intentional or accidental actions or inactions by our employees or others with access to our network, unauthorized access, cyberattacks by malicious third parties, supply chain attacks, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals

to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, 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. Furthermore, federal, state and international laws and regulations, such as HIPAA, the GDPR, or CCPA, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

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, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or 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 shifts 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.

The Tax Cuts and Jobs Act of 2017, or the Tax Act, among other things, changed U.S. federal income tax rates and the rules governing net operating loss carryforwards. Under the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely, but the deduction for these carryforwards in taxable years beginning after December 31, 2020 is limited to 80% of current-year taxable income. NOLs generated in tax years beginning before January 1, 2018 are not subject to the taxable income limitation, and continue to have a 20-year carryforward period. Deferred tax assets for NOLs are measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods, as well as the new limitation on use of NOLs, may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. 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 June 30, 2021.

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 intravenously 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, or the 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 foreign 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 war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and public health emergencies, such as the ongoing COVID-19 pandemic.

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 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 "Business—Government Regulation and Product Approval."

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 the Company, 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.

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 convince hospitals and/or clinicians to utilize 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.

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, or, 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 to the ACA. For example, the Tax Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate."

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it remains unclear when or how the Supreme Court will rule. Although the U.S. Supreme Court has yet to rule on the constitutionality of the ACA, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

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 pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, which will remain in effect through 2030, with a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015. At this time, the full impact to overall physician reimbursement as a result of the introduction of the Medicare quality payment program remains unclear.

Further, in the United States there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Further, we expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current or any future product candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction, particularly in light of the new presidential administration. If we or any third parties we may engage are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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. Further, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic. For additional information on healthcare reform, see "Business — Government Regulation and Product Approval."

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad. 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 collect, store, transfer use and share personal 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 to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal 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 may 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, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended, and regulations promulgated thereunder, or HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA, CPRA, and other similar bills pending in several states may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

In addition, all 50 U.S. states and the District of Columbia have enacted breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential information 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 may be costly. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

In addition, the European Union's General Data Protection Regulation (EU) 2016/679, or GDPR, became applicable on May 25, 2018. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies.

Further, the Court of Justice of the European Union ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the European Union and United States, was invalid and could no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual

clauses (“SCCs”), while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield. At present, there are few if any viable alternatives to the SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. Currently there is a four- to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, while the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving 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. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks Related to the Ownership of Our Common Stock

A public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to our IPO in August 2021, there had not been a public market for our common stock. If an active trading market for our common stock does not develop, you may not be able to sell your shares quickly or 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 may be volatile and fluctuate substantially, and you could lose all or part of your investment.

The market price of our common stock is likely to be 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 others, the following:

- the commencement, enrollment or results of our planned or future clinical trials of our product candidates or those of our competitors;
- the success of competitive products or therapies or announcements 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;
- market volatility due to the continued effects of and responses to the ongoing COVID-19 pandemic;
- 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 due to government intervention; and
- investors' general perception of us and our business.

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.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon shares of our common stock outstanding as of June 30, 2021, including the issuance of 4,000,000 shares of our common stock in the IPO, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock will, in the aggregate, beneficially own shares representing 68.7% of our outstanding common stock. If our executive officers, directors and stockholders who own more than 5% of our outstanding common stock acted together, they may be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in the management of our company in ways with which other stockholders disagree.

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 expect 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, 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. 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 terminate 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.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

A significant portion of our total outstanding shares are restricted or will be restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have outstanding 18,754,553 shares of common stock after the IPO, which includes the 4,000,000 shares sold in our IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining shares are currently restricted as a result of securities laws or lock-up agreements. Moreover, holders of an aggregate of 13,684,805 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We further intend to register all shares of common stock that we may issue in the future or have issued to date under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and to the lock-up agreements.

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 66⅔% 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 66⅔% 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, or 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 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 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 of 1933, as amended, or 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

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 do not currently have, and may never obtain, research coverage by industry or financial analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have 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 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.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, and particularly after we are no longer an emerging growth company, as defined under the Jobs Act, or EGC, or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and The Nasdaq Stock Market LLC impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or 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 for up to five years. 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. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 are 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.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. 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.

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

On August 3, 2021, the we completed our IPO in which we issued and sold 4,000,000 shares of our common stock at a public offering price of $10.00 per share pursuant to its Registration Statement on Form S-1, as amended (File No. 333-249530). We received net proceeds from the initial public offering of $32.6 million, after deducting underwriters' discounts, commissions and estimated offering-related costs of $7.4 million. B. Riley Securities Inc. acted as the sole book-running manager for the IPO.

No expenses incurred by the Company in connection with the IPO were paid directly or indirectly to (i) any of its officers or directors or their associates, (ii) any persons owning 10% or more of any class of its equity securities, or (iii) any of its affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

There has been no material change in the planned use of proceeds from the IPO from those disclosed in the Prospectus. We plan to invest the funds received in cash equivalents and other marketable securities in accordance with our investment policy. We have not

used any of the proceeds from the IPO.

(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.

Not applicable.

Item 6. Exhibits, Financial Statement Schedules.

(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	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39692), filed with the SEC on August 3, 2021).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-249530), filed with the SEC on November 5, 2020).
4.2	Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated May 7, 2018 (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-249530), filed with the SEC on October 16, 2020).
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 Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* This certification is being furnished solely to accompany this quarterly report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are 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: September 10, 2021

By: /s/ William Ho

William Ho
Chief Executive Officer
(Principal Executive Officer)

Date: September 10, 2021

By: /s/ Patrick McCall

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

Exhibit 31.1

CERTIFICATION

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)) 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) 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

(c) 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: September 10, 2021

By: /s/ William Ho

William Ho

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

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)) 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) 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

(c) 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: September 10, 2021

By: /s/ Patrick McCall

Patrick McCall

Chief Financial Officer

(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 June 30, 2021 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: September 10, 2021

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

Date: September 10, 2021

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